STATE OF MARYLAND

DEPARTMENT OF HEALTH (MDH)

REQUEST FOR PROPOSALS (RFP)

CANCER SURVEILLANCE, OPERATIONS, AND QUALITY ASSURANCE FOR THE MARYLAND CANCER REGISTRY

RFP NUMBER OCMP - 24-19692

ISSUE DATE: NOVEMBER 14,2023

NOTICE

A Prospective Offeror that has received this document from a source other than eMarylandMarketplace (eMMA) https://procurement.maryland.gov should register on eMMA. See **Section 4.2**.

MINORITY BUSINESS ENTERPRISES ARE ENCOURAGED TO RESPOND TO THIS SOLICITATION.

VENDOR FEEDBACK FORM

To help us improve the quality of State solicitations, and to make our procurement process more responsive and business friendly, please provide comments and suggestions regarding this solicitation. Please return your comments with your response. If you have chosen not to respond to this solicitation, please email or fax this completed form to the attention of the Procurement Officer (see Key Information Summary Sheet below for contact information).

Title: Cancer Surveillance, Operations, and Quality Assurance for the Maryland Cancer Registry
Solicitation No: 24-19692

1. If you have chosen not to respond to this solicitation, please indicate the reason(s) below:
   - Other commitments preclude our participation at this time
   - The subject of the solicitation is not something we ordinarily provide
   - We are inexperienced in the work/commodities required
   - Specifications are unclear, too restrictive, etc. (Explain in REMARKS section)
   - The scope of work is beyond our present capacity
   - Doing business with the State is simply too complicated. (Explain in REMARKS section)
   - We cannot be competitive. (Explain in REMARKS section)
   - Time allotted for completion of the Proposal is insufficient
   - Start-up time is insufficient
   - Bonding/Insurance requirements are restrictive (Explain in REMARKS section)
   - Proposal requirements (other than specifications) are unreasonable or too risky (Explain in REMARKS section)
   - MBE or VSBE requirements (Explain in REMARKS section)
   - Prior State of Maryland contract experience was unprofitable or otherwise unsatisfactory. (Explain in REMARKS section)
   - Payment schedule too slow
   - Other: _____

2. If you have submitted a response to this solicitation, but wish to offer suggestions or express concerns, please use the REMARKS section below. (Attach additional pages as needed.)

REMARKS:

_____

Vendor Name: _____ Date: _____

Contact Person: _____ Phone (____) _____ - _____

Address: _____

E-mail Address: _____

STATE OF MARYLAND

DEPARTMENT OF HEALTH (MDH)

KEY INFORMATION SUMMARY SHEET

Request for Proposals	Services - Cancer Surveillance, Operations, and Quality Assurance for the Maryland Cancer Registry
Solicitation Number:	OCMP-24-19692
RFP Issue Date:	November 14,2023
RFP Issuing Office:	Maryland Department of Health (MDH)
Procurement Officer: **e-mail:** **Office Phone:**	LaCynda Conaway Office of Contracts Management & Procurement 201 West Preston Street Baltimore, MD 21201 Mdh.solicitationquestions@maryland.gov 443-694-5490
Proposals are to be sent to:	Proposals will be accepted through the State's eMaryland Marketplace Advantage (eMMA) e-Procurement system.
Pre-Proposal Conference:	Monday, December 4 · 10:00 – 11:00am Google Meet joining info Video call link: https://meet.google.com/fnz-yhzn-qeb Or dial: (US) +1 470-248-1548 PIN: 794 574 376# More phone numbers: https://tel.meet/fnz-yhzn-qeb?pin=1247744362294 See **Attachment A** for directions and instructions.
Questions Due Date and Time	December 29, 2023 2:00pm Local Time
Proposal Due (Closing) Date and Time:	January 12, 2023 2:00pm Local Time Offerors are reminded that a completed Feedback Form is requested if a no-bid decision is made (see **page iv**).
MBE Subcontracting Goal:	0%

VSBE Subcontracting Goal:	0%
Contract Type:	Firm fixed price
Contract Duration:	Five (5) years
Primary Place of Performance:	201 W. Preston Street, Baltimore, MD 21201
SBR Designation:	No
Federal Funding:	Yes

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1. Minimum Qualifications

1.1 Offeror Minimum Qualifications

There are no Offeror Minimum Qualifications for this procurement.

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2 Contractor Requirements: Scope of Work

2.1 Summary Statement

2.1.1 The Department of Health ("MDH" or the "Department") is issuing this Request for Proposals (RFP) in order to provide cancer data surveillance, operations, database management, and quality assurance services for the Maryland Cancer Registry (MCR or Registry) in accordance with the data requirements of Annotated Code of Maryland Health-General §18-203 and §18-204 (http://www.lexisnexis.com/hottopics/mdcode/) Code of Maryland Regulations (COMAR) 10.14.01 (http://www.dsd.state.md.us/COMAR/ComarHome.html); Public Law 102-515 (Appendix 3); the standards set by the Centers for Disease Control and Prevention's (CDC) National Program of Cancer Registries (NPCR) (Appendix 4-1through 4-14) and North American Association of Central Cancer Registries (NAACCR). The Department is seeking a Contractor with prior public health data experience, including State cancer registry experience and experience using CDC 'Registry Plus' Software products further described below.

2.1.2 It is the State's intention to obtain goods and services, as specified in this RFP, from a Contract between the selected Offeror and the State.

2.1.3 The Department intends to make a single award as a result of this RFP. See RFP **Section 4.9 Award Basis** for more Contract award information.

2.1.4 An Offeror, either directly or through its subcontractor(s), must be able to provide all goods and services and meet all of the requirements requested in this solicitation and the successful Offeror (the Contractor) shall remain responsible for Contract performance regardless of subcontractor participation in the work.

2.1.5 A Contract award does not ensure a Contractor will receive all or any State business under the Contract.

2.1.6 Maryland State and local entities as defined in Finance and Procurement 13-110(a)(5)(i) and not-for-profit entities within the State of Maryland may purchase from the Contractor goods or services covered by the Contract at the same prices chargeable to the State. All such purchases by non-executive branch entities, non-State governments, government agencies or not-for-profit entities:

A. Shall constitute Contracts between the Contractor and that government, agency or not-for-profit entity;

B. Shall not constitute purchases by the State or State agencies under the Contract;

C. Shall not be binding or enforceable against the State;

D. May be subject to other terms and conditions agreed to by the Contractor and the purchaser.

2.1.7 All Contract prices, terms, and conditions must be provided to any Maryland local government or not-for-profit entity requesting services under the Contract. The

Contractor bears the risk of determining whether or not a government, agency or organization with which the Contractor is dealing is a State entity.

2.2 Background, Purpose, and Goals

The Maryland Cancer Registry (MCR) collects, maintains, and reports data on cancer incidences in the State of Maryland as mandated by Annotated Code of Maryland, Health-General § 18-203-204. The law mandates the electronic submission of incident cancer reports (reports of invasive cancers and certain in situ [pre-malignant] cancers) to the MCR by hospitals, radiation therapy centers, and freestanding diagnostic laboratories licensed in Maryland. The reporting law requires freestanding ambulatory care facilities, and physicians whose non-hospitalized cancer patients are not otherwise reported, to report cancer cases diagnosed or treated. It also requires the electronic submission of benign brain and Central Nervous System (CNS) tumors to the MCR. Additional requirements may be found in other applicable laws and regulations.

All Reporting Facilities are required to submit these electronic reports within six (6) months of initial cancer/tumor diagnosis or treatment. Data are received through the Internet, either via file upload or online data entry. For reporters with a low annual cancer caseload (defined as less than 100 cases), hard copy reports are accepted. Data are used to track trends and uncover geographic differences in cancer incidence, as well as provide a systematic basis for conducting broad-based programs in cancer prevention and control throughout the State.

The MCR is comprised of a central office (located at MDH) and a Contractor, identified through this RFP, which serves as the cancer surveillance, operations, database management, and quality assurance center for the MCR. In addition to custodial oversight of the MCR, the central office oversees administrative aspects of the operations. The Contractor receives and processes all cancer reports per the standards and requirements of MDH; consolidates all reports for each cancer occurrence into an individual tumor record; manages the MCR Internet portal, software, and master database; performs auditing and quality assurance/quality control (QA/QC) activities; and addresses any QA/QC concerns. The Contractor responds to inquiries from Reporting Facilities and follows up with facilities as needed, such as when reported cases are lower than expected. The Contractor provides timely monthly reports for the activities to the MCR central office. The Contractor is responsible for collecting, managing, preparing, and submitting complete, high-quality data to National Program of Cancer Registries (NPCR) and North American Association Central Cancer Registries (NAACCR) on behalf of the MCR.

2.3 MCR Software. All MCR data are processed and stored in software products provided by the CDC known as Registry Plus, located online at http://www.cdc.gov/cancer/npcr/tools/registryplus/index.htm. The CDC provides technical consultation and upgrades to the software free of charge. Software and hardware maintenance and technical consultation are performed by the Contractor. Registry Plus products comprise of a set of computer programs that provide the necessary functions to operate and manage a central cancer registry, including:

A. Web Plus, which allows the submission of abstracts by both file upload and direct data entry to the Contractor;

B. Prep Plus, which initially processes abstracts submitted, in order to prepare the abstracts for loading into CRS Plus;

C. CRS (Central Registry System) Plus, which manages the linkage, consolidation, storage, and maintenance of cancer registry data for patients, tumors, and abstracts;

D. Link Plus, which is used to compare files (both internal and external records) to the MCR master database;

E. eMaRC Plus, which creates abstracts from HL7 reports received from laboratories and Clinical Document Architecture (CDA) files received from Meaningful Use (MU) submissions; and

F. XML Exchange Plus, which is a tool for reading and writing data exchange files formatted according to the NAACCR XML Data Exchange Standard Implementation Guide.

G. Match Pro, a linkage Software from the National Institutes of Health (NIH) used to compare files (both internal and external records) to the MCR master database;

H. Fundamental Learning Collaborative for the Cancer Surveillance Community (FLccSC), a web-based portal which allows Central Cancer Registries (CCR) to customize a fully functioning state-specific 'Learning Management System.' The Contractor's education and training coordinator will post all educational materials with the exception of the NAACCR webinars (posted by the MCR Program Coordinator);

I. CRISP, the Maryland health information exchange used to look up patients, laboratory reports, and other information to improve data quality and completeness;

J. SAS, a statistical Software suite developed by SAS Institute for data management, advanced analytics, multivariate analysis, business intelligence, and predictive analytics; and

K. A secure website for the submission of files via Web Plus, as well as a secure document server for exchange of data between the MCR central office and researchers, the National Death Index and the Vital Statistics Department and an SFTP site for upload of lab reports from MDH.

2.3.1 **Submission of Records to the MCR.** The MCR has been utilizing web-based reporting for over a decade, and all hospitals submit data using Web Plus. All external states with whom the MCR exchanges data, submit records via file upload to Web Plus. As noted above, several small facilities are permitted to mail in reports using paper forms; however, MCR aims to transition these facilities to electronic submission within the next three (3) years.

2.3.2 **Audits.** The Contractor conducts hospital case-findings annually for all hospitals, while Re-abstraction audits are completed on a rotating five (5) year basis. Reporting Facilities receive a written report on audit results. Additionally, the MCR itself is audited by CDC's NPCR at least once every five (5) years.

2.3.3 Annual Reports. The MCR publishes an annual report on cancer incidence in Maryland, and MDH is required to deliver a Fiscal Year (FY) report to the Maryland General Assembly no later than September 1st of each year.

2.3.4 Technical Assistance. A hotline is used by the Contractor to provide technical assistance to Reporting Facilities.

2.3.5 Website. The MCR maintains a website which is located at: https://health.maryland.gov/phpa/cancer/Pages/mcr_home.aspx.

2.3.6 Average Processing of the MCR, as of FY21:

A. Hard Copy Abstracts: 3,500 per year;

B. HL7 Reports: 9,000 per year;

C. XML files: 31,000 per year;

D. Abstracts: 95,000 per year;

E. Consolidated Records: 78,000 per year;

F. Submission Records: 55,000 per year; and

G. Abstract Records in MCR Software, Total: 2 million.

2.3.7 Project Goals

A. Follow Maryland Cancer Reporting Law and Regulations. The MCR collects, maintains, and reports data on cancer incidence in the State of Maryland as mandated by Annotated Code of Maryland, Health-General § 18-203-204.

B. Meet National Program Standards. The MCR is a member of NAACCR and the CDC's NPCR and strives to ensure that all central registry operations are in compliance with both NAACCR and NPCR standards. The NAACCR program standards are included in the following documents: NAACCR Standards for Cancer Registries, Volume II: Data Standards and Data Dictionary, and NAACCR Standards for Cancer Registries, Volume III: Standards for Completeness, Quality, Analysis, and Management of Data. Both documents are available for download from the NAACCR website: www.NAACCR.org. The most recent NPCR program standards are attached as **Appendix 4-1.**

C. Achieve Annual Data Quality Review and Certification. MCR data are evaluated for certification (Certification) by NAACCR on an annual basis, using the most recent complete year of incidence data. The purpose of the review is to certify the quality of the data is sufficient to use in the calculation of standard incidence statistics. The MCR was most recently awarded 'Gold Certification.' The certification criteria for NAACCR are listed below:

Table 1. NAACCR Certification Criteria		
Data Element	**Gold Certification**	**Silver Certification**
Completeness	95% complete	90% complete
% Passing Edits	100% of records pass edits	97% of records pass edits
Death Certificate Only Cases (DCO)	≤ 3%	≤ 5%
Timeliness	Received by NAACCR due date (within 23 months of diagnosis)	
Duplicate Reports	≤ 1/1,000	≤ 2/1,000
Missing Data Fields: Sex, Age, County	≤ 2%	≤ 3%
Missing Data Field: Race	≤ 3%	≤ 5%

In addition to submitting data for NAACCR certification, the MCR submits data to NAACCR for Cancer in North America (CINA) use.

MCR data (i.e., 23-month and 12-month data) are also submitted to CDC's NPCR for evaluation each year, and the NPCR standards are listed in Appendix 4-1 through 4-14.

2.3.8 State Staff and Roles

In addition to the Procurement Officer and Contract Monitor, the State staff includes epidemiologists and a Program Coordinator who will work in conjunction with the Contractor.

A. State Project Manager (also the Contract Monitor)

1) The State will provide a State Project Manager who will be responsible for monitoring the contract, reviewing, and approving contract deliverables, and providing technical assistance to the Contractor.

a) The State Project Manager will provide the following:

i) Assistance with start-up documents

ii) Contact information for previous vendor

iii) Contact information for NPCR Registry Plus Software

iv) Assistance with data submission

v) Review/approval of documents sent to Reporting Facilities

vi) Assistance addressing issues with Reporting Facilities

vii) Assistance with other issues, as needed

viii) Contact information of next vendor for training

B. Other State Furnished Roles

1) The State will provide an epidemiologist who will be responsible for quality checking data, providing assistance with data writeback, and assisting with any additional issues of data.

2) The State will provide a Program Coordinator who will be responsible for processing invoices.

3) The State will provide a data analyst from the Maryland Department of Health (MDH) Data Office that will oversee data management standards and governance for contract activities.

2.3.9 Other State Responsibilities

A. The State is responsible for providing required information, data, documentation, and test data to facilitate the Contractor's performance of the work and will provide such additional assistance and services as is specifically set forth herein.

2.4 Responsibilities and Tasks

All services to be performed under the Contract, in addition to meeting the requirements identified under the RFP, shall be performed in accordance with guidelines and the standards set by:

1. NPCR (Appendices 3-1 through 3-14), NAACCR, and the data requirements of Annotated Code of Maryland Health – General §§ 18-203-204 (http://www.lexisnexis.com/hottopics/mdcode/)

2. Code of Maryland Regulations 10.14.01 (http://www.dsd.state.md.us/COMAR/ComarHome.html)

3. Public Law 102-515 (Appendix 3) and Maryland Department of Health Data Office policy and standards (https://health.maryland.gov/Documents/MDH%20Data%20Use%20Policy%2001.06.01.pdf)

4. (https://health.maryland.gov/Pages/mdhpolicies.aspx)These standards may change throughout the Contract, the Contractor is expected to meet all required standards for each incidence year.

The Contractor shall:

2.4.1 Cancer Registry Operations and Quality Assurance for the Maryland Cancer Registry.

2.4.1.1 Within twenty-one (21) days of the Notice to Proceed, maintain a computerized log, accessible in Microsoft EXCEL or Microsoft ACCESS, of facilities and personnel who

report data to the MCR including: facility ID, name, and demographic information; names and contact information of personnel (reporters and supervisors); a log of prior facility contacts; and a log of technical assistance provided.

2.4.1.1.1 Within seven (7) days of the Notice to Proceed, obtain from the prior MCR contractor, if not incumbent, copies of manual logs of facility contacts and technical assistance between 'Certified Tumor Registrars' (CTRs) and reporters. Update the facility log and the technical assistance log when contacts with reports are made. Any changes to the format of these files must have the approval of the Contract Monitor. The Contract Monitor will provide necessary contact information and facilitate this transfer.

2.4.1.1.2 Per the NPCR Program Standards (Appendix 4-1), develop and maintain a database of facilities and physicians to complete the 'NPCR Hospital, Pathology Laboratory, and Physician Progress Report' (Appendix 4-14), and follow the CDC's 'NPCR Physician Reporting Guidance' (Appendix 4-12) and NPCR's 'Electronic Reporting and Data Exchange Guidance' (Appendix 4-13).

2.4.1.2 Within thirty (30) days of the Notice to Proceed, maintain a computerized log of all abstracts received from each Reporting Facility that includes facility ID, number of abstracts received, date received, format of data received, and NAACCR version, if electronically submitted.

2.4.1.2.1 Within seven (7) days of the Notice to Proceed, obtain from the prior MCR contractor, if not incumbent, copies of hard copy logs and electronic logs of abstracts submitted to the MCR. Update these logs as additional abstracts or hard copies are received. Any changes to the format of these logs must be approved by the Contract Monitor. The Contract Monitor will provide necessary contact information and facilitate this transfer.

2.4.1.3 Upgrade or replace user software and hardware and make appropriate changes to customize Software if/when technical advancements dictate, such as when modifications are necessary to keep in compliance with MDH, NPCR standards, and NAACCR standards. The Contractor shall make further upgrade(s) or replacement(s) during the life of the Contract in order to maintain compliance with standards and keep pace with necessary technological advances.

2.4.1.4 Within forty-five (45) days of the Notice to Proceed, provide access for Department staff and other individuals approved by the Contract Monitor to periodically access data from the MCR, while maintaining data security.

2.4.1.4.1 Develop, implement, and maintain procedures for granting access to data by approved MCR staff and approved individuals. Process shall include all standards for access to State data platforms including Software and including compliant hardware.

2.4.1.4.2 Adhere to MDH Data Office processes, procedures and standards for work within the Contract or obtain an exception from the MDH Data Office.

2.4.1.4.3 Provide MDH with technical assistance and expertise on matters within the scope of work of the Contract, as needed.

2.4.1.5 Maintain and update data processing policies and procedures.

2.4.1.5.1 **Operational/Procedural Manual:** Within thirty (30) days after the Notice to Proceed, the Contractor will update the existing MCR Operations Manual. This manual shall incorporate, or reference materials produced by standard setters (e.g., NAACCR and NPCR). All MCR Contractor staff and the Contract Monitor shall be provided with a copy of or access to the manual. This manual and all changes thereto shall be subject to the approval of the Contract Monitor. The Contractor shall make changes in policies and procedures and update the operations/procedure manual based on Contractor need, or as requested by the Contract Monitor, and submit changes to the Contract Monitor, who will endeavor to review and seek revision or approve within thirty (30) days.

2.4.1.5.2 **Facility Manuals:** Review yearly documents for Reporting Facilities, including letters, user application forms, reporting requirements documents, and Web Plus user guides. Determine needed updates in consultation with the Contract Monitor. When updates are needed, as determined by the Contractor or the Contract Monitor, develop updated material, obtain approval of the Contract Monitor, and provide Reporting Facilities with PDF versions for posting to the web (Web).

2.4.1.5.3 **Disease Index**: The Contractor will review and update the Disease Index by October 30th yearly to make sure that all changes in International Classification of Disease (ICD)-10 Clinical Modification (CM) or later versions are incorporated into the MCR Disease Index.

2.4.1.5.4 **Cancer Reporting Handbook:** The Contractor will develop, in the first six (6) months of the contract, a **Cancer Reporting Handbook** that will contain important updates for cases diagnosed January 1, 2024, and forward, coding and reporting requirements to the MCR, and other vital information. The Contractor will update this handbook every year by June 30th.

2.4.1.6 Maintain and update System Administration Manual. Within forty-five (45) days after the Notice to Proceed, the Contractor shall update the 'Systems Administration Manual.' The Contractor shall revise the System Administration Manual when any changes are made to the policies and procedures relating to the Systems Administration Manual, and submit changes to the Contract Monitor, who will endeavor to review and seek revision or approve within thirty (30) days.

2.4.1.7 Maintain and update System Security policies and procedures. The Contractor shall:

2.4.1.7.1 Include in its technical Proposal a schematic of the proposed IT set up, including a visual picture showing the configuration of the hardware (e.g., servers, computers), Software, and firewalls, and a written description of the configuration.

2.4.1.7.2 Update new software applications, new functionality, new modules, significant changes, new data elements, new Software, hardware and storage shall be approved by the Data Office.

2.4.1.7.3 Store all reporting data on secured State platforms approved by the Data Office.

2.4.1.7.4 Agree that all data produced during the performance of the Contract is owned by the State.

2.3.1.7.5 Obtain approved by the Data Office for tools that transport data, report data, provide decisions or learn from the data such as ETL tools, business intelligence, reporting or artificial intelligence and adhere to the Data Office quality standards and process and procedures.

2.3.1.7.6 Maintain the confidentiality of the Contractor's MCR databases in accordance with Annotated Code of Maryland Health – General §§ 18-203 and 18-204, and Code of Maryland Regulations 10.14.01, and acknowledge agreement with the Data Use Policy of MDH at https://phpa.health.maryland.gov/cancer/Pages/mcr_data.aspx, which views the MCR database as a Department-owned database with data release subject to restrictions and conditions, included in Sections 3.7.4-3.7.9 of this RFP. 2.3.1.

2.3.1.7.7 Maintain the confidentiality of the Contractor's MCR databases in accordance with Annotated Code of Maryland Health – General §§ 18-203 and 18-204, and Code of Maryland Regulations 10.14.01, and acknowledge agreement with the Data Use Policy of MDH at https://phpa.health.maryland.gov/cancer/Pages/mcr_data.aspx, which views the MCR database as a Department-owned database with data release subject to restrictions and conditions, included in Sections 3.7.4-3.7.9 of this RFP.

2.3.1.7.8 Meet NPCR's data security standards and other security standards outlined in, but not limited to, the list below:

A. NAACCR Standards for Cancer Registries, Vol. III: Standards for Completeness, Quality, Analysis, and Management of Data, chapter 6 https://www.naaccr.org/standards-for-completeness-quality-analysis-and-management-of-data/;
B. VHA Directive 2007-023;
C. The Health Insurance Portability and Accountability Act (HIPAA) https://www.hhs.gov/hipaa/index.html; and
D. OMB Protection of Sensitive Agency Information Memo https://www.osec.doc.gov/opog/privacy/Memorandums/OMB_M-06-16.pdf.

2.3.1.7.9 Within fourteen (14) days after initial Notice to Proceed, implement a series of internal procedures to ensure that access to automated information is restricted to authorized persons on an as needed basis and control is maintained over all documents that contain sensitive information to ensure that these documents are available only to authorized persons.

2.3.1.7.10 Within fourteen (14) days after initial Notice to Proceed, implement full security measures to ensure the security and quality of all elements in the MCR database, through procedures that shall include the following:

A. Ensure that equipment is protected from theft and accidental or deliberate damage or misuse.

B. Ensure that once computer programs and data sets are completed and in routine use, they are protected against tampering. Carefully control access to and maintenance of computer programs and Contractor's MCR database.

C. Ensure that a copy of original data submitted is maintained and never altered.

D. Ensure that data are protected against inadvertent or deliberate destruction, modification, or dissemination.

E. Ensure procedures exist and are followed for backup, archiving, and disaster recovery for computer programs and the Contractor's MCR database.

F. Ensure that passwords are changed, access is denied, and other security procedures are in place to protect against ongoing access, sabotage, or both when staff resign, are terminated, or are no longer assigned to the MCR project.

2.3.1.7.11 Within thirty (30) days after initial Notice to Proceed, furnish the Contract Monitor with copies of the Contractor's plans, procedures, and protocols for ensuring that the Contractor's MCR database system and data managed by the system will be properly secured, maintained, and updated throughout the Contract term. The Maryland Department of Health Data Office must review and approve the plans, procedures and protocols.

2.3.1.7.12 Be responsible for maintaining the security and integrity of the MCR's data. The Contractor will promptly re-process data at no additional cost to MDH, in accordance with MDH's instructions, if the Contract Monitor or the Contractor finds that the Contractor has corrupted, altered, tampered with, or improperly coded or processed any data sets during the term of the Contract.

2.3.1.7.13 Within twenty-four (24) hours, the Contractor will report to the Contract Monitor all errors or anomalies in MCR data which could reasonably be believed to suggest that the security or integrity of the MCR or its data may be compromised. The Contractor will report to the Contract Monitor the results of its analysis of the same and in addition, the steps it has taken or intends to take to ensure the security and integrity of the MCR and its data. The Contractor will be responsible for implementing appropriate policies, procedures, and protocols to identify active or threatened breaches of the MCR's security or integrity.

2.3.1.7.14 Comply with MDH's and the Registry's encryption standards before any sensitive data are stored, sent, or received on a Contractor's laptop computer or mobile device. This applies to all Contractor and subcontractor-owned laptop computers and mobile devices containing Registry Data At Rest and in motion.

a) All laptop computers used on behalf of the Registry must be secured using a Federal Information Processing Standard (FIPS) 140-3 compliant whole-disk encryption solution. The cryptographic module used by an encryption or other cryptographic product should be tested and validated under the Cryptographic Module Validation Program to confirm compliance with the requirements of FIPS PUB 140-2 (as amended). For additional information, refer to the National Institute of Standards and Technology's (NIST) Security Management and Assurance.

b) All mobile devices, including non-registry laptops and portable media (i.e., USB storage devices, thumb drives), that contain sensitive Registry information shall be encrypted using a FIPS 140-3 compliant product. Data At Rest includes all Registry data regardless of where they are stored.

c) FIPS 140-3compliant key recovery mechanism shall be used so that encrypted information can be decrypted and accessed by authorized personnel. Use of encryption keys which are not recoverable by authorized personnel shall be avoided. Key recovery is required by and required to be in compliance with "OMB Guidance to Federal Agencies on Data Availability and Encryption, [PDF-7KB]", dated November 26, 2001.

d) Encryption key management will comply with all MDH and Registry policies and will provide adequate protection to prevent unauthorized decryption of the information.

e) All media used to store information shall be encrypted until it is sanitized or destroyed in accordance with MDH and Registry policies and procedures.

2.3.1.8 Register and process all tumor reports. The Contractor shall:

2.3.1.8.1 Develop and implement procedures for the timely receipt and processing of cancer reports into the cancer database. Maryland law requires facilities to submit cases quarterly, although more frequent submissions are encouraged. The Contractor shall log in all abstracts submitted by reporters within one (1) working day. The Contractor shall process all hospital tumor reports through CRS Plus within three (3) months of receipt. The Contractor shall process all other facilities' tumor reports through CRS Plus within four (4) months of receipt. The Contractor shall process any tumor reports through CRS Plus that were previously received, but not yet processed, within five (5) months.

2.3.1.8.2 Process hard copy abstracts received from Reporting Facilities within three (3) months of receipt. Most facilities submit reports electronically; however, physician and ambulatory care and surgery centers that diagnose or treat less than one hundred (100) cases annually, with permission, may submit hard copy abstracts to the MCR. Processing shall include coding data on the form and entering the data from hard copies into Web Plus, the main electronic database.

2.3.1.8.3 Process all electronic tumor reports received from reporting entities through Prep Plus and CRS Plus within three (3) months of receipt. There are currently six hundred and eighty (680) Maryland reporting entities (i.e., hospitals, laboratories, radiation therapy centers, ambulatory care / surgery centers, and physician offices) who submit cancer reports electronically to the MCR. Most electronic cancer reports are submitted online via the Web Plus system. Based on current figures, the MCR estimates that the Contractor will receive ninety-eight thousand (98,000) individual reports, including in situ (pre-malignant) cases, benign brain and CNS cases, and non-reportable cases annually.

2.3.1.8.4 Perform routine, standard edit checks on all reports received, in accordance with NPCR http://www.cdc.gov/cancer/npcr/index.htm and NAACCR www.NAACCR.org standards. The Contractor shall be responsible for the accuracy of the data it codes, enters, edits, and consolidates, and for maintaining the integrity of the data from year to year. At a minimum, the editing and review of the data shall include the following:

a) Routine visual review of abstracts and error reports. Visual review shall be at least 20% of incoming abstracts. If a facility has excessive errors, visual review for that facility shall increase to at least 50% of incoming abstracts until errors that were occurring are diminished.

b) Frequently occurring errors should be noted for training opportunities and inclusion in the MCR 'E-Update' or on FLccSC.

c) Installation and use of the most recent standard edit set metafiles as recommended by the Contractor and approved by the Contract Monitor. The Contractor shall facilitate running edit metafiles in Web Plus that are up to date by year and version of NAACCR record layout.

d) Application of edits at several points during the data flow including:

2.3.1.8.4.d.1 For abstracts, before submission to the MCR from facilities that have electronic data systems for tumor registration. The Contractor shall facilitate the running of edits by Reporting Facilities, especially hospitals, prior to data submission by making the MCR edit metafile available to facilities and Registry Software vendors;

2.3.1.8.4.d.2 For Web Plus direct data entry, at the time of release of an abstract;

2.3.1.8.4.d.3 For abstracts, at the time that CTRs process them in Prep Plus;

2.3.1.8.4.d.4 For MCR consolidated database records, in CRS Plus at the time of abstract consolidation; and

2.3.1.8.4.d.5 For the MCR consolidated database records, quarterly run the NPCR and NAACCR submission edits, make corrections, and submit edit summary sheets with quarterly reports to the Contract Monitor.

a) Detection of errors during the editing, documentation of errors found, and correction of these errors.

b) Detection and consolidation of multiple abstracts (tumor records) that match cases received in the current or prior years.

2.3.1.8.5 Review abstract data submitted by each facility to verify that the number of abstracts received are within expected number from previous submissions. For facilities which submit Accession Numbers, verify that there are no large sections of missing numbers. If so, the Contractor shall contact the facility to verify missing numbers.

2.3.1.8.6 Assist Eligible Providers (EPs) that apply for a 'Meaningful Use' (MU) account or other public health reporting requirements for the purpose of submitting electronic cancer reports.

2.3.1.8.7 Assist laboratories to use the AIMS platform, from the Association of Public Health Laboratories (APHL), and process cases submitted through the MDH portal.

2.3.1.9 **Consolidate tumor records.**

2.3.1.9.1 Within thirty (30) days of the Notice to Proceed, develop and implement procedures for the timely and accurate consolidation of cancer reports.

2.3.1.9.2 Consolidate tumor records and treatment information in accordance with any standards set forth by NAACCR, NPCR, or the National Cancer Institute's Surveillance Epidemiology and End Results (SEER) program. Consolidate tumor records using CTRs and perform consolidation on a routine basis within the time frame, as described in Section 2.3.1.8.1.

2.3.1.9.3 Detect and remove duplicate consolidated cases (that is, two or more consolidated records for the same tumor in an individual). The Contractor shall develop a strategy for the routine, continual detection and removal of duplicates from the MCR database – even after the current accession year has closed.

2.3.1.9.4 Provide consultation, technical assistance, and training to assure accurate, timely, and complete data from reporters (i.e., registrars, medical records personnel, and abstractors) at Reporting Facilities (i.e., hospitals, freestanding ambulatory care facilities, freestanding laboratories, therapeutic radiation therapy centers, and offices of physicians).

2.3.1.9.5 Adhere to all Data Office processes, procedures, standards, reporting, meeting requirements and policies.

2.3.1.9.6 Integrate new data, distribute and exchange data to external entities with required approval of the Data Office.

2.3.1.9.7 Provide technical assistance by phone or in person to individual Reporting Facilities during Normal State Business Hours (with an average of forty-five (45) telephone contacts, numerous e-mail consultations, and up to two (2) possible on-site consultations per month). Response time for telephone and e-mail consultation shall be no longer than one (1) working day after request is received or, for on-site consultation, no longer than ten (10) working days.

2.3.1.9.8 Assess the training needs of various Reporting Facilities; develop written guidance, policies, and procedures for Reporting Facilities; and provide technical assistance and training for Reporting Facilities.

2.3.1.10 Carry out QA/QC activities; assure appropriate data coding, consolidation, and documentation; and assure complete case ascertainment and high-quality data from all reporting sources in accordance with Maryland laws and regulations,

Data Office Quality standards and procedures, NAACCR standards, and NPCR standards.

2.3.1.10.1 Within thirty (30) days of Notice to Proceed, develop and implement a QA/QC implementation plan (including timeline) which, at a minimum, incorporates the following activities into routine operations:

a) Assignment of qualified individuals to perform QA/QC activities;

b) A routine schedule for edits and internal management reports;

c) A routine schedule for internal (Contractor) audits for QA/QC and data security, and provision of these reports to the Contract Monitor. The plan shall include written procedures for the internal monitoring of quality assurance procedures and written procedures and steps to be implemented if QA/QC goals are not met;

d) Procedures for documenting edits or changes made to data during processing; and

e) Routine training, assessment, and professional development of the Contractor's CTRs.

2.3.1.10.2 Perform case finding and quality review activities utilizing traditional and non-traditional sources to assure timeliness and completeness of cancer and benign brain and CNS tumor case reporting.

a) By June 30th of each year, obtain and utilize a "diagnostic index" for case finding from hospitals. Review the number of reports submitted to the MCR by the facility and compare to the diagnostic index to identify whether the facility is potentially under-reporting cases.

b) Obtain and utilize patient logs or computer printouts of selected freestanding therapeutic radiological center patients and ambulatory care facility patients for a given calendar year to compare to reported cases for case finding.

c) By June 30th of each year, complete selective case finding audits report. The facilities selected for the audits shall be approved by the Contract Monitor. At a minimum, all hospitals should be audited at least once every five (5) years. Facilities with poor reporting patterns may be subject to more frequent audits, at the discretion of the Contract Monitor. This activity shall begin with cases diagnosed during the year 2021. Provide the Contract Monitor with the audit report for approval and the audited facilities with the detailed final reports on the results of the audits (Section 2.3.1.18.4).

d) By June 30th of each year, complete re-abstraction of a random sample of the cancer/tumor reports received from selected Reporting Facilities to determine the accuracy of cancer data in the MCR database. The facilities and Cancer Sites selected for the audits shall be approved by the Contract Monitor. The number of cases to be re-abstracted are to be a minimum of five (5) cases per site unless approved by the Contract Monitor. At a minimum, all hospitals should be audited at least once every five (5) years. This activity shall begin with cases diagnosed during the year 2021. Provide the Contract Monitor with the Re-abstraction report for approval and the audited facilities with detailed reports on the results of the audits and recommendations for improvement, as necessary (Section 2.3.1.18.4).

e) Review and evaluate all "laboratory only" reports of cancer (i.e., those cancer cases on whom the MCR received only a case abstract report from a laboratory), at least annually including the referring/ordering physicians, obtain additional data on the case from the physician or CRISP, the Maryland Health information Exchange, and determine whether the physician should be enrolled as an MCR reporting source.

f) At least quarterly, utilize SAS or other Software approved by the Maryland Department of Health Data Office to conduct additional QA/QC analyses (e.g., analyses to identify changes during the consolidation process to fields that should not change over time (e.g., race, ethnicity, address at diagnosis, etc., unusual cancer counts/rates in a particular geographic location compared to data from prior years, or other data anomalies), investigate data anomalies, and take corrective action as needed.

2.3.1.11 **Obtain death data and incorporate data into MCR database**.

2.3.1.11.1 **'Death Case Finding and Follow Back':** By July 31st of each year, the Contractor shall complete Death Clearance activities. The Contractor will follow the procedures outlined in the most current version of the NAACCR Death Clearance Manual https://www.naaccr.org/wp-content/uploads/2020/04/DC_Manual_Appendix_I_updated_Final_04162020-1.pdf. The Contract Monitor will provide the Contractor with computerized death certificate data from the MDH Vital Statistics Administration. This file contains all deaths of Maryland residents where cancer is the primary cause of death or an underlying cause of death. The Contractor shall match the electronic file containing key fields against the MCR consolidated database. For deaths of individuals where cancer is a primary or underlying cause, but where the individual is not found in the MCR database, the Contractor shall divide the list into two (2) files for Follow Back: one file where the person died in a facility where the name of the hospital, nursing home, assisted living facility, or hospice is known (around three thousand (3,000) cases per year), and one (1) file where the death was not in a facility (around two thousand (2,000) cases per year). The Contractor will Follow Back to hospitals, nursing homes, assisted living facilities, or hospices to obtain a case abstract report with relevant cancer information, such as date of diagnosis, primary site(s), pathology, and histology of cancer, staging, treatment, etc. for entry into the MCR master database. For the out of facility file where there is no named hospital, nursing home, assisted living facility, or hospice, the Contractor will match these cases with the previously sent hospital disease indices. Any matches are then sent to that facility for additional information. The Contractor will send the remaining cases to the Contract Monitor to obtain electronic death certificates. Using the death certificate information, the Contractor will Follow Back to the physician who signed the death certificate to attempt to obtain a case abstract report with relevant cancer information, such as date of diagnosis, primary site(s), pathology, and histology of cancer, staging, treatment, etc. for entry into the MCR master database. The Contractor shall complete the Follow Back within sixty (60) days of receiving the death certificate information from MDH. The Contractor will write the Follow Back information to the MCR master database and code the 'Type of Reporting Source' as specified in the NAACCR Death Clearance Manual, including recoding the Type of Reporting Source to reflect the new source of report for those reported from another source.

2.3.1.11.2 **Vital Statistics Match Write Back.** The Contract Monitor will provide the Contractor with a computerized file of all individuals in the MCR master database who were matched to the Vital Statistics database. The Contractor shall match the file with the MCR database and update the vital status, the date of death, and cause of death for the cases, and will code Follow-up Source Central as Vital Statistics annually. The Contract Monitor will approve the write-back on

the test database before the Contractor completes the write-back on the production database.

2.3.1.11.3 **Social Security Death Index (SSDI) Write Back.** The Contract Monitor will provide the Contractor with a computerized file of individuals in the MCR master database that were matched to the SSDI database. The Contractor shall match the file with the MCR database and update the vital status and the date of death for the cases and will code Follow-up Source Central as SSDI at least on a bi-annual basis. The Contract Monitor will approve the write-back on the test database before the Contractor completes the write-back on the production database.

2.3.1.11.4 **National Death Index (NDI) Write Back.** The MCR is required to match with the NDI on an annual basis. The Contractor will need to complete the following:

A. Run and correct errors identified through the NDI edit evaluation program;
B. Provide the MCR with a computerized file of the edited (and error free) NDI extract; and
C. The Contract Monitor will provide the Contractor with a computerized file of individuals in the MCR master database that were matched to the NDI database. The Contractor shall match the file with the MCR database and update the vital status, the date of death, and the cause of death for the cases, and will code Follow-up Source Central as NDI.
D. The Contractor shall be asked to provide expertise or assistance in review of the MCR master database match with the NDI.

2.3.1.12 **Indian Health Service (IHS) Linkage.** The Contractor is expected to assist the Contract Monitor to complete the requirements for linkage with the IHS database and Write Back to the MCR database per the NPCR requirements. This linkage is expected to occur once every five (5) years (expected in 2026).

2.3.1.13 Geocode Write Back.

2.3.1.13.1 MDH is currently responsible for Geocoding the data provided by the Contractor.

2.3.1.13.2 Obtain from the Contract Monitor the geocoded data file and link the geocoded data to the MCR master database, when appropriate, after editing for compatibility, and consistency. The Contractor shall update the MCR master database with new geocoded information on county, census tract, block group, latitude, longitude, and census tract certainty. The Contractor is responsible for ensuring geocoded fields are not overwritten during subsequent data Write Backs, unless done so purposefully on an individual case basis.

2.3.1.13.3 Provide the means to identify cases where Geocoding information has been written to the cases and the county code written or updated by providing appropriate management reports.

2.3.1.13.4 Take over the Geocoding if the Registry Plus program can geocode in a manner approved by the Contract Monitor.

2.3.1.14 Additional Write Backs may need to be completed as directed by the Contract Monitor. The Contract Monitor will approve the write-back on the

test database before the Contractor completes the write-back on the production database.

2.3.1.15 **Conduct semi-annual interstate data exchange with jurisdictions with whom MDH has entered into exchange agreements and incorporate out-of-state reports into MCR database.** The data shall be exchanged, semi-annually in October and April, using the agreed upon NAACCR format and will have been edited to the extent possible. MDH has signed the National Interstate Data Exchange Agreement through NAACCR. This agreement as well as any individual state agreements that may be executed by MDH during the life of the Contract will be supported by the Contractor.

2.3.1.15.1 Submit semi-annual electronic cancer and benign brain and CNS tumor data on non-Maryland residents received by the MCR from reporting entities to jurisdictions with which MDH has exchange agreements. The Contractor shall submit the data to these states directly.

2.3.1.15.2 Monitor and contact (semi-annually) those states with exchange agreements that have not exchanged data, specifically for the surrounding states and the District of Columbia, verifying there were no Maryland residents diagnosed with cancer in those states during the reporting period.

2.3.1.16 Attend Meetings.

2.3.1.16.1 Make available Key Personnel, including but not limited to the director of operations, project director, quality assurance supervisor, database manager, and database administrator, to meet with appropriate Department personnel [up to daily if deemed necessary by the Contract Monitor, not to exceed fifty (50) meetings per year] to discuss transition to the new Contractor, policies and procedures, ongoing activities, and Contract deliverables. The Contractor will take minutes of these meetings and provide them to the Contract Monitor within seven (7) days of the meeting.

2.3.1.16.2 The Contractor's representative (Project Director) shall attend the MCR Cancer Registry Advisory Committee (CRAC) meetings (three times annually) to present an update on the status of Registry operations.

2.3.1.16.3 The Contractor's representative (including but not limited to Project Director or designated Education and Training Coordinator (ETC)) shall attend the Tumor Registrars Association of Maryland meetings (at least biannually) to present a brief update of Registry operations and give feedback to registrars on reporting issues.

2.3.1.16.4 The Contractor's Project Director will attend the annual Program Directors meeting, if invited by NPCR.

2.3.1.16.5 The Contractor shall send at least one (1) person (the designated ETC) to the annual NPCR "train the trainer" meeting.

2.3.1.16.6 Appropriate representative(s) (including but not limited to Project Director) from the Contractor's staff shall represent the MCR on the CDC's Registry Plus User's Group teleconferences (monthly) to learn of recent updates, problems, and share Maryland experiences with Registry Plus products, as needed.

2.3.1.16.7 Appropriate representative(s) (including but not limited to Project Director) from the Contractor's staff shall represent the MCR on the NPCR AERRO ePath Workgroup teleconferences (monthly) to learn of recent updates and problems, and to share Maryland experiences with Registry Plus products, as needed.

2.3.1.16.8 The Contractor shall attend and supply subject matter specialists to attend Maryland Department of Health Data Office Meetings.

2.3.1.16.9 Appropriate representative(s) (including but not limited to Project Director) from the Contractor's staff shall represent the MCR on the Meaningful Use workgroup teleconferences (quarterly) to learn of recent updates, problems, and to share Maryland experiences with Registry Plus products, as needed.

2.3.1.17 Prepare the following reports and documents:

2.3.1.17.1 **Management Reports.** Develop and either submit to the Contract Monitor, or make available for Contract Monitor's review, the following reports as specified in **Appendix 6** on a monthly, quarterly, or annual (calendar year) basis: administrative reports, facility reporting reports, abstract reports, consolidated record reports, and data processing reports. Reports shall be created and stored in compliance with the Maryland Department of Health Data Office standards.

2.3.1.17.2 **Monthly Management Reports**. Develop and email to the Contract Monitor a monthly management report, no later than the 6th day of the following month. The report shall also include:

a) Status of Contract deliverables, with key milestones and status of each deliverable;
b) Information technology activities;
c) Operational activities, including QA/QC activities conducted during the previous month;
d) Monthly, quarterly, and annual Management Reports (as specified in Appendix 6);
e) Audits performed and findings;
f) Meetings and conferences;

g) Technical help activities;
h) Training activities;
i) Interstate data exchange report; and
j) Any other content determined as necessary by the Contractor or the Contract Monitor.

2.3.1.17.3 Facility Reports.

a) Create a yearly report for each Reporting Facility to be sent to each facility which has submitted data during the previous year that includes the number of cases submitted and the mean of the number of cases submitted over the preceding three (3) years. The Contractor shall submit an electronic file directly to the Contract Monitor no later than the 30th day of April and shall submit one (1) copy of each facility's report (electronically or hard copy) to that facility no later than the 31st day of May.
b) Monitor facility submissions quarterly. The Contractor will contact the facilities where annual submissions fall more than 10% below the three (3) year mean of past submissions (as an expected number for that facility) or more than 100 cases, to find out why there has been a decrease. Two (2) hard copies and an electronic file of the annual submissions and expected numbers by facility are to be submitted annually to the Contract Monitor.

2.3.1.17.4 **Facility Audit Report (Case Finding and Re-Abstraction):** Provide the Contract Monitor with facility specific reports detailing the results of each audit performed, including an overall summary. An electronic file is to be submitted no later than forty-five (45) days after the conclusion of the audit. The Contractor shall include this information in a report submitted to each audited facility within sixty (60) days after the completion of all audit activities. During the last year of the contract, all reports shall be due on or by June 30th.

a) Case finding shall consist of review of the facilities' Disease Index, as well as review of pathology and cytology reports. The number of months of review will be dependent on the size of the facility and the approval of the Contract Monitor.
b) Re-abstraction is performed to assess the accuracy (agreement with source medical records) and reproducibility (agreement among data collectors) of Registry data. The number of cases re-abstracted will be dependent on the size of the facility and the approval of the Contract Monitor. The types and number of data fields reviewed are also to be approved by the Contract Monitor.

2.3.1.17.5 **Fiscal Year (FY) Report:** By July 3rd of each year, beginning with FY 2025 (July 1, 2024 – June 30, 2025), provide the Contract Monitor with an electronic file of a FY Report. The content and format of the FY Report may be modified at the discretion of the Contract Monitor or with approval of the Contract Monitor. During the last year of the Contract, the report shall be due in the last month of the Contract. The FY Report is to contain information on the Contractor's activities during the preceding fiscal year including:

a) Summary describing the current status of cancer reporting in Maryland;
b) Summary of all training, QA, and data processing activities completed during the fiscal year;
c) Any problems encountered to reach the required level of cases and quality of reporting for meeting NPCR certification;
d) Recommendations for improving the MCR data management system and upon approval of the Contract Monitor implement recommendations;
e) Activities and recommendations related to numbers and processing of benign brain and CNS tumor reports; and
f) Total number of abstracts submitted during the fiscal year, total number by state of residence at diagnosis; and total number of benign brain and CNS tumors by year of diagnosis and tumor behavior ICD-O-3 site (benign and borderline) in the MCR database.

2.3.1.17.6 Run the NPCR and NAACCR submission edits quarterly and submit the summary page of the edit reports to the Contract Monitor. The Contractor will review and resolve the edit errors found on a quarterly basis at minimum.

2.3.1.17.7 Assist the Contract Monitor with reports or surveys as requested from NPCR or NAACCR, including but not limited to the biennial 'Program Evaluation Instrument' and the annual 'Cost Assessment Tool.'

2.3.1.17.8 Provide additional QA/QC reports, as deemed necessary by the Contract Monitor.

2.3.1.18 Prepare evaluation data for all measures outlined in Appendix 5 and submit the data to the Contract Monitor's approval by July 31st each year. Prepare a 'Success Story' every year for NPCR with the Contract Monitor's approval. (See Appendix 4-7)

2.3.1.19 Participate in NPCR's data modernization strategy with the approval of the Contract Monitor. (See Appendix 4-6)

2.3.1.20 **Provide MDH a copy of the MCR master database.** Provide MDH with data that represents the total abstracts and consolidated records that have undergone complete QA/QC procedures.

2.3.1.20.1 On a quarterly basis, provide the Contract Monitor with a copy of the MCR master database. For the first three (3) Quarters, the Contractor will provide a copy of the limited fields in the MCR master database, including an abstract dataset, a consolidated dataset, a facility dataset, and a reporters' dataset. The Contract Monitor will identify the limited field list for inclusion. For the last quarter (December 31st copy) (see Section 2.3.1.21.3), the Contractor will provide the Contract Monitor a complete copy with all fields included in the MCR master database, including the abstract dataset, the consolidated dataset, the facility dataset, and the reporters' dataset.

2.3.1.20.2 Provide yearly by July 31st, a preliminary copy of the database with all preparations for data submission completed for the Contract Monitor to verify the quality of the data prior to submission. This copy may be one (1) of the quarterly database submissions from Section 2.3.1.18.1, with the approval of the Contract Monitor.

2.3.1.20.3 Provide by January 15th of each year, a finalized, geocoded, incidence dataset of consolidated records and a dataset of abstracts which, beginning in FY 2025, includes cases diagnosed during the 2022 incidence year that have undergone complete QA/QC control procedures. The goal is for this dataset to:

a) Contain the consolidated cancer records (including treatment information) representing more than or equal to 90% of the number of "expected cancer cases" given by NAACCR and NPCR for Maryland, and the consolidated benign brain and CNS tumor cases for the incidence year;
b) Contain less than or equal to two (2) duplicate records per 1,000 records;
c) Contain less than or equal to 5% "Death Certificate Only" cancer cases. Cancer cases obtained from death certificate review shall be clearly identified;
d) Have at least 97% of records pass the NAACCR, NPCR, and Maryland-specific edits;
e) Have less than or equal to 3% of missing data for the fields "Sex," "Age," and "County of Residence at Diagnosis"; and
f) Have less than or equal to 5% of missing data for "Race."

2.3.1.20.4 Develop measures to flag cases used for the final annual incidence dataset for easy retrieval from the MCR master database. This helps identify tumor reports used in "official" Department incidence calculations and tumor reports received after the close of the accession year.

2.3.1.20.5 Develop procedures for maintaining an archived incidence dataset (both abstract and consolidated records). A list of these files and their location shall be provided to the Contract Monitor by January 15th of each year.

2.3.1.20.6 By December 1st of each year, submit a finalized dataset to NAACCR, as specified by the NAACCR standards for the requested incidence years. The Contractor shall submit a copy of this submission to the Contract Monitor. The Contract Monitor will determine if the data will be submitted for Certification only or for Certification and submission for publication in NAACCR's Cancer in North America (CINA) and in the online 'CINA Deluxe.' Data will be submitted to NAACCR as follows:

Contract Year	Fiscal Year	Date of Submission	Certification for Incidence Year	CINA Years
1	2025	11/2024	2022	1995 through 2022
2	2026	11/2025	2023	1995 through 2023
3	2027	11/2026	2024	1995 through 2024
4	2028	11/2027	2025	1995 through 2025
5	2029	11/2028	2026	1995 through 2026

2.3.1.20.7 By November 30th of each year, the Contractor shall submit a finalized dataset to NPCR, as specified by the NPCR standards for the requested twenty-four (24) month data and twelve (12) month data. The Contractor shall submit a copy of this submission to the Contract Monitor. Data will be submitted to NPCR as follows:

Contract Year	Fiscal Year	Date of Submission	24 Month Data	12 Month Data
1	2025	11/2024	1995 through 2022	2023
2	2026	11/2025	1995 through 2023	2024
3	2027	11/2026	1995 through 2024	2025
4	2028	11/2027	1995 through 2025	2026
5	2029	11/2028	1995 through 2026	2027

2.3.1.20.8 The MCR Database is the property of MDH. Any use of MCR data, including analysis beyond the scope of the Contract, publication, presentation, or posters, must be approved by the Contract Monitor and must follow the MCR's Data Use Policy and Procedures.

Deliverables and Key Performance Indicators

All date references in this paragraph shall be used in a "No Later Than" context for the Contract, unless otherwise specifically noted in the main body of the contract. All time periods are calendar days and not Business Days unless otherwise specifically stated in the main body of this RFP. The chart set forth below is provided for convenience, but it may not be all inclusive. The Contractor is responsible for all tasks and deliverables set forth in this RFP whether or not set forth in the chart below.

	Description of Key Deliverables	**Paragraph**	**Initial Term**
3.1.1. Transition and Start-Up (May – June 2024)			
1	Kick-Off Meeting.	3.1.1.A.	Within ten (10) calendar days after the Notice to Proceed
2	Develop a work plan.	3.1.1.B.	Seventeen (17) calendar days after the Notice to Proceed
3	Assign fully qualified staff.	3.1.1.C.	Within twenty-one (21) calendar days of the Notice to Proceed
4	Provide and set up necessary computer hardware, including servers and computers to maintain	3.1.1.F.1.	Within twenty-one (21) calendar days of the Notice to Proceed

	the MCR database.		
5	Establish necessary secure Internet connections and local connectivity.	3.1.1.F.2. & 3.1.1.F.3.	Within twenty-one (21) calendar days of the Notice to Proceed
6	Obtain a copy of the latest version of the confidential MCR database and copies of hard copy logs and electronic logs of abstracts.	3.1.1.G.1.	Within twenty-one (21) calendar days of the Notice to Proceed
7	Obtain training from the current Contractor for up to four (4) people.	3.1.1.G.2.	Within twenty-one (21) calendar days of the Notice to Proceed
8	Install and utilize the current automated MCR data management system, Registry Plus, developed and supported by the federal CDC, and populated with MCR data.	3.1.1.G.3.	Within thirty (30) calendar days of the Notice to Proceed
9	Develop and implement procedures for the electronic submission and processing of laboratory pathology reports.	3.1.1.G.6.	Within thirty (30) calendar days of the Notice to Proceed
10	Obtain, install, and utilize SAS and any other Software or coding obtained from the prior Contractor.	3.1.1.G.4	Within thirty (30) calendar days of the Notice to Proceed

Description of Key Deliverables	**Paragraph**	**Initial Term**
2.3.1 Cancer Registry Operations and Quality Assurance for the Maryland Cancer Registry. Beginning July 1, 2024		
1	Maintain a computerized log of facilities and personnel who report data to the MCR.	2.3.1.1	Within twenty-one (21) calendar days of the Notice to Proceed
2	Obtain copies of manual logs of facility contacts and technical assistance between CTRs and reporters.	2.3.1.1.1	Within seven (7) calendar days of the Notice to Proceed
3	Maintain a computerized log of all	2.3.1.2	Within thirty (30) calendar days of the

	abstracts received from each reporting facility.		Notice to Proceed
4	Obtain copies of hard copy logs and electronic logs of abstracts submitted to the MCR.	2.3.1.2.1	Within seven (7) calendar days of the Notice to Proceed
5	Provide means for approved MDH staff to periodically access data.	2.3.1.4	Within forty-five (45) calendar days of the Notice to Proceed
6	Update the existing MCR Operations Manual.	2.3.1.5.1	Within thirty (30) calendar days after the Notice to Proceed
7	Review and update the Disease Index.	2.3.1.5.3	By October 30th of each year
8	Maintain and update System Administration manual.	2.3.1.6	Within forty-five (45) calendar days after the Notice to Proceed
9	Implement procedures to ensure that: (1) access is restricted to authorized persons, and (2) control is maintained.	2.3.1.7.5	Within fourteen (14) calendar days after initial Notice to Proceed
10	Implement full security measures to ensure the security and quality of the MCR database.	2.3.1.7.6	Within fourteen (14) calendar days after initial Notice to Proceed
11	Maintain the security and integrity of the MCR's data.	2.3.1.7.7	Ongoing
12	Develop and implement procedures for the timely receipt and processing of cancer reports.	2.3.1.8.1	Register within one (1) working day of receipt and process hospital abstract through CRS Plus within three (3) months and non-hospital abstracts through CRS Plus within four (4) months
13	Process hard copy abstracts received from each reporting facility.	2.3.1.8.2	Within three (3) months of receipt
14	Process all electronic tumor reports received from each reporting entity.	2.3.1.8.3	Within three (3) months of receipt
15	Perform routine, standard edit checks on all reports.	2.3.1.8.4	Ongoing
16	Develop and implement procedures to consolidate tumor records.	2.3.1.9	Within thirty (30) calendar days of Notice to Proceed
17	Provide technical assistance to Reporting Facilities.	2.3.1.10.1	No longer than one (1) working day for email and ten (10) working days for on-site training after request received

18	Develop and implement a QA/QC implementation plan.	2.3.1.11.1	Within thirty (30) calendar days of Notice to Proceed
19	Perform case finding and quality review activities utilizing traditional and non-traditional sources to assure timeliness and completeness of cancer and benign brain and CNS tumor case reporting.	2.3.1.11.2	By June 30th of each year
20	Complete Death Clearance activities and incorporate data into MCR database.	2.3.1.12	By July 31st of each year
21	Conduct semiannual interstate data exchange with States.	2.3.1.15	Semi-annually in October and April
22	Perform additional Write Backs to incorporate data into the MCR database from Geocoding, and other activities conducted by the MCR central office.	2.3.1.13, 2.3.1.14, and 2.3.1.15	Ongoing
23	Prepare Management Reports.	2.3.1.18.1	Monthly, quarterly, or annually as specified in Appendix 6
24	Prepare Monthly Management Reports.	2.3.1.18.2	No later than the 6th day of the following month
25	Prepare Facility Reports.	2.3.1.18.3	No later than the 30th day of April to the Contract Monitor
26	Prepare Facility Audit Reports (Case Finding & Re-abstraction).	2.3.1.18.4	No later than forty-five (45) days after the conclusion of the audit to the Contract Monitor
27	Prepare a Fiscal Year Report.	2.3.1.18.5	By July 10th of each year
28	Run the NPCR and NAACCR submission edits.	2.3.1.18.6	Quarterly
29	Provide the Contract Monitor a copy of the MCR master database.	2.3.1.22.1	Quarterly
30	Provide a preliminary copy of the database with all preparations for submission.	2.3.1.22.2	By July 31st of each year
31	Provide a finalized, geocoded, incidence dataset of consolidated records and the master abstracts	2.3.1.22.3	By January 15th of each year

	which have undergone complete QA/QC control procedures.		
32	Maintain an archived incidence dataset (both abstract and consolidated records).	2.3.1.22.5	By January 15th of each year
33	Submit finalized dataset to NAACCR.	2.3.1.22.6	By December 1st of each year
34	Submit finalized dataset to NPCR for the twenty-four (24) month data and the twelve (12) month data.	2.3.1.22.7	By November 30th of each year
35	Assist with the transition to a new Contractor for the subsequent solicitation of this contract if the incumbent Contractor is not the successful Offeror in the subsequent solicitation.	2.3.1.23	Within the three (3) months before the end of the Contract term

2.3.2 Contractor-Supplied Hardware, Software, and Materials

A. By responding to this RFP and accepting a Contract award, the Offeror specifically agrees that for any Software, hardware or hosting service that it proposes, the State will have the right to purchase such item(s) from another source, instead of from the selected Offeror.

B. The State shall be permitted limited user-specific application configuration settings.

C. The Contractor is responsible for the acquisition and operation of all hardware, Software and network support related to the services being provided and shall keep all Software current.

D. All Upgrades and regulatory updates shall be provided at no additional cost.

E. The State also requires that the Offeror provide fully functional, generally available Software and multiple-user licenses as needed throughout the life of the Contract.

F. The Offeror shall install and provide all documentation for the Software furnished under the Contract.

2.3.3 Required Project Policies, Guidelines, and Methodologies

The Contractor shall be required to comply with all applicable laws, regulations, policies, standards and guidelines affecting Information Technology projects, which may be created or changed periodically. Offeror is required to review all applicable links provided below and State compliance in its response.

It is the responsibility of the Contractor to ensure adherence and to remain abreast of new or revised laws, regulations, policies, standards and guidelines affecting project execution. These include, but are not limited to:

A. The State of Maryland System Development Life Cycle (SDLC) methodology at: http://doit.maryland.gov/SDLC/Pages/agile-sdlc.aspx;

B. The State of Maryland Information Technology Security Policy and Standards at: http://www.DoIT.maryland.gov- keyword: Security Policy;

C. The State of Maryland Information Technology Non-Visual Standards at: http://doit.maryland.gov/policies/Pages/ContractPolicies.aspx;

D. The State of Maryland Information Technology Project Oversight at: https://doit.maryland.gov/epmo/Pages/MITDP/oversight.aspx#:~:text=%E2%80%8BMITDP%20Oversight%20is%20based,MITDPs%2C%20regardless%20of%20fund%20source.

E. The Contractor shall follow project management methodologies consistent with the most recent edition of the Project Management Institute's Project Management Body of Knowledge Guide; and

2.3.4 Product Requirements

A. Offerors may propose open-source Software; however, the Offeror must provide operational support for the proposed Software as part of its Proposal.

B. Offeror shall be authorized to furnish the proposed goods and services. Offerors proposing to resell services of another entity must be authorized by such other entity (See RFP **Section 5.3.2.**).

C. No international processing for State Data: As described in **Section 3.7 Security Requirements**, Offerors are advised that any processing or storage of data outside of the continental U.S. is prohibited.

D. Any Contract award is contingent on the State's agreement, during the Proposal evaluation process, to any applicable terms of use and any other agreement submitted under **Section 5.3.2.** Such agreed upon terms of use shall apply consistently across services ordered under the Contract.

E. The Contractor shall not establish any auto-renewal of services beyond the period identified in Contract documents.

F. In addition to any notices of renewal sent to the Department, Contractors shall email notices of renewal to the e-mail address designated by the Contract Monitor.

2.3.5 Maintenance and Support

Maintenance and support, and Contractor's ongoing maintenance and support obligations, are defined as follows:

A. Maintenance commences at the start of the contract. Billing for such maintenance and support shall commence after 30 days.

B. Software maintenance includes all future Software updates and system enhancements applicable to system modules licensed without further charge to all licensed users maintaining a renewable Software support contract.

C. Support shall be provided for superseded releases and back releases still in use by the State.

D. For the first year and all subsequent Contract years, the following services shall be provided for the current version and one previous version of any Software provided with the Deliverables, commencing upon the second year of the contract.

1) Error Correction. Upon notice by State of a problem with the Software (which problem can be verified), reasonable efforts to correct or provide a working solution for the problem.

2) Material Defects. Contractor shall notify the State of any material errors or defects in the Deliverables known or made known to Contractor from any source during the life of the Contract that could cause the production of inaccurate or otherwise materially incorrect results. The Contractor shall initiate actions as may be commercially necessary or proper to effect corrections of any such errors or defects.

3) Updates. Contractor will provide to the State at no additional charge all new releases and bug fixes (collectively referred to as "Updates") for any Software Deliverable developed or published by the Contractor and made available to its other customers.

E. Operations tasks to include virus scans

F. Activity reporting

2.3.5.20 Technical Support

A. "Technical Support" means Contractor-provided assistance for the services or Solution furnished under the Contract, after initial end-user support confirms a technical issue that requires additional troubleshooting capabilities; sometimes referenced as Tier II – IV support.

B. Technical Support shall be available during Normal State Business Hours.

C. Contractor Personnel providing technical support shall be familiar with the State's account (i.e., calls shall be responded to within 1 business day).

D. The State shall be provided with information on Software problems encountered at other locations, along with the solution to those problems, when relevant to State Software.

2.3.5.21 Backup

The Contractor shall:

A. Perform backups of the Web, application, and database servers on a regular basis. This shall include daily incremental backups and full weekly backups of all volumes of servers;

B. Retain daily backups for one (1) month and weekly backups shall be retained for two (2) years;

C. Store daily backups off-site.

2.4 Deliverables

2.4.1 Deliverable Submission

A. For every deliverable, the Contractor shall request the Contract Monitor confirm receipt of that deliverable by sending an e-mail identifying the deliverable name and date of receipt.

B. For every deliverable, the Contractor shall submit to the Contract Monitor, by e-mail, an Agency Deliverable Product Acceptance Form (DPAF), an example of which is provided on the DoIT web page here: http://doit.maryland.gov/contracts/Documents/_procurementForms/DeliverableProductAcceptanceForm-DPAFsample.pdf.

C. Unless specified otherwise, written deliverables shall be compatible with Microsoft Office, Microsoft Project or Microsoft Visio within two (2) versions of the current version. At the Contract Monitor's discretion, the Contract Monitor may request one hard copy of a written deliverable.

D. A standard deliverable review cycle will be elaborated and agreed-upon between the State and the Contractor. This review process is entered into when the Contractor completes a deliverable.

E. For any written deliverable, the Contract Monitor may request a draft version of the deliverable, to comply with the minimum deliverable quality criteria listed in **Section 2.4.3 Minimum Deliverable Quality**. Drafts of each final deliverable, except status reports, are required at least two weeks in advance of when the final deliverables are due (with the exception of deliverables due at the beginning of the project where this lead time is not possible, or where draft delivery date is explicitly specified). Draft versions of a deliverable shall comply with the minimum deliverable quality criteria listed in **Section 2.4.3 Minimum Deliverable Quality**.

2.4.2 Deliverable Acceptance

A. A final deliverable shall satisfy the scope and requirements of this RFP for that deliverable, including the quality and acceptance criteria for a final deliverable as defined in **Section 2.4.4 Deliverable Descriptions/Acceptance Criteria**.

B. The Contract Monitor shall review a final deliverable to determine compliance with the acceptance criteria as defined for that deliverable. The Contract Monitor is responsible for coordinating comments and input from various team members and stakeholders. The Contract Monitor is responsible for providing clear guidance and direction to the Contractor in the event of divergent feedback from various team members.

C. The Contract Monitor will issue to the Contractor a notice of acceptance or rejection of the deliverable in the DPAF (see online sample). Following the return of the DPAF indicating "Accepted" and signed by the Contract Monitor, the Contractor shall submit a proper invoice in accordance with the procedures in **Section 3.3**. The invoice must be accompanied by a copy of the executed DPAF or payment may be withheld.

D. In the event of rejection, the Contract Monitor will formally communicate in writing any deliverable deficiencies or non-conformities to the Contractor, describing in those deficiencies what shall be corrected prior to acceptance of the deliverable in sufficient detail for the Contractor to

address the deficiencies. The Contractor shall correct deficiencies and resubmit the corrected deliverable for acceptance within the agreed-upon time period for correction.

2.4.3 Minimum Deliverable Quality

The Contractor shall subject each deliverable to its internal quality-control process prior to submitting the deliverable to the State.

Each deliverable shall meet the following minimum acceptance criteria:

A. Be presented in a format appropriate for the subject matter and depth of discussion.

B. Be organized in a manner that presents a logical flow of the deliverable's content.

C. Represent factual information reasonably expected to have been known at the time of submittal.

D. In each section of the deliverable, include only information relevant to that section of the deliverable.

E. Contain content and presentation consistent with industry best practices in terms of deliverable completeness, clarity, and quality.

F. Meets the acceptance criteria applicable to that deliverable, including any State policies, functional or non-functional requirements, or industry standards.

G. Contains no structural errors such as poor grammar, misspellings, or incorrect punctuation.

H. Must contain the date, author, and page numbers. When applicable for a deliverable, a revision table must be included.

I. A draft written deliverable may contain limited structural errors such as incorrect punctuation and shall represent a significant level of completeness toward the associated final written deliverable. The draft written deliverable shall otherwise comply with minimum deliverable quality criteria above.

2.4.4 Deliverable Descriptions/Acceptance Criteria

In addition to the items identified in the table below, the Contractor may suggest other subtasks, artifacts, or deliverables to improve the quality and success of the assigned tasks.

Deliverables Summary Table*

ID #	Percentage	Deliverable Description	Acceptance Criteria	Due Date / Frequency
2.3.1.18.2 & 2.3.1.17.1	1/12 of 50% of the annual total amount	Monthly Management Reports	Submission of items in the monthly report and Completion of the meeting minutes	By the 15th of each month / monthly

2.3.11.2.5	4% of the annual total amount	Laboratory only Follow Back	Completion of Follow Back of laboratory only cases, and acceptable incorporation into the MCR master consolidated records.	Prior to data submission / Annually
2.3.1.14	4% of the annual total amount	Geocoding	Completion of Write Back of geocoded data, and acceptable incorporation into the MCR master consolidated records.	By September 30th / Annually
2.3.1.18.4	8% of the annual total amount	Case Finding and Re-abstraction Audits	Completion of case finding audits and Re-abstraction audits	By June 30th / Annually
2.3.1.12	8% of the annual total amount	Death Data	Completion of obtaining death data and incorporation into the MCR database	By July 31st / Annually
2.3.1.21.6	7% of the annual total amount	NAACCR Submission	Timely submission of Maryland data to NAACCR (December 1st of each year)	By December 1st / Annually
2.2.8.C	1% of the annual total amount	NAACCR Gold	Upon the MCR's data making gold NAACCR certification level	By the end of the Fiscal Year / Annually
2.3.1.21.7	7% of the annual total amount	NPCR Submission	Timely submission of "24 month" and "12 month" Maryland data to the NPCR by November of each year.	By November 30th / Annually
Appendix 4-10	1% of the annual total amount	NPCR Advanced National Data Quality Standard	Achieving the Advanced National Data Quality Standard (formerly known as the twelve-month standard) from NPCR each year.	By the end of the Fiscal Year / Annually

3.3.6	10% of the annual total amount	Retainage	At the end of the Contract year upon successful completion of all deliverables	By the end of the Fiscal Year / Annually

*The deliverables summary table may not list every contractually required deliverable. Offerors and Contractors should read the RFP thoroughly for all Contract requirements and deliverables.

2.5 Service Level Agreement (SLA)

2.5.1 Definitions

A. A "Problem" is defined as any situation or issue reported via a help desk ticket that is related to the system operation that is not an enhancement request.

B. "Problem resolution time" is defined as the period of time from when the help desk ticket is opened to when it is resolved.

C. Monthly Charges: for purposes of SLA credit calculation, Monthly Charges are defined as the charges set forth in **Attachment B, Financial Proposal Form,** invoiced during the month of the breach for the monthly fixed services, or, in the event of annual billing, 1/12 of the annual invoice amount **Financial Proposal Form.**

2.5.2 SLA Requirements

The Contractor shall:

A. Be responsible for the following Service Level Assessment (SLA):

B. The MCR's data meeting the NAACCR's silver certification level is of importance to the Department because the data cannot be published if it falls below that standard. As a result of this importance, a SLA shall be applied to ensure adequate focus is maintained on the quality of the data submitted to NAACCR. The SLA shall define minimum performance standards that the Contractor shall deliver in order to receive full payment for submission of MCR data. The Contractor's failure to deliver a level of service specified in the SLA shall result in a reduction in the amount paid to the Contractor.

C. The SLA shall be made on an annual basis for the duration of the Contract. For each year that the Contractor's MCR data does not meet at least the silver certification level as determined by NAACCR, the Contractor agrees to forfeit 2% of the annual amount from the payment for Retainage as described in **Section 2.4.4 Deliverables Summary Table item #9.** Retainage payment would be 8% of the annual total amount.

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3. Contractor Requirements: General

3.1 Contract Initiation Requirements

A. **Conduct a Kick-Off Meeting**. Within ten (10) days after the Notice to Proceed, the Contractor shall organize and conduct a Kick-Off Meeting. The Contractor shall present for discussion any proposed modifications to the Work Plan previously submitted as part of its Technical Proposal. The timeline and Work Plan shall meet all due dates for deliverables noted in the "Deliverables and Key Performance Indicators" set forth at **Section 2.3.3** of this RFP. Any subsequent amendments to the Work Plan shall be in writing and signed and approved by both the Contract Monitor and the Contractor.

B. **Develop a Work Plan for satisfactory completion of all Contract deliverables**. Within seven (7) days after the Kick-Off Meeting and seventeen (17) days after the Notice to Proceed, the Contractor shall submit an electronic finalized detailed Work Plan in Microsoft Word. All activities listed in the Work Plan are subject to approval by MDH and the Contract Monitor.

C. Meet Staffing Requirements. Within twenty-one (21) days of the Notice to Proceed, the Contractor shall have all fully qualified staff per the Contractor's proposed organizational structure and shall, at a minimum, include the key staff positions listed in **Sections 3.10.2** and **3.10.3.**

D. **Participate in orientation.** The Contract Monitor will provide orientation for the Contractor's project staff. The orientation will include review of Maryland laws and regulations, national standards, current policies and procedures, where to obtain Software used, and technical requirements.

E. **Allow full participation of the Contract Monitor** in the ongoing, on-site start-up operations of the Contractor, including interacting directly with Contractor staff, viewing abstract processing, participating in customizing Registry Plus Software, selecting edit sets, and other aspects of database management and quality assurance that the Contract Monitor deems necessary.

F. **Provide and set-up the information technology infrastructure** to support electronic reporting by facilities over secure Internet connections to the MCR database, Registry Plus, and a Web-based document server for secure data exchange. All servers will be located in the U.S.

1) Within twenty-one (21) days of the Notice to Proceed, provide and set up necessary computer hardware, including servers and computers for MCR Contractor staff, necessary to maintain the MCR database. The Contractor shall include the cost of hardware and Software in the financial Proposal. All hardware and Software shall be compatible with the Registry Plus Software. System requirements can be found at https://www.cdc.gov/cancer/npcr/tools/registryplus/tech.htm

2) Within twenty-one (21) days of the Notice to Proceed, establish necessary secure Internet connections and local connectivity for Contractor staff to access the MCR servers and databases. Within twenty-one (21) days of the Notice to Proceed, provide connectivity for all Reporting Facilities to the MCR database on a secure Web server.

3) Maintain secure Web access to the MCR seven (7) days per week for Web Plus online data entry and data file uploading. Access must be available at least 99.9% of the

time with minimal down time to allow for updates not to exceed five (5) Business Days.

4) Set-up and maintain a doc server for the exchange of files between the Contractor and MDH and between MDH and 3rd party researchers as well as other entities such as the National Death Index and the MDH Vital Statistics Department as requested by MDH.

5) Setup and maintain an SFTP site for the exchange of laboratory reports and meaningful use reports.

G. Maintain the MCR Contractor database using Registry Plus Software, developed and supported by the CDC, for approved MCR Reporting Facilities.

1) Within twenty-one (21) days of the Notice to Proceed, obtain from the prior MCR contractor a copy of the latest version of the confidential MCR databases in Registry Plus (http://www.cdc.gov/cancer/npcr/tools/registryplus/), and copies of hard copy logs and electronic logs of abstracts submitted to the MCR as well as any additional items needed for the setup of the Registry Plus Software. Work with the NPCR IT on the set up of Registry Plus.

2) Within twenty-one (21) days of the Notice to Proceed and with the Contract Monitor's assistance, obtain and provide training from prior Contractor (if the selected Contractor is not the incumbent) for up to four (4) people on how to manage and administer the program Software and databases of the Registry Plus system, including, but not limited to: changing edits in the various components of the Registry Plus system; setting up specialty reporting (physician, laboratory, radiation facility, ambulatory care facility) in Web Plus; managing abstracts through each component of the Registry Plus system; creating data sets for MDH, NAACCR and NPCR; and performing data exchange with other states and the District of Columbia (DC). MDH requires the training to involve at least the Contractor's Database Manager and Quality Assurance Supervisor; other participants are at the discretion of the Contractor.

3) Within thirty (30) days of the Notice to Proceed, install and utilize the current automated MCR data management system, Registry Plus, developed and supported by the CDC, and populated with MCR data, and train staff in the operation of Registry Plus. The Contractor shall work closely with CDC programmers to update all components of the Software, as required, and shall participate in the Registry Plus Users Group and NPCR AERRO ePath work group. (The Contract Monitor will provide necessary contact information and will facilitate this transfer). MDH maintains the right to utilize another data management system, at the Contract Monitor's discretion. There shall be no modifications or upgrades to the Software without the approval of the Contract Monitor.)

4) Within thirty (30) days of the Notice to Proceed, purchase one or more licenses to install SAS analytic Software, and with the Contract Monitor's assistance, obtain and provide training from prior Contractor (if the selected Contractor is not the incumbent) on existing SAS codes used for QA/QC. Also, obtain, install, and utilize any other Software or coding obtained from the prior Contractor.

5) Maintain the MCR database in a physical location in Maryland within a seventy-five (75) mile radius of MDH, which is located in Baltimore City (201 W. Preston Street). The rationale for this requirement is that the Contract Monitor provides technical and

administrative oversight of MCR operations which includes on-site visits to the MCR Contractor. In addition, appropriate Contractor Personnel are required to attend regular meetings per **Section 2.3.1.17** with MCR staff as well as other meetings as necessary.

6) Within thirty (30) days of the Notice to Proceed, develop and implement procedures for the electronic submission and processing of laboratory reports utilizing NAACCR standards, if filed separately.

7) Within thirty (30) days of the Notice to Proceed, develop and implement procedures for the electronic submission and processing for file through the SFTP site.

8) Restrict reporting via Web Plus data entry or file upload to those Facility Reporters who have submitted signed Web Plus user agreements and are therefore authorized to access the database.

3.2 Contract Transition

3.2.1 The Contractor shall provide transition assistance as requested by the State to facilitate the orderly transfer of services to the State or a follow-on contractor, for a period up to 90 days prior to Contract end date, or the termination thereof. Such transition efforts shall consist, not by way of limitation, of:

A. Provide additional services and support as requested to successfully complete the transition;

B. Maintain the services called for by the Contract at the required level of proficiency;

C. Provide updated System Documentation, as appropriate; and

D. Provide current operating procedures (as appropriate).

3.2.2 The Contractor shall work toward a prompt and timely transition, proceeding in accordance with the directions of the Contract Monitor. The Contract Monitor may provide the Contractor with additional instructions to meet specific transition requirements prior to the end of the Contract.

3.2.3 The Contractor shall ensure that all necessary knowledge and materials for the tasks completed are transferred to the custody of State personnel or a third party, as directed by the Contract Monitor.

3.2.4 The Contractor shall support end-of-Contract transition efforts with technical and project support to include but not be limited to:

A. The Contractor shall provide a draft Transition-Out Plan 120 Business Days in advance of Contract end date.

B. The Transition-Out Plan shall address at a minimum the following areas:

1) Any staffing concerns/issues related to the closeout of the Contract;

2) Communications and reporting process between the Contractor, the Department and the Contract Monitor;

3) Security and system access review and closeout;

4) Any hardware/Software inventory or licensing including transfer of any point of contact for required Software licenses to the Department or a designee;

5) Any final training/orientation of Department or new contractor staff;

6) Connectivity services provided, activities and approximate timelines required for Transition-Out;

7) Knowledge transfer, to include:

   a) A working knowledge of the current system environments as well as the general business practices of the Department;

   b) Review with the Department the procedures and practices that support the business process and current system environments;

   c) Working knowledge of all technical and functional matters associated with the Solution, its architecture, data file structure, interfaces, any batch programs, and any hardware or Software tools utilized in the performance of the Contract;

   d) Documentation that lists and describes all hardware and Software tools utilized in the performance of the Contract;

   e) A working knowledge of various utilities and corollary Software products used in support and operation of the Solution;

8) Plans to complete tasks and any unfinished work items (including open change requests, and known bug/issues); and

9) Any risk factors with the timing and the Transition-Out schedule and transition process. The Contractor shall document any risk factors and suggested solutions.

10) Within ninety (90) days before July 1, 2029, train up to six (6) people employed by the new Contractor at the site of the new contractor and using the hardware and Software of the new contractor. Training shall include, but not be limited to, administering the database of the Registry Plus system, including how to change edits in the various components of the Registry Plus system, managing abstracts through each component of the Registry Plus system, creating data sets for MDH, for NAACCR, and for NPCR using any developed or otherwise utilized Software programs and performing data exchange with other states. The training is anticipated to involve at least the Contractor's Database Manager and Quality Assurance Supervisor for up to twenty (20) Business Days.

11) Provide the new contractor with the hard copy abstracts and pathology reports submitted by Reporting Facilities during the period of the Contract; electronically submitted reports by Reporting Facilities during the period of the Contract; and all documentation of interaction with Reporting Facilities (e.g., facility encounter logs).

12) At the end of the Contract period, close the Web access for Reporting Facilities, so that facilities can no longer upload or perform direct data entry of MCR data to the incumbent Contractor. Forward all hard copies received after the end of the Contract period to the new contractor.

C. The Contractor shall ensure all documentation and data including, but not limited to, System Documentation and current operating procedures, is current and

complete with a hard and soft copy in a format prescribed by the Contract Monitor.

D. The Contractor shall provide copies of any current daily and weekly back-ups to the Department, or a third party as directed by the Contract Monitor as of the final date of transition, but no later than the final date of the Contract.

E. Access to any data or configurations of the furnished product and services shall be available after the expiration of the Contract as described in **Section 3.2.5**.

3.2.5 Return and Maintenance of State Data

A. Draft procedures that will be used to purge all MCR data from the Contractor's hardware and other storage devices, media, mobile devices, etc. and send the procedures to the Contract Monitor for review and approval. After approval of the procedures by the Contract Monitor, purge all MCR data from the hardware of the Contractor. Upon completion of the purge of all MCR data, the former Contractor will sign and submit a 'Data Disposal Affidavit' to the Contract Monitor.

B. Upon termination or the expiration of the Contract Term, the Contractor shall: (a) return to the State all State data in either the form it was provided to the Contractor or in a mutually agreed format along with the schema necessary to read such data; (b) preserve, maintain, and protect all State data until either a direction by the State to delete such data or the expiration of 90 days ("the retention period") from the date of termination or expiration of the Contract term; (c) after the retention period, the Contractor shall securely dispose of and permanently delete all State data in all of its forms, such as disk, CD/DVD, backup tape and paper such that it is not recoverable, according to National Institute of Standards and Technology (NIST)-approved methods with certificates of destruction to be provided to the State; and (d) prepare an accurate accounting from which the State may reconcile all outstanding accounts. The final monthly invoice for the services provided hereunder shall include all charges for the 90-day data retention period.

C. During any period of service suspension, the Contractor shall maintain all State data in its then existing form, unless otherwise directed in writing by the Contract Monitor.

D. In addition to the foregoing, the State shall be entitled to any post-termination/expiration assistance generally made available by the Contractor with respect to the services.

3.3 Invoicing

3.3.1 General

A. The Contractor shall e-mail the original of each invoice, that is signed and dated and include the deliverable authorization with the invoice to the Contract Monitor and Delores Rich at e-mail address: delores.rich@maryland.gov.

B. All invoices for services shall be verified by the Contractor as accurate at the time of submission.

C. An invoice not satisfying the requirements of a Proper Invoice (as defined at COMAR 21.06.09.01 and .02) cannot be processed for payment. To be considered a Proper Invoice, invoices must include the following information, without error:

1) Contractor name and address;
2) Remittance address;
3) Federal taxpayer identification (FEIN) number, social security number, as appropriate;
4) Invoice period (i.e., time period during which services covered by invoice were performed);
5) Invoice date;
6) Invoice number;
7) State assigned Contract number;
8) State assigned (Blanket) Purchase Order number(s);
9) Goods or services provided;
10) Amount due;
11) A copy of staff members' time sheets and
12) Any additional documentation required by regulation or the Contract.

D. Invoices that contain both fixed price and time and material items shall clearly identify each item as either fixed price or time and material billing.

E. The Department reserves the right to reduce or withhold Contract payment in the event the Contractor does not provide the Department with all required deliverables within the time frame specified in the Contract or otherwise breaches the terms and conditions of the Contract until such time as the Contractor brings itself into full compliance with the Contract.

F. Any action on the part of the Department, or dispute of action by the Contractor, shall be in accordance with the provisions of Md. Code Ann., State Finance and Procurement Article §§ 15-215 through 15-223 and with COMAR 21.10.04.

G. The State is generally exempt from federal excise taxes, Maryland sales and use taxes, District of Columbia sales taxes and transportation taxes. The Contractor; however, is not exempt from such sales and use taxes and may be liable for the same.

H. Invoices for final payment shall be clearly marked as "FINAL" and submitted when all work requirements have been completed and no further charges are to be incurred under the Contract. In no event shall any invoice be submitted later than 60 calendar days from the Contract termination date.

3.3.2 Invoice Submission Schedule

The Contractor shall submit invoices in accordance with the following schedule:

A. For items of work for which there is one-time pricing (see **Attachment B** – Financial Proposal Form) those items shall be billed in the month following the acceptance of the work by the Department.

B. For items of work for which there is annual pricing (see **Attachment B** – Financial Proposal Form) those items shall be billed in equal monthly installments for the applicable Contract year in the month following the performance of the services.

3.3.3 Deliverable Invoicing

A. Deliverable invoices shall be accompanied by notice(s) of acceptance issued by the State for all invoices submitted for payment. Payment of invoices will be withheld if a signed DPAF is not submitted (see online example at http://doit.maryland.gov/contracts/Documents/_procurementForms/DeliverableProductAcceptanceForm-DPAFsample.pdf).

B. Payment for deliverables will only be made upon completion and acceptance of the deliverables as defined in **Section 2.4**.

3.3.4 For the purposes of the Contract an amount will not be deemed due and payable if:

A. The amount invoiced is inconsistent with the Contract;

B. The proper invoice has not been received by the party or office specified in the Contract;

C. The invoice or performance is in dispute or the Contractor has failed to otherwise comply with the provisions of the Contract;

D. The item or services have not been accepted;

E. The quantity of items delivered is less than the quantity ordered;

F. The items or services do not meet the quality requirements of the Contract;

G. If the Contract provides for progress payments, the proper invoice for the progress payment has not been submitted pursuant to the schedule;

H. If the Contract provides for withholding a retainage and the invoice is for the retainage, all stipulated conditions for release of the retainage have not been met; or

I. The Contractor has not submitted satisfactory documentation or other evidence reasonably required by the Procurement Officer or by the Contract concerning performance under the Contract and compliance with its provisions.

3.3.5 Travel Reimbursement

Travel will not be reimbursed under this RFP.

3.4 Liquidated Damages

3.4.1 MBE Liquidated Damages

Inapplicable because there is no MBE goal for this RFP.

3.4.2 Liquidated Damages other than MBE

This section is not applicable to this RFP.

3.5 Disaster Recovery and Data

The following requirements apply to the Contract:

3.5.1 Redundancy, Data Backup and Disaster Recovery

A. Unless specified otherwise in the RFP, Contractor shall maintain or cause to be maintained disaster avoidance procedures designed to safeguard State data and other confidential information, Contractor's processing capability and the availability of hosted services, in each case throughout the Contract term. Any force majeure provisions of the Contract do not limit the Contractor's obligations under this provision.

B. The Contractor shall have robust contingency and disaster recovery (DR) plans in place to ensure that the services provided under the Contract will be maintained in the event of disruption to the Contractor/subcontractor's operations (including, but not limited to, disruption to information technology systems), however caused.

1) The Contractor shall furnish a DR site.

2) The DR site shall be at least 100 miles from the primary operations site and have the capacity to take over complete production volume in case the primary site becomes unresponsive.

C. The contingency and DR plans must be designed to ensure that services under the Contract are restored after a disruption within twenty-four (24) hours from notification and a recovery point objective of one (1) hour or less prior to the outage in order to avoid unacceptable consequences due to the unavailability of services.

D. The Contractor shall test the contingency/DR plans at least twice annually to identify any changes that need to be made to the plan(s) to ensure a minimum interruption of service. Coordination shall be made with the State to ensure limited system downtime when testing is conducted. At least one (1) annual test shall include backup media restoration and failover/fallback operations at the DR location. The Contractor shall send the Contract Monitor a notice of completion following completion of DR testing.

E. Such contingency and DR plans shall be available for the Department to inspect and practically test at any reasonable time, and subject to regular updating, revising, and testing throughout the term of the Contract.

3.5.2. Data Export/Import The Contractor shall, at no additional cost or charge to the State, in an industry standard/non-proprietary format:

1) perform a full or partial import/export of State data within 24 hours of a request; or

2) provide to the State the ability to import/export data at will and provide the State with any access and instructions which are needed for the State to import or export data.

B. Any import or export shall be in a secure format per the Security Requirements.

3.5.3 Data Ownership and Access

A. Data, databases and derived data products created, collected, manipulated, or directly purchased as part of a RFP are the property of the State. The purchasing

State agency is considered the custodian of the data and shall determine the use, access, distribution and other conditions based on appropriate State statutes and regulations.

B. Public jurisdiction user accounts and public jurisdiction data shall not be accessed, except (1) in the course of data center operations, (2) in response to service or technical issues, (3) as required by the express terms of the Contract, including as necessary to perform the services hereunder or (4) at the State's written request.

C. The Contractor shall limit access to and possession of State data to only Contractor Personnel whose responsibilities reasonably require such access or possession and shall train such Contractor Personnel on the confidentiality obligations set forth herein.

D. At no time shall any data or processes – that either belong to or are intended for the use of the State or its officers, agents or employees – be copied, disclosed or retained by the Contractor or any party related to the Contractor for subsequent use in any transaction that does not include the State.

E. The Contractor shall not use any information collected in connection with the services furnished under the Contract for any purpose other than fulfilling such services.

3.5.4 Provisions in Sections 3.5.1 – 3.5.3 shall survive expiration or termination of the Contract. Additionally, the Contractor shall flow down the provisions of Sections 3.5.1- 3.5.3 (or the substance thereof) in all subcontracts.

3.6 Insurance Requirements

The Contractor shall maintain, at a minimum, the insurance coverages outlined below, or any minimum requirements established by law if higher, for the duration of the Contract, including option periods, if exercised:

3.6.1 The following type(s) of insurance and minimum amount(s) of coverage are required:

A. Commercial General Liability - of $1,000,000 combined single limit per occurrence for bodily injury, property damage, and personal and advertising injury and $3,000,000 annual aggregate. The minimum limits required herein may be satisfied through any combination of primary and umbrella/excess liability policies.

B. Errors and Omissions/Professional Liability - $1,000,000 per combined single limit per claim and $3,000,000 annual aggregate.

C. Crime Insurance/Employee Theft Insurance - to cover employee theft with a minimum single loss limit of $1,000,000 per loss, and a minimum single loss retention not to exceed $10,000. The State of Maryland and the Department should be added as a "loss payee."

D. Cyber Security / Data Breach Insurance – (For any service offering hosted by the Contractor) five million dollars ($5,000,000) per occurrence. The coverage must be valid at all locations where work is performed or data or other information concerning the State's claimants or employers is processed or stored.

E. Worker's Compensation - The Contractor shall maintain such insurance as necessary or as required under Workers' Compensation Acts, the Longshore and Harbor Workers' Compensation Act, and the Federal Employers' Liability Act, to not be less than one million dollars ($1,000,000) per occurrence (unless a state's law requires a greater amount of coverage). Coverage must be valid in all states where work is performed.

F. Automobile or Commercial Truck Insurance - The Contractor shall maintain Automobile or Commercial Truck Insurance (including owned, leased, hired, and non-owned vehicles) as appropriate with Liability, Collision, and PIP limits no less than those required by the State where the vehicle(s) is registered, but in no case less than those required by the State of Maryland.

3.6.2 The State shall be listed as an additional insured on the faces of the certificates associated with the coverages listed above, including umbrella policies, excluding Workers' Compensation Insurance and professional liability.

3.6.3 All insurance policies shall be endorsed to include a clause requiring the insurance carrier provide the Procurement Officer, by certified mail, not less than 30 days' advance notice of any non-renewal, cancellation, or expiration. The Contractor shall notify the Procurement Officer in writing, if policies are cancelled or not renewed within five (5) days of learning of such cancellation or nonrenewal. The Contractor shall provide evidence of replacement insurance coverage to the Procurement Officer at least 15 days prior to the expiration of the insurance policy then in effect.

3.6.4 Any insurance furnished as a condition of the Contract shall be issued by a company authorized to do business in the State.

3.6.5 The recommended awardee must provide current certificate(s) of insurance with the prescribed coverages, limits and requirements set forth in this section within five (5) Business Days from notice of recommended award. During the period of performance for multi-year contracts, the Contractor shall provide certificates of insurance annually, or as otherwise directed by the Contract Monitor.

3.6.6 Subcontractor Insurance

The Contractor shall require any subcontractors to obtain and maintain comparable levels of coverage and shall provide the Contract Monitor with the same documentation as is required of the Contractor.

3.7 Security Requirements

The following requirements are applicable to the Contract:

3.7.1 Employee Identification

A. Contractor Personnel shall display his or her company ID badge in a visible location at all times while on State premises. Upon request of authorized State personnel, each Contractor Personnel shall provide additional photo identification.

B. Contractor Personnel shall cooperate with State site requirements, including but not limited to, being prepared to be escorted at all times, and providing information for State badge issuance.

C. Contractor shall remove any Contractor Personnel from working on the Contract where the State determines, in its sole discretion, that Contractor Personnel has not adhered to the Security requirements specified herein.

D. The State reserves the right to request that the Contractor submit proof of employment authorization of non-United States Citizens, prior to commencement of work under the Contract.

3.7.2 Security Clearance / Criminal Background Check

A security clearance is not required for Contractor Personnel assigned to the Contract.

3.7.3 On-Site Security Requirement(s)

THIS SECTION IS NOT APPLICABLE TO THIS RFP.

3.7.4 Information Technology

(a) Contractors shall comply with and adhere to the State IT Security Policy and Standards. These policies may be revised from time to time and the Contractor shall comply with all such revisions. Updated and revised versions of the State IT Policy and Standards are available online at: www.doit.maryland.gov – keyword: Security Policy.

(b) The Contractor shall not connect any of its own equipment to a State LAN/WAN without prior written approval by the State. The Contractor shall complete any necessary paperwork as directed and coordinated with the Contract Monitor to obtain approval by the State to connect Contractor-owned equipment to a State LAN/WAN.

The Contractor shall:

1) Implement administrative, physical, and technical safeguards to protect State data that are no less rigorous than accepted industry best practices for information security such as those listed below (see **Section 3.7.5**);

2) Ensure that all such safeguards, including the manner in which State data is collected, accessed, used, stored, processed, disposed of and disclosed, comply with applicable data protection and privacy laws as well as the terms and conditions of the Contract; and

3) The Contractor, and Contractor Personnel, shall (i) abide by all applicable federal, State and local laws, rules and regulations concerning security of Information Systems and Information Technology and (ii) comply with and adhere to the State IT Security Policy and Standards as each may be amended or revised from time to time. Updated and revised versions of the State IT Policy and Standards are available online at: www.doit.maryland.gov – keyword: Security Policy.

3.7.5 Data Protection and Controls

A. Contractor shall ensure a secure environment for all State data and any hardware and Software (including but not limited to servers, network and data components) provided or used in connection with the performance of the Contract and shall apply or cause application of appropriate controls so as to maintain such a secure environment ("Security Best Practices"). Such Security Best Practices shall comply with an accepted industry standard, such as the NIST cybersecurity framework.

B. To ensure appropriate data protection safeguards are in place, the Contractor shall implement and maintain the following controls at all times throughout the Term of the Contract (the Contractor may augment this list with additional controls):

1) Establish separate production, test, and training environments for systems supporting the services provided under the Contract and ensure that production data is not replicated in test or training environment(s) unless it has been previously anonymized or otherwise modified to protect the confidentiality of Sensitive Data elements. The Contractor shall ensure the appropriate separation of production and non-production environments by applying the data protection and control requirements listed in **Section 3.7.5**.

2) Apply hardware and Software hardening procedures as recommended by Center for Internet Security (CIS) guides https://www.cisecurity.org/ Security Technical Implementation Guides (STIG) https://public.cyber.mil/stigs/, or similar industry best practices to reduce the systems' surface of vulnerability, eliminating as many security risks as possible and documenting what is not feasible or not performed according to best practices. Any hardening practices not implemented shall be documented with a plan of action and milestones including any compensating control. These procedures may include but are not limited to removal of unnecessary Software, disabling or removing unnecessary services, removal of unnecessary usernames or logins, and the deactivation of unneeded features in the Contractor's system configuration files.

3) Ensure that State data is not comingled with non-State data through the proper application of compartmentalization Security Measures.

4) Apply data encryption to protect Sensitive Data at all times, including in transit, at rest, and also when archived for backup purposes. Unless otherwise directed, the Contractor is responsible for the encryption of all Sensitive Data.

5) For all State data the Contractor manages or controls, data encryption shall be applied to such data in transit over untrusted networks.

6) Encryption algorithms which are utilized for encrypting data shall comply with current Federal Information Processing Standards (FIPS), "Security Requirements for Cryptographic Modules", FIPS PUB 140-3:

https://csrc.nist.gov/publications/detail/fips/140/3/final

https://csrc.nist.gov/Projects/cryptographic-module-validation-program/fips-140-3-standards

7) Enable appropriate logging parameters to monitor user access activities, authorized and failed access attempts, system exceptions, and critical information security events as recommended by the operating system and application manufacturers and information security standards, including Maryland Department of Information Technology's Information Security Policy.

8) Retain the aforementioned logs and review them at least daily to identify suspicious or questionable activity for investigation and documentation as to their cause and remediation, if required. The Department shall have the right to inspect these policies and procedures and the Contractor or subcontractor's performance to

confirm the effectiveness of these measures for the services being provided under the Contract.

9) Ensure system and network environments are separated by properly configured and updated firewalls.

10) Restrict network connections between trusted and untrusted networks by physically or logically isolating systems from unsolicited and unauthenticated network traffic.

11) By default "deny all" and only allow access by exception.

12) Review, at least annually, the aforementioned network connections, documenting and confirming the business justification for the use of all service, protocols, and ports allowed, including the rationale or compensating controls implemented for those protocols considered insecure but necessary.

13) Perform regular vulnerability testing of operating system, application, and network devices. Such testing is expected to identify outdated Software versions; missing Software patches; device or Software misconfigurations; and to validate compliance with or deviations from the security policies applicable to the Contract. Contractor shall evaluate all identified vulnerabilities for potential adverse effect on security and integrity and remediate the vulnerability no later than 30 days following the earlier of vulnerability's identification or public disclosure, or document why remediation action is unnecessary or unsuitable. The Department shall have the right to inspect the Contractor's policies and procedures and the results of vulnerability testing to confirm the effectiveness of these measures for the services being provided under the Contract.

14) Enforce strong user authentication and password control measures to minimize the opportunity for unauthorized access through compromise of the user access controls. At a minimum, the implemented measures should be consistent with the most current Maryland Department of Information Technology's Information Security Policy (https://doit.maryland.gov/policies/Pages/default.aspx), including specific requirements for password length, complexity, history, and account lockout.

15) Ensure State data is not processed, transferred, or stored outside of the United States ("U.S."). The Contractor shall provide its services to the State and the State's end users solely from data centers in the U.S. Unless granted an exception in writing by the State, the Contractor shall not allow Contractor Personnel to store State data on portable devices, including personal computers, except for devices that are used and kept only at its U.S. data centers. The Contractor shall permit its Contractor Personnel to access State data remotely only as required to provide technical support.

16) Ensure Contractor's Personnel shall not connect any of its own equipment to a State LAN/WAN without prior written approval by the State, which may be revoked at any time for any reason. The Contractor shall complete any necessary paperwork as directed and coordinated with the Contract Monitor to obtain approval by the State to connect Contractor -owned equipment to a State LAN/WAN.

17) Ensure that anti-virus and anti-malware Software is installed and maintained on all systems supporting the services provided under the Contract; that the anti-virus and

anti-malware Software is automatically updated; and that the Software is configured to actively scan and detect threats to the system for remediation. The Contractor shall perform routine vulnerability scans and take corrective actions for any findings.

18) Conduct regular external vulnerability testing designed to examine the service provider's security profile from the Internet without benefit of access to internal systems and networks behind the external security perimeter. Evaluate all identified vulnerabilities on Internet-facing devices for potential adverse effect on the service's security and integrity and remediate the vulnerability promptly or document why remediation action is unnecessary or unsuitable. The Department shall have the right to inspect these policies and procedures and the performance of vulnerability testing to confirm the effectiveness of these measures for the services being provided under the Contract.

3.7.6 Security Logs and Reports Access

A. For a SaaS or non-State hosted solution, the Contractor shall provide reports to the State in a mutually agreeable format.

B. Reports shall include latency statistics, user access, user access IP address, user access history and security logs for all State files related to the Contract.

3.7.7 Security Plan

A. The Contractor shall protect State data according to a written security policy ("Security Plan") no less rigorous than that of the State and shall supply a copy of such policy to the State for validation, with any appropriate updates, on an annual basis.

B. The Security Plan shall detail the steps and processes employed by the Contractor as well as the features and characteristics which will ensure compliance with the **Security Incident Response**

3.7.8 PCI Compliance

This requirement not applicable to this RFP

3.7.9 Security Incident Response

A. The Contractor shall notify the Department in accordance with **Section 3.7.9A-B** when any Contractor system that may access, process, or store State data or State systems experiences a Security Incident or a Data Breach as follows:

1) notify the Department within twenty-four (24) hours of the discovery of a Security Incident by providing notice via written or electronic correspondence to the Contract Monitor, Department chief information officer and Department chief information security officer;

2) notify the Department within two (2) hours if there is a threat to Contractor's Solution as it pertains to the use, disclosure, and security of State data; and

3) provide written notice to the Department within one (1) Business Day after Contractor's discovery of unauthorized use or disclosure of State data and thereafter all information the State (or Department) requests concerning such unauthorized use or disclosure.

B. Contractor's notice shall identify:

1) the nature of the unauthorized use or disclosure;

2) the State data used or disclosed,

3) who made the unauthorized use or received the unauthorized disclosure;

4) what the Contractor has done or shall do to mitigate any deleterious effect of the unauthorized use or disclosure; and

5) what corrective action the Contractor has taken or shall take to prevent future similar unauthorized use or disclosure.

6) The Contractor shall provide such other information, including a written report, as reasonably requested by the State.

C. The Contractor may need to communicate with outside parties regarding a Security Incident, which may include contacting law enforcement, fielding media inquiries and seeking external expertise as mutually agreed upon, defined by law or contained in the Contract. Discussing Security Incidents with the State should be handled on an urgent as-needed basis, as part of Contractor communication and mitigation processes as mutually agreed upon, defined by law or contained in the Contract.

D. The Contractor shall comply with all applicable laws that require the notification of individuals in the event of unauthorized release of State data or other event requiring notification, and, where notification is required, assume responsibility for informing all such individuals in accordance with applicable law and to indemnify and hold harmless the State (or Department) and its officials and employees from and against any claims, damages, and actions related to the event requiring notification.

3.7.10 Data Breach Responsibilities

A. If the Contractor reasonably believes or has actual knowledge of a Data Breach, the Contractor shall, unless otherwise directed:

1) Notify the appropriate State-identified contact within 24 hours by telephone in accordance with the agreed upon security plan or security procedures unless a shorter time is required by applicable law;

2) Cooperate with the State to investigate and resolve the Data Breach;

3) Promptly implement commercially reasonable remedial measures to remedy the Data Breach; and

4) Document responsive actions taken related to the Data Breach, including any post-incident review of events and actions taken to make changes in business practices in providing the services.

B. If a Data Breach is a direct result of the Contractor's breach of its Contract obligation to encrypt State data or otherwise prevent its release, the Contractor shall bear the costs associated with (1) the investigation and resolution of the Data Breach; (2) notifications to individuals, regulators or others required by State law; (3) a credit monitoring service required by State or federal law; (4) a website or a toll-free number and call center for affected individuals required by State law; and (5) complete all corrective actions as

reasonably determined by Contractor based on root cause; all [(1) through (5)] subject to the Contract's limitation of liability.

3.7.11 The State shall, at its discretion, have the right to review and assess the Contractor's compliance to the security requirements and standards defined in the Contract.

3.7.12 Provisions in **Sections 3.7.1 – 3.7.9** shall survive expiration or termination of the Contract. Additionally, the Contractor shall flow down the provisions of **Sections 3.7.4-3.7.9** (or the substance thereof) in all subcontracts.

3.8 Problem Escalation Procedure

3.8.1 The Contractor must provide and maintain a Problem Escalation Procedure (PEP) for both routine and emergency situations. The PEP must state how the Contractor will address problem situations as they occur during the performance of the Contract, especially problems that are not resolved to the satisfaction of the State within appropriate timeframes.

3.8.2 The Contractor shall provide contact information to the Contract Monitor, as well as to other State personnel as directed should the Contract Monitor not be available.

3.8.3 The Contractor must provide the PEP no later than ten (10) Business Days after Notice to Proceed. The PEP, including any revisions thereto, must also be provided within ten (10) Business Days after the start of each Contract year and within ten (10) Business Days after any change in circumstance which changes the PEP. The PEP shall detail how problems with work under the Contract will be escalated in order to resolve any issues in a timely manner. The PEP shall include:

A. The process for establishing the existence of a problem;

B. Names, titles, and contact information for progressively higher levels of personnel in the Contractor's organization who would become involved in resolving a problem;

C. For each individual listed in the Contractor's PEP, the maximum amount of time a problem will remain unresolved with that individual before the problem escalates to the next contact person listed in the Contractor's PEP;

D. Expedited escalation procedures and any circumstances that would trigger expediting them;

E. The method of providing feedback on resolution progress, including the frequency of feedback to be provided to the State;

F. Contact information for persons responsible for resolving issues after normal business hours (e.g., evenings, weekends, holidays) and on an emergency basis; and

G. A process for updating and notifying the Contract Monitor of any changes to the PEP.

3.8.4 Nothing in this section shall be construed to limit any rights of the Contract Monitor or the State which may be allowed by the Contract or applicable law.

3.9 SOC 2 Type 2 Audit Report

3.9.1 A SOC 2 Type 2 Audit applies to the Contract. The applicable trust services criteria are: Security, Availability, Processing Integrity, Confidentiality, and Privacy – as defined in the Guidance document identified in Section 3.9.2.

3.9.2 In the event the Contractor provides services for identified critical functions, handles Sensitive Data, or hosts any related implemented system for the State under the Contract, the Contractor shall have an annual audit performed by an independent audit firm of the Contractor's handling of Sensitive Data or the Department's critical functions. Critical functions are identified as all aspects and functionality of the Solution including any add-on modules and shall address all areas relating to Information Technology security and operational processes. These services provided by the Contractor that shall be covered by the audit will collectively be referred to as the "Information Functions and Processes." Such audits shall be performed in accordance with audit guidance: Reporting on an Examination of Controls at a Service Organization Relevant to Security, Availability, Processing Integrity, Confidentiality, or Privacy (SOC 2) as published by the American Institute of Certified Public Accountants (AICPA) and as updated from time to time, or according to the most current audit guidance promulgated by the AICPA or similarly-recognized professional organization, as agreed to by the Department, to assess the security of outsourced client functions or data (collectively, the "Guidance") as follows:

A. The type of audit to be performed in accordance with the Guidance is a SOC 2 Type 2 Audit (referred to as the "SOC 2 Audit" or "SOC 2 Report"). All SOC2 Audit Reports shall be submitted to the Contract Monitor as specified in Section F below. The initial SOC 2 Audit shall be completed within a timeframe to be specified by the State. The audit period covered by the initial SOC 2 Audit shall start with the Contract Effective Date unless otherwise agreed to in writing by the Contract Monitor. All subsequent SOC 2 Audits after this initial audit shall be performed at a minimum on an annual basis throughout the Term of the Contract and shall cover a 12-month audit period or such portion of the year that the Contractor furnished services. The SOC 2 Audit shall report on the suitability of the design and operating effectiveness of controls over the Information Functions and Processes to meet the requirements of the Contract, including the Security Requirements identified in **Section 3.7**, relevant to the trust services criteria identified in 3.9.1: as defined in the aforementioned Guidance.

B. The audit scope of each year's SOC 2 Report may need to be adjusted (including the inclusion or omission of the relevant trust services criteria of Security, Availability, Processing Integrity, Confidentiality, and Privacy) to accommodate any changes to the environment since the last SOC 2 Report. Such changes may include but are not limited to the addition of Information Functions and Processes through modifications to the Contract or due to changes in Information Technology or the operational infrastructure. The Contractor shall ensure that the audit scope of each year's SOC 2 Report engagement shall accommodate these changes by including in the SOC 2 Report all appropriate controls related to the current environment supporting the Information Functions and Processes, including those controls required by the Contract.

C. The scope of the SOC 2 Report shall include work performed by any subcontractors that provide essential support to the TO Contractor or essential support to the Information Functions and Processes provided to the Department

under the Contract. The Contractor shall ensure the audit includes all such subcontractors operating in performance of the Contract.

D. All SOC 2 Audits, including those of the Contractor, shall be performed at no additional expense to the Department.

E. The Contractor shall provide to the Contract Monitor, within 30 calendar days of the issuance of each SOC 2 Report, a complete copy of the final SOC 2 Report(s) and a documented corrective action plan addressing each audit finding or exception contained in the SOC 2 Report. The corrective action plan shall identify in detail the remedial action to be taken by the Contractor along with the date(s) when each remedial action is to be implemented.

F. If the Contractor currently has an annual, independent information security assessment performed that includes the operations, systems, and repositories of the Information Functions and Processes being provided to the Department under the Contract, and if that assessment generally conforms to the content and objective of the Guidance, the Department will determine in consultation with appropriate State government technology and audit authorities whether the Contractor's current information security assessments are acceptable in lieu of the SOC 2 Report(s).

G. If the Contractor fails during the Contract term to obtain an annual SOC 2 Report by the date specified in **Section 3.9.2.A**, the Department shall have the right to retain an independent audit firm to perform an audit engagement of a SOC 2 Report of the Information Functions and Processes utilized or provided by the Contractor and under the Contract. The Contractor agrees to allow the independent audit firm to access its facility/is for purposes of conducting this audit engagement(s) and will provide the necessary support and cooperation to the independent audit firm that is required to perform the audit engagement of the SOC 2 Report. The Department will invoice the Contractor for the expense of the SOC 2 Report(s) or deduct the cost from future payments to the Contractor or will withhold retainage payments.

H. Provisions in **Section 3.9.1-2** shall survive expiration or termination of the Contract. Additionally, the Contractor and shall flow down the provisions of **Section 3.9.1-2** (or the substance thereof) in all subcontracts.

3.10 Experience and Personnel

3.10.1 Preferred Offeror Experience

The following organizational experience is expected and will be evaluated as part of the Technical Proposal (see also the Offeror experience, capability and references evaluation factor from **Section 6.2.3**):

A. Demonstrated public health data experience (at least 10 years) and at least 2 years of State cancer registry experience.

B. Prior senior level experience using CDC Registry Plus Software products.

C. Breadth of knowledge in SQL, XML, .NET and cloud-based programs.

D. Expertise in SAS and a current Software license, or the ability to purchase a license.

3.10.2 Personnel Experience

The following experience is expected and will be evaluated as part of the Technical Proposal (see also the capability of proposed resources evaluation factor from **Section 6.2.2**). Offeror shall provide personnel resumes (see appendices 7, Labor Resume Form) for each of the proposed key personnel.

All key personnel identified in section 3.10.3 must be 100% full time employee (FTE) and meet all of the following requirements:

A. Individual with five (5) years of experience in managing databases and in supervising data collection, data processing, data analysis, and data quality assurance of those databases. The individual should also have a basic understanding of central cancer registry operations.

B. Individual with knowledge of all aspects of central cancer registry operations including, but not limited to: data collection, quality assurance, data processing, and database management. He/she will also have knowledge of the clinical aspects of cancer. Credentials shall consist of one of the following: a Certified Tumor Registrar (CTR) with at least four (4) years of experience operating a hospital or central cancer registry, OR an individual with a graduate degree in medicine (MD), statistics, public health, or epidemiology with at least three (3) years of experience operating a cancer registry or other health registry.

C. Individual with a CTR and at least ten (10) years of experience in quality control at a hospital-based or central cancer registry. It is preferred that this individual also have central cancer registry experience.

D. CTR credential, or obtain it within 6 months of hire, with seventy-five percent (75%) of hires having at least five (5) years of experience to:
   1) Perform registration and processing of reports;
   2) Perform case-finding and Re-abstraction audits at Reporting Facilities;
   3) Perform quality assurance and case consolidation activities;
   4) Provide technical support for Reporting Facilities; and
   5) Assure timely completion of all tasks and reports required by the Contract.

E. Individual with three (3) years of experience managing a relational database and three (3) years of experience with SQL, SAS, XML .NET, and cloud-based computing.

F. Individual with experienced in maintaining the hardware for a SQL, XML, .NET and cloud-based database, and the Web servers and firewall(s) required for connectivity between facilities and the MCR database, assuring security of the database, and electronic transfer and access to data.

G. Individual with ten (10) years of experience as a CTR and three (3) years as a trainer.

3.10.3 Key Personnel Identified

For the Contract, the following positions to be identified in the Technical Proposal will be considered Key Personnel and shall be required to meet the qualifications stated in **Section 3.10.2.**

A. **Director of Operations:** This individual shall be responsible for the overall implementation of the Contract and successful completion of all deliverables.

B. **Project Director:** This individual will be responsible for the daily management of the project.

C. **Quality Assurance Supervisor:** This individual will oversee all quality assurance and quality control activities, including performance of CTRs. (See Appendix 4-9.)

D. **Certified Tumor Registrars.**

E. **Database Manager:** The Contractor will provide a Database Manager who will update and provide support for the Registry Plus suite of applications and provide support for Reporting Facilities which submit electronic data reports (e.g., set up user IDs and passwords, answer technical questions). In addition, this individual will customize Web Plus, Prep Plus, and CRS Plus with Maryland edit metafiles, facility display types, default values, etc. This individual will maintain two (2) Microsoft ACCESS or Microsoft EXCEL databases (one to maintain a list of Reporting Facilities and contacts of the MCR, and one to log in abstracts received), as well as produce extracts of the consolidated or abstracts database for analysis by the Contractor and MDH. He/she will be able to perform updates and changes as required by NPCR and NAACCR, as well as perform queries as needed for routine and requested management reports, apply new data from Geocoding, death updates and other writebacks to the existing database, and de-duplicate the database according to NAACCR and NPCR standards.

F. **Database Administrator:** The Contractor will provide a Database Administrator who will oversee security and integrity of the database assuring that any queries of, and changes to, the MCR database are made in accordance with established MCR procedures.

G. **Education and Training Coordinator (ETC):** The Contractor will provide a CTR who will be knowledgeable in all aspects of the Registry Plus program. The ETC will train facility reporters on Web Plus data entry, Web Plus data upload, and the rules of case abstraction and coding in accordance with NPCR and NAACCR standards. The ETC will also develop and maintain a Reporters Manual. (See Appendix 4-8.)

H. **Other Experienced Personnel:** The Contractor shall provide other support staff sufficient in number and training to ensure timely and accurate completion of Contract deliverables. These positions do not have a minimum experience requirement.

3.10.4 Contractor Personnel Experience Equivalency

(Including Key Personnel submitted in response to this RFP)

A. A Substitution of Education for Experience: Bachelor's Degree or higher may be substituted for the general and specialized experience for those labor categories

requiring a High School Diploma. A Master's Degree may be substituted for two years of the general and specialized experience for those labor categories requiring a Bachelor's Degree. Substitution shall be reviewed and approved by the State at its discretion.

B. Substitution of Experience for Education: Substitution of experience for education may be permitted at the discretion of the State.

C. Substitution of Professional Certificates for Experience: Professional certification (e.g., Microsoft Certified Solutions Expert, SQL Certified Database Administrator) may be substituted for up to two (2) years for general and specialized experience at the discretion of the State.

3.10.5 Contractor Personnel Maintain Certifications

Any Contractor Personnel provided under this RFP shall maintain in good standing any required professional certifications for the duration of the Contract.

3.10.6 Work Hours

Unless otherwise specified, the following work hours requirements are applicable:

A. Business Hours Support: Contractor shall assign Contractor Personnel to support Normal State Business Hours (see definition in **Appendix 1**).

A. Contractor Personnel may also be required to provide occasional support outside of normal State Business Hours, including evenings, overnight, and weekends, to support specific efforts and emergencies, such as to resolve system repair or restoration.

3.11 Substitution of Personnel

3.11.1 Continuous Performance of Key Personnel

When Key Personnel are identified for the Contract, the following apply:

A. Key Personnel shall be available to perform Contract requirements as of the NTP Date. Unless explicitly authorized by the Contract Monitor or specified in the Contract, Key Personnel shall be assigned to the State of Maryland as a dedicated resource.

B. Key Personnel shall perform continuously for the duration of the Contract, or such lesser duration as specified in the Technical Proposal. Key Personnel may not be removed by the Contractor from working under the Contract without the prior written approval of the Contract Monitor.

C. The provisions of this section apply to Key Personnel identified in any Task Order Proposal and agreement, if issued, and any Work Order Request and Work Order, if issued.

3.11.2 Definitions

For the purposes of this section, the following definitions apply:

A. **Extraordinary Personal Event** – means any of: leave under the Family Medical Leave Act; an Incapacitating injury or Incapacitating illness; or other circumstances that in the sole discretion of the State warrant an extended leave of

absence, such as extended jury duty or extended military service that precludes the individual from performing his/her job duties under the Contract.

B. Incapacitating – means any health circumstance that substantially impairs the ability of an individual to perform the job duties described for that individual's position in the RFP or the Contractor's Technical Proposal.

3.11.3 Contractor Personnel General Substitution Provisions

The following provisions apply to all the circumstances of Contractor Personnel substitution described in **Section 3.11.4**.

A. The Contractor shall demonstrate to the Contract Monitor's satisfaction that the proposed substitute has qualifications at least equal to those of the Contractor Personnel proposed to be replaced.

B. The Contractor shall provide the Contract Monitor with a substitution request that shall include:

1) A detailed explanation of the reason(s) for the substitution request;

2) The resume of the proposed substitute, signed by the substituting individual and his/her formal supervisor;

3) The official resume of the current personnel for comparison purposes; and

4) Evidence of any required credentials.

C. The Contract Monitor may request additional information concerning the proposed substitution and may interview the proposed substitute personnel prior to deciding whether to approve the substitution request.

D. The Contract Monitor will notify the Contractor in writing of: (i) the acceptance or denial, or (ii) contingent or temporary approval for a specified time limit, of the requested substitution. The Contract Monitor will not unreasonably withhold approval of a proposed Contractor Personnel replacement.

3.11.4 Replacement Circumstances

A. Directed Personnel Replacement

1) The Contract Monitor may direct the Contractor to replace any Contractor Personnel who, in the sole discretion of the Contract Monitor, are perceived as being unqualified, non-productive, unable to fully perform the job duties, disruptive, or known, or reasonably believed, to have committed a major infraction(s) of law, Department policies, or Contract requirements. Normally, a directed personnel replacement will occur only after prior notification of problems with requested remediation, as described in paragraph **3.11.4.A.2**.

2) If deemed appropriate in the discretion of the Contract Monitor, the Contract Monitor may give written notice of any Contractor Personnel performance issues to the Contractor, describing the problem and delineating the remediation requirement(s). The Contractor shall provide a written response to the remediation requirements in a Remediation Plan within ten (10) days of the date of the notice and shall immediately implement the Remediation Plan upon written acceptance by

the Contract Monitor. If the Contract Monitor rejects the Remediation Plan, the Contractor shall revise and resubmit the plan to the Contract Monitor within five (5) days, or in the timeframe set forth by the Contract Monitor in writing.

3) Should performance issues persist despite an approved Remediation Plan, the Contract Monitor may give written notice of the continuing performance issues and either request a new Remediation Plan within a specified time limit or direct the substitution of Contractor Personnel whose performance is at issue with a qualified substitute, including requiring the immediate removal of the Contractor Personnel at issue.

4) Replacement or substitution of Contractor Personnel under this section shall be in addition to, and not in lieu of, the State's remedies under the Contract or which otherwise may be available at law or in equity.

5) If the Contract Monitor determines to direct substitution under **3.11.4.A.1**, if at all possible, at least fifteen (15) days advance notice shall be given to the Contractor. However, if the Contract Monitor deems it necessary and in the State's best interests to remove the Contractor Personnel with less than fifteen (15) days' notice, the Contract Monitor may direct the removal in a timeframe of less than fifteen (15) days, including immediate removal.

6) In circumstances of directed removal, the Contractor shall, in accordance with paragraph **3.11.4.A.1** of this section, provide a suitable replacement for approval within fifteen (15) days of the notification of the need for removal, or the actual removal, whichever occurs first.

B. Key Personnel Replacement

1) To replace any Key Personnel in a circumstance other than as described in **Section 3.11.4.B**, including transfers and promotions, the Contractor shall submit a substitution request as described in **Section 3.11.3** to the Contract Monitor at least fifteen (15) days prior to the intended date of change. A substitution may not occur unless and until the Contract Monitor approves the substitution in writing.

2) Key Personnel Replacement Due to Sudden Vacancy

a) The Contractor shall replace Key Personnel whenever a sudden vacancy occurs (e.g., Extraordinary Personal Event, death, resignation, termination). A termination or resignation with thirty (30) days or more advance notice shall be treated as a replacement under **Section 3.11.4.B.1**.

b) Under any of the circumstances set forth in this paragraph B, the Contractor shall identify a suitable replacement and provide the same information and items required under **Section 3.11.3** within fifteen (15) days of the actual vacancy occurrence or from when the Contractor first knew or should have known that the vacancy would be occurring, whichever is earlier.

3) Key Personnel Replacement Due to an Indeterminate Absence

a) If any Key Personnel has been absent from his/her job for a period of ten (10) days and it is not known or reasonably anticipated that the individual will be returning to work within the next twenty (20) days to fully resume all job duties, before the 25th day of continuous absence, the Contractor shall

identify a suitable replacement and provide the same information and items to the Contract Monitor as required under **Section 3.11.3**.

b) However, if this person is available to return to work and fully perform all job duties before a replacement has been authorized by the Contract Monitor the Contract Monitor may, at his/her sole discretion, authorize the original personnel to continue to work under the Contract, or authorize the replacement personnel to replace the original personnel, notwithstanding the original personnel's ability to return.

3.11.5 Substitution Prior to and Within 30 Days After Contract Execution

Prior to Contract execution or within thirty (30) days after Contract execution, the Offeror may not substitute proposed Key Personnel except under the following circumstances (a) for actual full-time personnel employed directly by the Offeror: the vacancy occurs due to the sudden termination, resignation, or approved leave of absence due to an Extraordinary Personal Event, or the death of such personnel; and (b) for any temporary staff, subcontractors or 1099 contractors: the vacancy occurs due to an Incapacitating event or the death of such personnel. To qualify for such a substitution, the Offeror must demonstrate to the State's satisfaction the event necessitating substitution. Proposed substitutions shall be of equal caliber or higher, in the State's sole discretion. Proposed substitutes deemed by the State to be less qualified than the originally proposed individual may be grounds for pre-award disqualification or post-award termination.

3.12 Minority Business Enterprise (MBE) Reports

If this solicitation includes an MBE Goal (see **Section 4.26**), the Contractor shall:

A. Submit the following reports by the 10th of each month to the Contract Monitor and the Department's MBE Liaison Officer:

1) A Prime Contractor Paid/Unpaid MBE Invoice Report (**Attachment D-4A**) listing any unpaid invoices, over 45 days old, received from any certified MBE subcontractor, the amount of each invoice and the reason payment has not been made; and

2) (If Applicable) An MBE Prime Contractor Report (**Attachment D-4B**) identifying an MBE prime's self-performing work to be counted towards the MBE participation goals.

B. Include in its agreements with its certified MBE subcontractors a requirement that those subcontractors submit an MBE Subcontractor Paid/Unpaid Invoice Report (**Attachment D-5**) by the 10th of each month to the Contract Monitor and the Department's MBE Liaison Officer that identifies the Contract and lists all payments to the MBE subcontractor received from the Contractor in the preceding reporting period month, as well as any outstanding invoices, and the amounts of those invoices.

C. Maintain such records as are necessary to confirm compliance with its MBE participation obligations. These records must indicate the identity of certified minority and non-minority subcontractors employed on the Contract, type of work performed by each, and actual dollar value of work performed. Subcontract agreements documenting the work performed by all MBE participants must be retained by the Contractor and furnished to the Procurement Officer on request.

D. Consent to provide such documentation as reasonably requested and to provide right-of-entry at reasonable times for purposes of the State's representatives verifying compliance with the MBE participation obligations. The contractor must retain all records concerning MBE participation and make them available for State inspection for three years after final completion of the Contract.

E. Upon completion of the Contract and before final payment and release of retainage, submit a final report in affidavit form and under penalty of perjury, of all payments made to, or withheld from MBE subcontractors.

3.13 Veteran Small Business Enterprise (VSBE) Reports

If this solicitation includes a VSBE Goal (see **Section 4.27**), the Contractor shall:

A. Submit the following reports by the 10th of the month following the reporting period to the Contract Monitor and the Department VSBE representative:

1) VSBE Participation Prime Contractor Paid/Unpaid VSBE Invoice Report (**Attachment E-3**) listing any unpaid invoices, over 45 days old, received from any VSBE subcontractor, the amount of each invoice and the reason payment has not been made; and

2) **Attachment E-4**, the VSBE Participation Subcontractor Paid/Unpaid VSBE Invoice Report by the 10th of the month following the reporting period to the Contract Monitor and the VSBE Liaison Officer.

B. Include in its agreements with its VSBE subcontractors a requirement that those subcontractors submit monthly by the 10th of the month following the reporting period to the Contract Monitor and Department VSBE representative a report that identifies the prime Contract and lists all payments received from Contractor in the preceding reporting period month, as well as any outstanding invoices, and the amount of those invoices (**Attachment E-4**).

C. Maintain such records as are necessary to confirm compliance with its VSBE participation obligations. These records must indicate the identity of VSBE and non-VSBE subcontractors employed on the contract, the type of work performed by each, and the actual dollar value of work performed. The subcontract agreement documenting the work performed by all VSBE participants must be retained by the Contractor and furnished to the Procurement Officer on request.

D. Consent to provide such documentation as reasonably requested and to provide right-of-entry at reasonable times for purposes of the State's representatives verifying compliance with the VSBE participation obligations. The Contractor must retain all records concerning VSBE participation and make them available for State inspection for three years after final completion of the Contract.

E. At the option of the Department, upon completion of the Contract and before final payment and release of retainage, submit a final report in affidavit form and under penalty of perjury, of all payments made to, or withheld from VSBE subcontractors.

3.14 Work Orders

THIS SECTION IS INAPPLICABLE TO THIS RFP.

3.15 Additional Clauses

The Contractor shall be subject to the requirements in this section and shall flow down the provisions of **Sections 3.15.1 – 3.15.5** (or the substance thereof) in all subcontracts.

3.15.1 Custom Software

A. As described in the sample Contract (**Attachment M**), the State shall solely own any custom Software, including, but not limited to application modules developed to integrate with a COTS, source-codes, maintenance updates, documentation, and configuration files, when developed under the Contract.

B. Upon a Contractor's voluntary or involuntary filing of bankruptcy or any other insolvency proceeding, Contractor's dissolution, Contractor's discontinuance of support of any Software or system, the Contractor shall convey to the State all rights, title, and interests in all custom Software, licenses, Software source codes, and all associated System Documentation that comprises any solutions proposed as a part of the Contract These rights include, but are not limited to, the rights to use, and cause others to use on behalf of the State, said Software, Software documentation, licenses, Software source codes, and System Documentation.

3.15.2 Custom Source Code

A. For all custom Software provided to the State pursuant to any Contract, the Contractor shall either provide the source code directly to the State in a form acceptable to the State or deliver two copies of each Software source code and Software source code documentation.

B. The State shall have the right to audit custom Software source code and corresponding Software source code documentation for each Software product that comprises the solution as represented by the Contractor. This audit shall be scheduled at any time that is convenient for the parties to be present. The State shall be provided with Software or other tools required to view all Software source code.

C. The Contractor shall provide the current source code and documentation for all custom Software to the State at the time of Contract termination.

3.15.3 Purchasing and Recycling Electronic Products

A. State Finance and Procurement Article, Md. Code Ann. § 14-414, requires State agencies purchasing computers and other electronic products in categories covered by EPEAT to purchase models rated EPEAT Silver or Gold unless the requirement is waived by the DoIT. This information is located on the DGS web site: https://dgs.maryland.gov/Pages/GreenPurchasing/index.aspx

B. Guidelines provided by DGS require planning and coordination of the proper disposition of Information Technology equipment. State Finance and Procurement Article, Md. Code Ann. § 14-415, requires State agencies awarding contracts for services to recycle electronic products to award the contract to a recycler that is R2 or e-Stewards certified. This information is located on the DGS web site: https://dgs.maryland.gov/Pages/GreenPurchasing/index.aspx

C. Guidelines provided by DoIT discuss information and guidance on the proper disposition of IT equipment, media sanitization, and protecting confidential

information stored on media. This information is located in the State's Information Technology (IT) Security Policy https://doit.maryland.gov/policies/Pages/20-07-IT-Security-Policy.aspx **Section 6.5** Media Protection provides guidance on proper precautions to protect confidential information stored on media.

3.15.4 Change Control and Advance Notice

A. Unless otherwise specified in an applicable Service Level Agreement, the Contractor shall give seven (7) days advance notice to the State of any upgrades or modifications that may impact service availability and performance.

B. Contractor may not modify the functionality or features of any SaaS provided hereunder if such modification materially degrades the functionality of the SaaS.

3.15.5 The State of Maryland's Commitment to Purchasing Environmentally Preferred Products and Services (EPPs)

Maryland's State Finance & Procurement Article §14-410 defines environmentally preferable purchasing as "the procurement or acquisition of goods and services that have a lesser or reduced effect on human health and the environment when compared with competing goods or services that serve the same purpose." Accordingly, Bidders are strongly encouraged to offer EPPs to fulfill this Contract, to the greatest extent practicable.

3.15.6 No-Cost Extensions

In accordance with BPW Advisory 1995-1 item 7.b, in the event there are unspent funds remaining on the Contract, prior to the Contract's expiration date the Procurement Officer may modify the Contract to extend the Contract beyond its expiration date for a period up to, but not exceeding, one-third of the base term of the Contract (e.g., eight-month extension on a two-year contract) for the performance of work within the Contract's scope of work. Notwithstanding anything to the contrary, no funds may be added to the Contract in connection with any such extension.

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4. Procurement Instructions

4.1 Pre-Proposal Conference

4.1.1 A Pre-Proposal conference (Conference) will be held at the date, time, and location indicated on the Key Information Summary Sheet.

4.1.2 Attendance at the Conference is not mandatory, but all interested parties are encouraged to attend in order to facilitate better preparation of their Proposals. If the solicitation includes an MBE goal, failure to attend the Conference will be taken into consideration as part of the evaluation of an Offeror's good faith efforts if there is a waiver request.

4.1.3 Following the Conference, the attendance record and summary of the Conference will be distributed via the same mechanism described for amendments and questions (see **Section 4.2.1** eMMA).

4.1.4 Those wishing to attend the web conference may request a meeting invitation by emailing Cancer Surveillance, Operations, and Quality Assurance for the Maryland Cancer Registry at Procurement Officer no later than 2:00 PM per Attachment A An invitation e-mail is required for registration, and therefore attendance. Upon receipt of the email, the Procurement Officer will reply with a registration email with a link that may be used to register for the conference. Registration must be completed by 2:00 PM See **Attachment A**

4.2 eMaryland Marketplace Advantage (eMMA)

4.2.1 eMMA is the electronic commerce system for the State of Maryland. The RFP, Conference summary and attendance sheet, Offerors' questions and the Procurement Officer's responses, addenda, and other solicitation-related information will be made available via eMMA.

4.2.2 In order to receive a Contract award, a vendor must be registered on eMMA. Registration is free. Go to emma.maryland.gov, click on "New Vendor? Register Now" to begin the process, and then follow the prompts.

4.3 Questions

4.3.1 All questions, including concerns regarding any applicable MBE or VSBE participation goals, shall identify in the subject line the Solicitation Number and Title 24-19699 - Cancer Surveillance, Operations, and Quality Assurance for the Maryland Cancer Registry), and shall be submitted in writing via e-mail to the Procurement Officer by the due date listed on the Key Information Summary Sheet. The Procurement Officer, based on the availability of time to research and communicate an answer, shall decide whether an answer can be given before the Proposal due date.

4.3.2 Answers to all questions that are not clearly specific only to the requestor will be distributed via the same mechanism as for RFP amendments and posted on eMMA.

4.3.3 The statements and interpretations contained in responses to any questions, whether responded to verbally or in writing, are not binding on the Department unless it issues an amendment in writing.

4.4 Procurement Method

A Contract will be awarded in accordance with the Competitive Sealed Proposals method under COMAR 21.05.03.

4.5 Proposal Due (Closing) Date and Time

4.5.1 Proposals, in the number and form set forth in **Section 5 Proposal Format**, must be received by the Procurement Officer no later than the Proposal due date and time indicated on the Key Information Summary Sheet in order to be considered.

4.5.2 Requests for extension of this date or time shall not be granted.

4.5.3 Offerors submitting Proposals should allow sufficient delivery time to ensure timely receipt by the Procurement Officer. Except as provided in COMAR 21.05.03.02.F and 21.05.02.10, Proposals received after the due date and time listed in the Key Information Summary Sheet will not be considered.

4.5.4 The date and time of an e-mail submission is determined by the date and time of arrival in the e-mail address indicated on the Key Information Summary Sheet.

4.5.5 Proposals may be modified or withdrawn by written notice received by the Procurement Officer before the time and date set forth in the Key Information Summary Sheet for receipt of Proposals.

4.5.6 Proposals may not be submitted by e-mail or facsimile. Proposals will not be opened publicly.

4.5.7 Potential Offerors not responding to this solicitation are requested to submit the "Notice to Vendors" form, which includes company information and the reason for not responding (e.g., too busy, cannot meet mandatory requirements).

4.6 Multiple or Alternate Proposals

Multiple or alternate Proposals will not be accepted.

4.7 Economy of Preparation

Proposals should be prepared simply and economically and provide a straightforward and concise description of the Offeror's Proposal to meet the requirements of this RFP.

4.8 Public Information Act Notice

4.8.1 The Offeror should give specific attention to the clear identification of those portions of its Proposal that it considers confidential or proprietary commercial information or trade secrets, and provide justification why such materials, upon request, should not be disclosed by the State under the Public Information Act, Md. Code Ann., General Provisions Article, Title 4 (See also RFP **Section 5.3.2.B** "Claim of Confidentiality"). This information should be identified by page and section number and placed after the Title Page and before the Table of Contents in the Technical Proposal and if applicable, separately in the Financial Proposal.

4.8.2 Offerors are advised that, upon request for this information from a third party, the Procurement Officer is required to make an independent determination whether the information must be disclosed.

4.9 Award Basis

A Contract shall be awarded to the responsible Offeror(s) submitting the Proposal that has been determined to be the most advantageous to the State, considering price and evaluation factors set forth in this RFP (see COMAR 21.05.03.03F), for providing the goods and services as specified in this RFP. See RFP **Section 6** for further award information.

4.10 Oral Presentation

Offerors may be required to make oral presentations to State representatives. Oral presentations are considered part of the Technical Proposal. Offerors must confirm in writing any substantive oral clarification of, or change in, their Proposals made in the course of discussions. Any such written clarifications or changes then become part of the Offeror's Proposal. The Procurement Officer will notify Offerors of the time and place of oral presentations.

4.11 Duration of Proposal

Proposals submitted in response to this RFP are irrevocable for the latest of the following: 120 days following the Proposal due date and time, best and final offers if requested (see **Section 6.5.2**), or the date any protest concerning this RFP is finally resolved. This period may be extended at the Procurement Officer's request only with the Offeror's written agreement.

4.12 Revisions to the RFP

4.12.1 If the RFP is revised before the due date for Proposals, the Department shall post any addenda to the RFP on eMMA and shall endeavor to provide such addenda to all prospective Offerors that were sent this RFP or are otherwise known by the Procurement Officer to have obtained this RFP. It remains the responsibility of all prospective Offerors to check eMMA for any addenda issued prior to the submission of Proposals.

4.12.2 Acknowledgment of the receipt of all addenda to this RFP issued before the Proposal due date shall be included in the Transmittal Letter accompanying the Offeror's Technical Proposal.

4.12.3 Addenda made after the due date for Proposals will be sent only to those Offerors that remain under award consideration as of the issuance date of the addenda.

4.12.4 Acknowledgement of the receipt of addenda to the RFP issued after the Proposal due date shall be in the manner specified in the addendum notice.

4.12.5 Failure to acknowledge receipt of an addendum does not relieve the Offeror from complying with the terms, additions, deletions, or corrections set forth in the addendum, and may cause the Proposal to be deemed not reasonably susceptible of being selected for award.

4.13 Cancellations

4.13.1 The State reserves the right to cancel this RFP, accept or reject any and all Proposals, in whole or in part, received in response to this RFP, waive or permit the cure of minor irregularities, and conduct discussions with all qualified or potentially qualified Offerors in any manner necessary to serve the best interests of the State.

4.13.2 The State reserves the right, in its sole discretion, to award a Contract based upon the written Proposals received without discussions or negotiations.

4.13.3 In the event a government entity proposes and receives the recommendation for award, the procurement may be cancelled, and the award processed in accordance with COMAR 21.01.03.01.A(4).

4.13.4 If the services that are the subject of the RFP are currently being provided under an interagency agreement with a public institution of higher education and the State determines that the services can be provided more cost effectively by the public institution of higher education, then the RFP

may be cancelled in accordance with Md. Code Ann., State Finance and Procurement Art., § 3-207(b)(2).

4.14 Incurred Expenses

The State will not be responsible for any costs incurred by any Offeror in preparing and submitting a Proposal, in making an oral presentation, providing a demonstration, or performing any other activities related to submitting a Proposal in response to this solicitation.

4.15 Protest/Disputes

Any protest or dispute related to this solicitation, or the Contract award shall be subject to the provisions of COMAR 21.10 (Administrative and Civil Remedies).

4.16 Offeror Responsibilities

4.16.1 Offerors must be able to provide all goods and services and meet all of the requirements requested in this solicitation and the successful Offeror shall be responsible for Contract performance including any subcontractor participation.

4.16.2 All subcontractors shall be identified and a complete description of their role relative to the Proposal shall be included in the Offeror's Proposal. If applicable, subcontractors utilized in meeting the established MBE or VSBE participation goal(s) for this solicitation shall be identified as provided in the appropriate Attachment(s) to this RFP (see **Section 4.26** "Minority Participation Goal" and **Section 4.27** "VSBE Goal").

4.16.3 If the Offeror is the subsidiary of another entity, all information submitted by the Offeror, including but not limited to references, financial reports, or experience and documentation (e.g. insurance policies, bonds, letters of credit) used to meet minimum qualifications, if any, shall pertain exclusively to the Offeror, unless the parent organization will guarantee the performance of the subsidiary. If applicable, the Offeror's Proposal shall contain an explicit statement, signed by an authorized representative of the parent organization, stating that the parent organization will guarantee the performance of the subsidiary.

4.16.4 A parental guarantee of the performance of the Offeror under this Section will not automatically result in crediting the Offeror with the experience or qualifications of the parent under any evaluation criteria pertaining to the actual Offeror's experience and qualifications. Instead, the Offeror will be evaluated on the extent to which the State determines that the experience and qualifications of the parent are applicable to and shared with the Offeror, any stated intent by the parent to be directly involved in the performance of the Contract, and the value of the parent's participation as determined by the State.

4.17 Acceptance of Terms and Conditions

By submitting a Proposal in response to this RFP, the Offeror, if selected for award, shall be deemed to have accepted the terms and conditions of this RFP and the Contract, attached hereto as **Attachment M**. Any exceptions to this RFP or the Contract shall be clearly identified in the Executive Summary of the Technical Proposal. **All exceptions will be taken into consideration when evaluating the Offeror's Proposal. The Department reserves the right to accept or reject any exceptions.**

4.18 Proposal Affidavit

A Proposal submitted by the Offeror must be accompanied by a completed Proposal Affidavit. A copy of this Affidavit is included as **Attachment C** of this RFP.

4.19 Contract Affidavit

All Offerors are advised that if a Contract is awarded as a result of this solicitation, the successful Offeror will be required to complete a Contract Affidavit. A copy of this Affidavit is included for informational purposes as **Attachment N** of this RFP. This Affidavit must be provided within five (5) Business Days of notification of recommended award. For purposes of completing Section "B" of this Affidavit (Certification of Registration or Qualification with the State Department of Assessments and Taxation), a business entity that is organized outside of the State of Maryland is considered a "foreign" business.

4.20 Compliance with Laws/Arrearages

By submitting a Proposal in response to this RFP, the Offeror, if selected for award, agrees that it will comply with all federal, State, and local laws applicable to its activities and obligations under the Contract.

By submitting a response to this solicitation, each Offeror represents that it is not in arrears in the payment of any obligations due and owing the State, including the payment of taxes and employee benefits, and shall not become so in arrears during the term of the Contract if selected for Contract award.

4.21 Verification of Registration and Tax Payment

Before a business entity can do business in the State, it must be registered with the State Department of Assessments and Taxation (SDAT). SDAT is located at the State Office Building, Room 803, 301 West Preston Street, Baltimore, Maryland 21201. For registration information, visit https://www.egov.maryland.gov/businessexpress.

It is strongly recommended that any potential Offeror complete registration prior to the Proposal due date and time. The Offeror's failure to complete registration with SDAT may disqualify an otherwise successful Offeror from final consideration and recommendation for Contract award.

4.22 False Statements

Offerors are advised that Md. Code Ann., State Finance and Procurement Article, § 11-205.1 provides as follows:

4.22.1. In connection with a procurement contract a person may not willfully:

A. Falsify, conceal, or suppress a material fact by any scheme or device.

B. Make a false or fraudulent statement or representation of a material fact.

C. Use a false writing or document that contains a false or fraudulent statement or entry of a material fact.

4.22.2. A person may not aid or conspire with another person to commit an act under **Section 4.22.1**.

4.22.3. A person who violates any provision of this section is guilty of a felony and on conviction is subject to a fine not exceeding $20,000 or imprisonment not exceeding five (5) years or both.

4.23 Payments by Electronic Funds Transfer

By submitting a Proposal in response to this solicitation, the Offeror, if selected for award:

4.23.1 Agrees to accept payments by electronic funds transfer (EFT) unless the State Comptroller's Office grants an exemption. Payment by EFT is mandatory for contracts exceeding $200,000. The successful Offeror shall register using the COT/GAD X-10 Vendor Electronic Funds (EFT) Registration Request Form.

4.23.2 Any request for exemption must be submitted to the State Comptroller's Office for approval at the address specified on the COT/GAD X-10 form, must include the business identification information as stated on the form, and must include the reason for the exemption. The COT/GAD X-10 form may be downloaded from the Comptroller's website at: http://comptroller.marylandtaxes.com/Vendor_Services/Accounting_Information/Static_Files/GADX10Form20150615.pdf.

4.24 Prompt Payment Policy

This procurement and the Contract(s) to be awarded pursuant to this solicitation are subject to the Prompt Payment Policy Directive issued by the Governor's Office of Small, Minority & Women Business Affairs (GOSBA) and dated August 1, 2008. Promulgated pursuant to Md. Code Ann., State Finance and Procurement Article, §§ 11-201, 13-205(a), and Title 14, Subtitle 3, and COMAR 21.01.01.03 and 21.11.03.01, the Directive seeks to ensure the prompt payment of all subcontractors on non-construction procurement contracts. The Contractor shall comply with the prompt payment requirements outlined in the Contract, **Section 31 "Prompt Pay Requirements**" (see **Attachment M**). Additional information is available on GOSBA's website at: http://www.gomdsmallbiz.maryland.gov/documents/legislation/promptpaymentfaqs.pdf.

4.25 Electronic Procurements Authorized

4.25.1 Under COMAR 21.03.05, unless otherwise prohibited by law, the Department may conduct procurement transactions by electronic means, including the solicitation, proposing, award, execution, and administration of a contract, as provided in Md. Code Ann., Maryland Uniform Electronic Transactions Act, Commercial Law Article, Title 21.

4.25.2 Participation in the solicitation process on a procurement contract for which electronic means has been authorized shall constitute consent by the Offeror to conduct by electronic means all elements of the procurement of that Contract which are specifically authorized under the solicitation or Contract. In the case of electronic transactions authorized by this RFP, electronic records and signatures by an authorized representative satisfy a requirement for written submission and signatures.

4.25.3 "Electronic means" refers to exchanges or communications using electronic, digital, magnetic, wireless, optical, electromagnetic, or other means of electronically conducting transactions. Electronic means includes e-mail, internet-based communications, electronic funds transfer, specific electronic bidding platforms (e.g., https://procurement.maryland.gov), and electronic data interchange.

4.25.4 In addition to specific electronic transactions specifically authorized in other sections of this solicitation (e.g., RFP § 4.23 describing payments by Electronic Funds Transfer), the following transactions are authorized to be conducted by electronic means on the terms as authorized in COMAR 21.03.05:

A. The Procurement Officer may conduct the procurement using eMMA to issue:

1) The RFP;

2) Any amendments and requests for best and final offers;

3) Pre-Proposal conference documents;

4) Questions and responses;

5) Communications regarding the solicitation or Proposal to any Offeror or potential Offeror;

6) Notices of award selection or non-selection; and

7) The Procurement Officer's decision on any Proposal protest or Contract claim.

8) Filing of protests.

B. The Offeror or potential Offeror may use eMMA or e-mail to:

1) Ask questions regarding the solicitation;

2) Reply to any material received from the Procurement Officer by electronic means that includes a Procurement Officer's request or direction to reply by e-mail or through eMMA, but only on the terms specifically approved and directed by the Procurement Officer

3) Submit a "No Proposal Response" to the RFP.

C. The Procurement Officer, the Contract Monitor, and the Contractor may conduct day-to-day Contract administration, except as outlined in **Section 4.25.5** of this subsection, utilizing e-mail or other electronic means if authorized by the Procurement Officer or Contract Monitor.

4.25.5 The following transactions related to this procurement and any Contract awarded pursuant to it are **not authorized** to be conducted by electronic means:

A. Submission of initial Proposals, except through eMMA;

B. Submission of documents determined by the Department to require original signatures (e.g., Contract execution, Contract modifications); or

C. Any transaction, submission, or communication where the Procurement Officer has specifically directed that a response from the Contractor or Offeror be provided in writing or hard copy.

4.25.6 Any e-mail transmission is only authorized to the e-mail addresses for the identified person as provided in the solicitation, the Contract, or in the direction from the Procurement Officer or Contract Monitor.

4.26 MBE Participation Goal

There is no MBE subcontractor participation goal for this procurement.

4.27 VSBE Goal

There is no VSBE participation goal for this procurement.

4.28 Living Wage Requirements

A. Maryland law requires that contractors meeting certain conditions pay a living wage to covered employees on State service contracts over $100,000. Maryland Code Ann., State Finance and Procurement Article, § 18-101 et al. The Commissioner of Labor and Industry at the Maryland Department of Labor requires that a contractor subject to the Living Wage law submit payroll records for covered employees and a signed statement indicating that it paid a living wage to covered employees; or receive a waiver from Living Wage reporting requirements. See COMAR 21.11.10.05.

B. If subject to the Living Wage law, Contractor agrees that it will abide by all Living Wage law requirements, including but not limited to reporting requirements in COMAR 21.11.10.05. Contractor understands that failure of Contractor to provide such documents is a material breach of the terms and conditions and may result in Contract termination, disqualification by the State from participating in State contracts, and other sanctions. Information pertaining to reporting obligations may be found by going to the Maryland Department of Labor website http://www.dllr.state.md.us/labor/prev/livingwage.shtml.

C. Additional information regarding the State's living wage requirement is contained in **Attachment F**. Offerors must complete and submit the Maryland Living Wage Requirements Affidavit of Agreement (**Attachment F-1**) with their Proposals. If the Offeror fails to complete and submit the required documentation, the State may determine the Offeror to not be responsible under State law.

D. Contractors and subcontractors subject to the Living Wage Law shall pay each covered employee at least the minimum amount set by law for the applicable Tier area. The specific living wage rate is determined by whether a majority of services take place in a Tier 1 Area or a Tier 2 Area of the State. The specific Living Wage rate is determined by whether a majority of services take place in a Tier 1 Area or Tier 2 Area of the State.

   1) The Tier 1 Area includes Montgomery, Prince George's, Howard, Anne Arundel and Baltimore Counties, and Baltimore City. The Tier 2 Area includes any county in the State not included in the Tier 1 Area. In the event that the employees who perform the services are not located in the State, the head of the unit responsible for a State Contract pursuant to §18-102(d) of the State Finance and Procurement Article shall assign the tier based upon where the recipients of the services are located. If the Contractor provides more than 50% of the services from an out-of-State location, the State agency determines the wage tier based on where the majority of the service recipients are located. In this circumstance, the Contract will be determined to be a Tier (enter "1" or "2," depending on where the majority of the service recipients are located) Contract.

   2) The Contract will be determined to be a Tier 1 Contract or a Tier 2 Contract depending on the location(s) from which the Contractor provides 50% or more of the services. The Offeror must identify in its Proposal the location(s) from which services will be provided, including the location(s) from which 50% or more of the Contract services will be provided.

3) If the Contractor provides 50% or more of the services from a location(s) in a Tier 1 jurisdiction(s) the Contract will be a Tier 1 Contract.

4) If the Contractor provides 50% or more of the services from a location(s) in a Tier 2 jurisdiction(s), the Contract will be a Tier 2 Contract.

E. If the Contractor provides more than 50% of the services from an out-of-State location, the State agency determines the wage tier based on where the majority of the service recipients are located. See COMAR 21.11.10.07.

F. The Offeror shall identify in the Proposal the location from which services will be provided.

G. **NOTE:** Whereas the Living Wage may change annually, the Contract price will not change because of a Living Wage change or a change in the State minimum wage.

4.29 Federal Funding Acknowledgement

4.29.1 There are programmatic conditions that apply to the Contract due to federal funding **(see Attachment G**).

4.29.2 The total amount of federal funds allocated for the Prevention and Health Promotion Administration is $402,201.55 in Maryland State Fiscal Year 2023. This represents 65% of all funds budgeted for the unit in that fiscal year. This does not necessarily represent the amount of funding available for any particular grant, contract, or solicitation.

4.29.3 The Contract contains federal funds. The source of these federal funds is Cancer Prevention and Control Programs for State, Territorial and Tribal Organizations. The Catalog of Federal Domestic Assistance number is: 93.898. The conditions that apply to all federal funds awarded by the Department are contained in Federal Funds **Attachment G**. Any additional conditions that apply to this particular federally funded contract is contained as supplements to Federal Funds **Attachment G** and Offerors are to complete and submit these Attachments with their Proposals as instructed in the Attachments. Acceptance of this agreement indicates the Offeror's intent to comply with all conditions which are part of the Contract.

4.30 Conflict of Interest Affidavit and Disclosure

4.30.1 The Offeror shall complete and sign the Conflict-of-Interest Affidavit and Disclosure (**Attachment H**) and submit it with its Proposal.

4.30.2 By submitting a Conflict-of-Interest Affidavit and Disclosure, the Contractor shall be construed as certifying all Contractor Personnel and subcontractors are also without a conflict of interest as defined in COMAR 21.05.08.08A.

4.30.3 Additionally, a Contractor has an ongoing obligation to ensure that all Contractor Personnel are without conflicts of interest prior to providing services under the Contract. For policies and procedures applying specifically to Conflict of Interests, the Contract is governed by COMAR 21.05.08.08.

4.30.4 Participation in Drafting of Specifications: Disqualifying Event: Offerors are advised that Md. Code Ann. State Finance and Procurement Article §13-212.1(a) provides generally that "an individual who assists an executive unit in the drafting of specifications, an invitation for bids, a request for Proposals for a procurement, or the selection or award made in response to an

invitation for bids or a request for Proposals, or a person that employs the individual, may not: (1) submit a bid or Proposal for that procurement; or (2) assist or represent another person, directly or indirectly, who is submitting a bid or Proposal for that procurement." Any Offeror submitting a Proposal in violation of this provision shall be classified as "not responsible." See COMAR 21.05.03.03.

4.31 Non-Disclosure Agreement

4.31.1 Non-Disclosure **Agreement (Offeror)**

A Non-Disclosure Agreement (Offeror) is not required for this procurement.

4.31.2 Non-Disclosure Agreement (Contractor)

All Offerors are advised that this solicitation and any Contract(s) are subject to the terms of the Non-Disclosure Agreement (NDA) contained in this solicitation as **Attachment I**. This Agreement must be provided within five (5) Business Days of notification of recommended award; however, to expedite processing, it is suggested that this document be completed and submitted with the Proposal.

4.32 HIPAA - Business Associate Agreement

Based on the determination by the Department that the functions to be performed in accordance with this solicitation constitute Business Associate functions as defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the recommended awardee shall execute a Business Associate Agreement as required by HIPAA regulations at 45 C.F.R. §164.500 *et seq.* and set forth in **Attachment J**. This Agreement must be provided within five (5) Business Days of notification of proposed Contract award. However, to expedite processing, it is suggested that this document be completed and submitted with the Proposal. Should the Business Associate Agreement not be submitted upon expiration of the five (5) Business Day period as required by this solicitation, the Procurement Officer, upon review of the Office of the Attorney General and approval of the Secretary, may withdraw the recommendation for award and make the award to the responsible Offeror with the next highest overall-ranked Proposal.

4.33 Nonvisual Access

This solicitation does not contain Information Technology (IT) provisions requiring Nonvisual Access.

4.34 Mercury and Products That Contain Mercury

This solicitation does not include the procurement of products known to likely include mercury as a component.

4.35 Location of the Performance of Services Disclosure

The Offeror is required to complete the Location of the Performance of Services Disclosure. A copy of this Disclosure is included as **Attachment L**. The Disclosure must be provided with the Proposal.

Services under this Contract must be performed in the United States.

4.36 Department of Human Services (DHS) Hiring Agreement

All Offerors are advised that if a Contract is awarded as a result of this solicitation, the successful Offeror will be required to complete a DHS Hiring Agreement. A copy of this Agreement is included as **Attachment O**. This Agreement must be provided within five (5) Business Days of notification of recommended award.4.27.

4.37 Small Business Reservice (SBR) Procurement

This solicitation is not designated as a Small Business Reserve (SBR) Procurement.

4.38 Maryland Healthy Working Families Act Requirements

On February 11, 2018, the Maryland Healthy Working Families Act went into effect. All offerors should be aware of how this Act could affect your potential contract award with the State of Maryland. See the Department of Labor, Licensing and Regulations web site for Maryland Healthy Working Families Act Information: http://dllr.maryland.gov/paidleave/.

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5 Proposal Format

5.1Two Part Submission

Offerors shall submit Proposals in separate volumes (or envelopes):

1. Volume I –Technical Proposal
2. Volume II – Financial Proposal

5.2 Proposal Delivery and Packaging

5.2.1 Proposals delivered by facsimile and email shall not be considered.

5.2.2 Provide no pricing information in the Technical Proposal. Provide no pricing information on the media submitted in the Technical Proposal.

5.2.3 Offerors may submit Proposals through the State's internet based electronic procurement system eMMA.

5.2.4 The Procurement Officer must receive all electronic Proposal material by the RFP due date and time specified in the Key Information Summary Sheet. Requests for extension of this date or time will not be granted. Except as provided in COMAR 21.05.03.02F, Proposals received by the Procurement Officer after the due date will not be considered.

5.2.5 Offerors shall provide their Proposals in two separate envelopes through eMMA following the Quick Reference Guides (QRG) labelled "**5 - eMMA QRG Responding to Solicitations (RFP)**" for double envelope submissions.

5.2.6 Two Part (Double Envelope) Submission:

A. Technical Proposal consisting of:

1) Technical Proposal and all supporting material in Microsoft Word format, version 2007 or greater,

2) Technical Proposal in searchable Adobe PDF format,

3) a second searchable Adobe copy of the Technical Proposal, with confidential and proprietary information redacted (see **Section 4.8**), and

B. Financial Proposal consisting of:

1) Financial Proposal entered into the price form spreadsheet within eMMA and all supporting material in Microsoft Word format, version 2007 or greater format,

2) Financial Proposal in searchable Adobe PDF format,

3) A second searchable Adobe copy of the Financial Proposal, with confidential and proprietary information removed (see **Section 4.8**).

5.3 Volume I - Technical Proposal

NOTE: Omit all **pricing information** from the Technical Proposal (Volume I). Include pricing information only in the Financial Proposal (Volume II).

5.3.1. In addition to the instructions below, responses in the Offeror's Technical Proposal shall reference the organization and numbering of Sections in the

RFP (e.g., "Section 2.2.1 Response . . .; "**Section 2.2.2** Response . . .,"). All pages of both Proposal volumes shall be consecutively numbered from beginning (Page 1) to end (Page "x").

5.3.2. The Technical Proposal shall include the following documents and information in the order specified as follows. Each section of the Technical Proposal shall be separated by a TAB as detailed below:

A. Title Page and Table of Contents (Submit under TAB A)

The Technical Proposal should begin with a Title Page bearing the name and address of the Offeror and the name and number of this RFP. A Table of Contents shall follow the Title Page for the Technical Proposal, organized by section, subsection, and page number.

B. Claim of Confidentiality (If applicable, submit under TAB A-1)

Any information which is claimed to be confidential or proprietary information should be identified by page and section number and placed after the Title Page and before the Table of Contents in the Technical Proposal, and if applicable, separately in the Financial Proposal. An explanation for each claim of confidentiality shall be included (see **Section 4.8 "Public Information Act Notice"**). The entire Proposal cannot be given a blanket confidentiality designation - any confidentiality designation must apply to specific sections, pages, or portions of pages of the Proposal and an explanation for each claim shall be included.

C. Offeror Information Sheet and Transmittal Letter (Submit under TAB B)

The Offeror Information Sheet (see **Appendix 2**) and a Transmittal Letter shall accompany the Technical Proposal. The purpose of the Transmittal Letter is to transmit the Proposal and acknowledge the receipt of any addenda to this RFP issued before the Proposal due date and time. Transmittal Letter should be brief, be signed by an individual who is authorized to commit the Offeror to its Proposal and the requirements as stated in this RFP.

D. Executive Summary (Submit under TAB C)

The Offeror shall condense and highlight the contents of the Technical Proposal in a separate section titled "Executive Summary."

In addition, the Summary shall indicate whether the Offeror is the subsidiary of another entity, and if so, whether all information submitted by the Offeror pertains exclusively to the Offeror. If not, the subsidiary Offeror shall include a guarantee of performance from its parent organization as part of its Executive Summary (see **Section 4.16 "Offeror Responsibilities"**).

The Executive Summary shall also identify any exceptions the Offeror has taken to the requirements of this RFP, the Contract (**Attachment M**), or any other exhibits or attachments. Acceptance or rejection of exceptions is within the sole discretion of the State. **Exceptions to terms and conditions, including requirements, may result in having the Proposal deemed unacceptable or classified as not reasonably susceptible of being selected for award.**

E. Minimum Qualifications Documentation (If applicable, Submit under TAB D)

The Offeror shall submit any Minimum Qualifications documentation that may be required, as set forth in RFP **Section 1**. If references are required in **RFP Section 1**, those references shall be submitted in this section and shall contain the information described in both **Section 1** and **Section 5.3.2**.

F. Offeror Technical Response to RFP Requirements and Proposed Work Plan (Submit under TAB E)

1) The Offeror shall address each RFP requirement (RFP **Section 2** and **Section 3**) in its Technical Proposal with a cross reference to the requirement and describe how its proposed goods and services, including the goods and services of any proposed subcontractor(s), will meet or exceed the requirement(s). If the State is seeking Offeror agreement to any requirement(s), the Offeror shall state its agreement or disagreement. Any paragraph in the Technical Proposal that responds to an RFP requirement shall include an explanation of how the work will be performed. The response shall address each requirement in **Section 2** and **Section 3** in order and shall contain a cross reference to the requirement.

2) Any exception to a requirement, term, or condition may result in having the Proposal classified as not reasonably susceptible of being selected for award or the Offeror deemed not responsible.

3) The Offeror shall give a definitive section-by-section description of the proposed plan to meet the requirements of the RFP, i.e., a Work Plan. The Work Plan shall include the specific methodology, techniques, and number of staff, if applicable, to be used by the Offeror in providing the required goods and services as outlined in RFP **Section 2**, Contractor Requirements: Scope of Work. The description shall include an outline of the overall management concepts employed by the Offeror and a project management plan, including project control mechanisms and overall timelines. Project deadlines considered contract deliverables must be recognized in the Work Plan.

4) Implementation Schedule - Offeror shall provide the proposed implementation schedule with its Proposal.

5) The Offeror shall identify the location(s) from which it proposes to provide services, including, if applicable, any current facilities that it operates, and any required construction to satisfy the State's requirements as outlined in this RFP.

6) The Offeror shall provide a draft Problem Escalation Procedure (PEP) that includes, at a minimum, titles of individuals to be contacted by the Contract Monitor should problems arise under the Contract and explains how problems with work under the Contract will be escalated in order to resolve any issues in a timely manner. Final procedures shall be submitted as indicated in **Section 3.8**.

7) The Offeror shall provide a Backup solution/ strategy recommendation as part of its Proposal.

8) Disaster Recovery and Security Model description - For hosted services, the Offeror shall include its DR strategy, and for on premise, a description of a recommended DR strategy.

9) The Offeror shall include a deliverable description and schedule describing the proposed Deliverables as mapped to the State SDLC and the Deliverables table in **Section 2.4.4**. The schedule shall also detail proposed submission due date/frequency of each recommended Deliverable.

10) The Offeror shall include an SLA as identified in **Section 2.5**, including service level metrics offered and a description how the metrics are measured, any SLA credits should

the service level metrics not be met, and how the State can verify the service level. The Offeror shall describe how service level performance is reported to the State.

11) Description of technical risk of migrating from the existing system.

12) Non-Compete Clause Prohibition:

The Department seeks to maximize the retention of personnel working under the Contract whenever there is a transition of the Contract from one contractor to another so as to minimize disruption due to a change in contractor and maximize the maintenance of institutional knowledge accumulated by such personnel. To help achieve this objective of staff retention, each Offeror shall agree that if awarded the Contract, the Offeror's employees and agents filling the positions set forth in the staffing requirements of Section 3.10.3 working on the State contract shall be free to work for the contractor awarded the State contract notwithstanding any non-compete clauses to which the employee(s) may be subject. The Offeror agrees not to enforce any non-compete restrictions against the State with regard to these employees and agents if a different vendor succeeds it in the performance of the Contract. To evidence compliance with this non-compete clause prohibition, each Offeror must include an affirmative statement in its technical Proposal that the Offeror, if awarded a Contract, agrees that its employees and agents shall not be restricted from working with or for any successor contractor that is awarded the State business.

13) Product Requirements

a) Offerors may propose open-source software; however, the Offeror must provide operational support for the proposed software.

b) Details for each offering: The Offeror shall provide the following information for each offering:

i) Offering Name;

ii) Offeror relationship with manufacturer (e.g., manufacturer, reseller, partner);

iii) Manufacturer;

iv) Short description of capability;

v) Version (and whether version updates are limited in any way);

vi) License type (e.g., user, CPU, node, transaction volume);

vii) Subscription term (e.g., annual);

viii) License restrictions, if any;

ix) Operational support offered (e.g., customer support, help desk, user manuals online or hardcopy), including description of multiple support levels (if offered), service level measures and reporting;

x) Continuity of operations and disaster recovery plans for providing service at 24/7/365 level;

xi) Ability of the offering to read and export data in existing State enterprise data stores. Offerors in their Proposals shall describe the interoperability

of data that can be imported or exported from the Solution, including generating industry standard formats;

xii) Any processing or storage of data outside of the continental U.S;

xiii) Any limitations or constraints in the offering, including any terms or conditions (e.g., terms of service, ELA, AUP, professional services agreement, master agreement) – see also **Section 5.3.2.**

xiv) Compatibility with the State's existing single sign-on system, SecureAuth or other single sign-on approaches;

xv) APIs offered, and what type of content can be accessed and consumed;

xvi) Update / upgrade roadmap and procedures, to include planned changes in the next 12 months, frequency of system update (updates to Software applied) and process for updates/upgrades;

xvii) Frequency of updates to data services, including but not limited to, datasets provided as real-time feeds, and datasets updated on a regular basis (e.g., monthly, quarterly, annually, one-time);

xviii) What type of third-party assessment (such as a SOC 2 Type II audit) is performed, the nature of the assessment (e.g., the trust services criteria and scope of assessment), and whether the results of the assessment pertinent to the State will be shared with the State. See also **Section 3.9**;

xix) Offeror shall describe its security model and procedures supporting handling of State data. If more than one level of service is offered, the Offeror shall describe such services. Include, at a minimum:

(1) procedures for and requirements for hiring staff (such as background checks),

(2) any non-disclosure agreement Contractor Personnel sign,

(3) whether the service is furnished out of the continental U.S. (see security requirements in **Section 3.7**),

(4) Certifications such as FedRAMP,

(5) Third party security auditing, including FISMA,

(6) Published Security Incident reporting policy, and

(7) Cybersecurity insurance, if any, maintained.

G. Experience and Qualifications of Proposed Staff (Submit under TAB F)

As part of the evaluation of the Proposal for this RFP, Offerors shall propose exactly three (3) key resources and shall describe in a Staffing Plan how additional resources shall be acquired to meet the needs of the Department. All other planned positions shall be described generally in the Staffing Plan and may not be used as evidence of fulfilling company or personnel minimum qualifications.

The Offeror shall identify the qualifications and types of staff proposed to be utilized under the Contract including information in support of the Personnel Experience criteria in **Section 3.10.2 and 3.10.3**. Specifically, the Offeror shall:

1) Describe in detail how the proposed staff's experience and qualifications relate to their specific responsibilities, including any staff of proposed subcontractor(s), as detailed in the Work Plan.

2) Include individual resumes for Key Personnel, including Key Personnel for any proposed subcontractor(s), who are to be assigned to the project if the Offeror is awarded the Contract. Each resume should include the amount of experience the individual has had relative to the Scope of Work set forth in this solicitation.

3) Include letters of intended commitment to work on the project, including letters from any proposed subcontractor(s). Offerors should be aware of restrictions on substitution of Key Personnel prior to RFP award (see Substitution Prior to and Within 30 Days After Contract Execution in Section 3.11.5).

4) Provide an Organizational Chart outlining Personnel and their related duties. The Offeror shall include job titles and the percentage of time each individual will spend on his/her assigned tasks. Offerors using job titles other than those commonly used by industry standards must provide a crosswalk reference document.

5) If proposing differing personnel work hours than identified in the RFP, describe how and why it proposes differing personnel work hours.

H. Offeror Qualifications and Capabilities (Submit under TAB G)

The Offeror shall include information on past experience with similar projects and services including information in support of the Offeror Experience criteria in **Section 3.10.1**. The Offeror shall describe how its organization can meet the requirements of this RFP and shall also include the following information:

1) The number of years the Offeror has provided the similar goods and services;

2) The number of clients/customers and geographic locations that the Offeror currently serves;

3) The names and titles of headquarters or regional management personnel who may be involved with supervising the services to be performed under the Contract;

4) The Offeror's process for resolving billing errors; and

5) An organizational chart that identifies the complete structure of the Offeror including any parent company, headquarters, regional offices, and subsidiaries of the Offeror.

I. References (Submit under TAB H)

At least three (3) references are requested from customers who are capable of documenting the Offeror's ability to provide the goods and services specified in this RFP. References used to meet any Minimum Qualifications (see RFP **Section 1**) may be used to meet this request. Each reference shall be from a client for whom the Offeror has provided goods and services within the past five (5) years and shall include the following information:

1) Name of client organization;

2) Name, title, telephone number, and e-mail address, if available, of point of contact for client organization; and

3) Value, type, duration, and description of goods and services provided.

The Department reserves the right to request additional references or utilize references not provided by the Offeror. Points of contact must be accessible and knowledgeable regarding Offeror performance.

J. List of Current or Prior State Contracts (Submit under TAB I)

Provide a list of all contracts with any entity of the State of Maryland for which the Offeror is currently performing goods and services or for which services have been completed within the last five (5) years. For each identified contract, the Offeror is to provide:

1) The State contracting entity;

2) A brief description of the goods and services provided;

3) The dollar value of the contract;

4) The term of the contract;

5) The State employee contact person (name, title, telephone number, and, if possible, e-mail address); and

6) Whether the contract was terminated before the end of the term specified in the original contract, including whether any available renewal option was not exercised.

Information obtained regarding the Offeror's level of performance on State contracts will be used by the Procurement Officer to determine the responsibility of the Offeror and considered as part of the experience and past performance evaluation criteria of the RFP.

K. Financial Capability (Submit under TAB J)

The Offeror must include in its Proposal a commonly accepted method to prove its fiscal integrity. If available, the Offeror shall include Financial Statements, preferably a Profit and Loss (P&L) statement and a Balance Sheet, for the last two (2) years (independently audited preferred).

In addition, the Offeror may supplement its response to this Section by including one or more of the following with its response:

1) Dun & Bradstreet Rating;

2) Standard and Poor's Rating;

3) Lines of credit;

4) Evidence of a successful financial track record; and

5) Evidence of adequate working capital.

L. Certificate of Insurance (Submit under TAB K)

The Offeror shall provide a copy of its current certificate of insurance showing the types and limits of insurance in effect as of the Proposal submission date. The current insurance types and limits do not have to be the same as described in **Section 3.6**. See **Section 3.6** for the required insurance certificate submission for the apparent awardee.

M. Subcontractors (Submit under TAB L)

The Offeror shall provide a complete list of all subcontractors that will work on the Contract if the Offeror receives an award, including those utilized in meeting the MBE and VSBE subcontracting goal(s), if applicable. This list shall include a full description of the duties each subcontractor will perform and why/how each subcontractor was deemed the most qualified for this project. If applicable, subcontractors utilized in meeting the established MBE or VSBE participation goal(s) for this solicitation shall be identified as provided in the appropriate attachment(s) of this RFP.

N. Legal Action Summary (Submit under TAB M)

This summary shall include:

1) A statement as to whether there are any outstanding legal actions or potential claims against the Offeror and a brief description of any action;

2) A brief description of any settled or closed legal actions or claims against the Offeror over the past five (5) years;

3) A description of any judgments against the Offeror within the past five (5) years, including the court, case name, complaint number, and a brief description of the final ruling or determination; and

4) In instances where litigation is ongoing and the Offeror has been directed not to disclose information by the court, provide the name of the judge and location of the court.

O. Economic Benefit Factors (Submit under TAB N)

1) The Offeror shall submit with its Proposal a narrative describing benefits that will accrue to the Maryland economy as a direct or indirect result of its performance of the Contract. Proposals will be evaluated to assess the benefit to Maryland's economy specifically offered. The economic benefit offered should be consistent with the Offeror's Total Proposal Price from **Attachment B**, the Financial Proposal Form. See COMAR 21.05.03.03A (3).

2) Proposals that identify specific benefits as being contractually enforceable commitments will be rated more favorably than Proposals that do not identify specific benefits as contractual commitments, all other factors being equal.

3) Offerors shall identify any performance guarantees that will be enforceable by the State if the full level of promised benefit is not achieved during the Contract term.

4) As applicable, for the full duration of the Contract, including any renewal period, or until the commitment is satisfied, the Contractor shall provide to the Procurement Officer or other designated agency personnel reports of the actual attainment of each benefit listed in response to this section. These benefit attainment reports shall be provided quarterly, unless elsewhere in these specifications a different reporting frequency is stated.

5) In responding to this section, the following do not generally constitute economic benefits to be derived from the Contract:

   a) generic statements that the State will benefit from the Offeror's superior performance under the Contract;

b) descriptions of the number of Offeror employees located in Maryland other than those that will be performing work under the Contract; or

c) tax revenues from Maryland-based employees or locations, other than those that will be performing, or used to perform, work under the Contract.

6) Discussion of Maryland-based employees or locations may be appropriate if the Offeror makes some projection or guarantee of increased or retained presence based upon being awarded the Contract.

7) Examples of economic benefits to be derived from a contract may include any of the following. For each factor identified below, identify the specific benefit and contractual commitments and provide a breakdown of expenditures in that category:

a) The Contract dollars to be recycled into Maryland's economy in support of the Contract, through the use of Maryland subcontractors, suppliers and joint venture partners. **Do not include actual fees or rates paid to subcontractors or information from your Financial Proposal;**

b) The number and types of jobs for Maryland residents resulting from the Contract. Indicate job classifications, number of employees in each classification and the aggregate payroll to which the Offeror has committed, including contractual commitments at both prime and, if applicable, subcontract levels; and whether Maryland employees working at least 30 hours per week and are employed at least 120 days during a 12-month period will receive paid leave. If no new positions or subcontracts are anticipated as a result of the Contract, so state explicitly;

c) Tax revenues to be generated for Maryland and its political subdivisions as a result of the Contract. Indicate tax category (sales taxes, payroll taxes, inventory taxes and estimated personal income taxes for new employees). Provide a forecast of the total tax revenues resulting from the Contract;

d) Subcontract dollars committed to Maryland small businesses and MBEs; and

e) Other benefits to the Maryland economy which the Offeror promises will result from awarding the Contract to the Offeror, including contractual commitments. Describe the benefit, its value to the Maryland economy, and how it will result from, or because of the Contract award. Offerors may commit to benefits that are not directly attributable to the Contract, but for which the Contract award may serve as a catalyst or impetus.

P. Technical Proposal - Required Forms and Certifications (Submit under TAB O)

1) All forms required for the Technical Proposal are identified in Table 1 of **Section 7** – RFP Attachments and Appendices. Unless directed otherwise by instructions within an individual form, complete, sign, and include all required forms in the Technical Proposal, under TAB O.

2) Offerors shall furnish any and all agreements and terms and conditions the Offeror expects the State to sign or to be subject to in connection with or in order to use the Offeror's services under this Contract. This includes physical copies of all agreements referenced and incorporated in primary documents, including but not limited to any Software licensing agreement for any Software proposed to be licensed to the State under

this Contract (e.g., EULA, Enterprise License Agreements, Professional Service agreement, Master Agreement) and any AUP. The State does not agree to terms and conditions not provided in an Offeror's Technical Proposal and no action of the State, including but not limited to the use of any such Software, shall be deemed to constitute acceptance of any such terms and conditions. Failure to comply with this section renders any such agreement unenforceable against the State.

3) For each service, hardware or Software proposed as furnished by a third-party entity, Offeror must identify the third-party provider and provide a letter of authorization or such other documentation demonstrating the authorization for such services. In the case of an open-source license, authorization for the open source shall demonstrate compliance with the open source license.

4) A Letter of Authorization shall be on letterhead or through the provider's e-mail. Further, each Letter of Authorization shall be less than twelve (12) months old and must provide the following information:

   i) Third-party POC name and alternate for verification

   ii) Third-party POC mailing address

   iii) Third-party POC telephone number

   iv) Third-party POC email address

   v) If available, a Re-Seller Identifier

5.4 Volume II – Financial Proposal

The Financial Proposal shall contain all price information in the format specified in **Attachment B**. The Offeror shall complete the Financial Proposal Form only as provided in the Financial Proposal Instructions and the Financial Proposal Form itself. Do not amend, alter, or leave blank any items on the Financial Proposal Form or include additional clarifying or contingent language on or attached to the Financial Proposal Form. Failure to adhere to any of these instructions may result in the Proposal being determined to be not reasonably susceptible of being selected for award and rejected by the Department.

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6 Evaluation and Selection Process

6.1 Evaluation Committee

Evaluation of Proposals will be performed in accordance with COMAR 21.05.03 by a committee established for that purpose and based on the evaluation criteria set forth below. The Evaluation Committee will review Proposals, participate in Offeror oral presentations and discussions, and provide input to the Procurement Officer. The Department reserves the right to utilize the services of individuals outside of the established Evaluation Committee for advice and assistance, as deemed appropriate.

During the evaluation process, the Procurement Officer may determine at any time that a particular Offeror is not susceptible for award.

6.2 Technical Proposal Evaluation Criteria

The criteria to be used to evaluate each Technical Proposal are listed below in descending order of importance. Unless stated otherwise, any sub-criteria within each criterion have equal weight.

6.2.1. Offeror's Technical Response to Requirements and Work Plan (See RFP **§ 5.3.2.F**)

The State prefers the Offeror's Technical Proposal to illustrate a comprehensive understanding of work requirements and mastery of the subject matter, including an explanation of how the work will be performed. Proposals which include limited responses to work requirements such as "concur" or "will comply" will receive a lower ranking than those Proposals that demonstrate an understanding of the work requirements and include plans to meet or exceed them.

6.2.2. Experience and Qualifications of Proposed Staff (See RFP **§ 3.10.2**)

6.2.3. Offeror Qualifications and Capabilities, including proposed subcontractors (See RFP **§ 3.10.1**)

6.2.4. Economic Benefit to State of Maryland (See RFP **§ 5.3.O**)

6.3 Financial Proposal Evaluation Criteria

All Qualified Offerors (see **Section 6.4.2.D**) will be ranked from the lowest (most advantageous) to the highest (least advantageous) price based on the 'Total Proposal Price' within the stated guidelines set forth in this RFP and as submitted on **Attachment B** - Financial Proposal Form.

6.4 Reciprocal Preference

6.4.1 Although Maryland law does not authorize procuring agencies to favor resident Offerors in awarding procurement contracts, many other states do grant their resident businesses preferences over Maryland contractors. COMAR 21.05.01.04 permits procuring agencies to apply a reciprocal preference under the following conditions:

A. The Maryland resident business is a responsible Offeror;

B. The most advantageous Proposal is from a responsible Offeror whose principal office, or principal base of operations is in another state;

C. The other state gives a preference to its resident businesses through law, policy, or practice; and

D. The preference does not conflict with a federal law or grant affecting the procurement Contract.

6.4.2 The preference given shall be identical to the preference that the other state, through law, policy, or practice gives to its resident businesses.

6.5 Selection Procedures

6.5.1 General

A. The Contract will be awarded in accordance with the Competitive Sealed Proposals (CSP) method found at COMAR 21.05.03. The CSP method allows for the conducting of discussions and the revision of Proposals during these discussions. Therefore, the State may conduct discussions with all Offerors that have submitted Proposals that are determined to be reasonably susceptible of being selected for contract award or potentially so. However, the State reserves the right to make an award without holding discussions.

B. With or without discussions, the State may determine the Offeror to be not responsible or the Offeror's Proposal to be not reasonably susceptible of being selected for award at any time after the initial closing date for receipt of Proposals and prior to Contract award.

6.5.2 Selection Process Sequence

A. A determination is made that the MDOT Certified MBE Utilization and Fair Solicitation Affidavit (**Attachment D-1A**) is included and is properly completed, if there is a MBE goal. In addition, a determination is made that the VSBE Utilization Affidavit and subcontractor Participation Schedule (**Attachment E-1**) is included and is properly completed, if there is a VSBE goal.

B. Technical Proposals are evaluated for technical merit and ranked. During this review, oral presentations and discussions may be held. The purpose of such discussions will be to assure a full understanding of the State's requirements and the Offeror's ability to perform the services, as well as to facilitate arrival at a Contract that is most advantageous to the State. Offerors will be contacted by the State as soon as any discussions are scheduled.

C. Offerors must confirm in writing any substantive oral clarifications of, or changes in, their Technical Proposals made in the course of discussions. Any such written clarifications or changes then become part of the Offeror's Technical Proposal. Technical Proposals are given a final review and ranked.

D. The Financial Proposal of each Qualified Offeror (a responsible Offeror determined to have submitted an acceptable Proposal) will be evaluated and ranked separately from the Technical evaluation. After a review of the Financial Proposals of Qualified Offerors, the Evaluation Committee or Procurement Officer may again conduct discussions to further evaluate the Offeror's entire Proposal.

E. When in the best interest of the State, the Procurement Officer may permit Qualified Offerors to revise their initial Proposals and submit, in writing, Best and Final Offers (BAFOs). The State may make an award without issuing a request for a BAFO. **Offerors may only perform limited substitutions of proposed personnel as allowed in Section 3.11 (Substitution of Personnel**).

6.5.3 Award Determination

Upon completion of the Technical Proposal and Financial Proposal evaluations and rankings, each Offeror will receive an overall ranking. The Procurement Officer will recommend award of the Contract to the responsible Offeror that submitted the Proposal determined to be the most advantageous to the State. In making this most advantageous Proposal determination, technical factors will receive equal weight with financial factors.

6.6 Documents Required upon Notice of Recommendation for Contract Award

Upon receipt of a Notification of Recommendation for Contract award, the apparent awardee shall complete and furnish the documents and attestations as directed in Table 1 of **Section 7** – **RFP Attachments and Appendices**.

7 RFP ATTACHMENTS AND APPENDICES

Instructions Page

A Proposal submitted by the Offeror must be accompanied by the completed forms and affidavits identified as "with Proposal" in the "When to Submit" column in Table 1 below. All forms and affidavits applicable to this RFP, including any applicable instructions or terms, are identified in the "Applies" and "Label" columns in Table 1.

For documents required as part of the Proposal:

1. For e-mail submissions, submit one (1) copy of each with signatures.
2. For paper submissions, submit two (2) copies of each with original signatures. All signatures must be clearly visible.

All Offerors are advised that if a Contract is awarded as a result of this solicitation, the successful Offeror will be required to complete certain forms and affidavits after notification of recommended award. The list of forms and affidavits that must be provided is described in Table 1 below in the "When to Submit" column.

For documents required after award, submit three (3) copies of each document within the appropriate number of days after notification of recommended award, as listed in Table 1 below in the "When to Submit" column.

Table 1: RFP ATTACHMENTS AND APPENDICES

Applies?	When to Submit	Label	Attachment Name
Y	Before Proposal	A	Pre-Proposal Conference Response Form
Y	With Proposal	B	Financial Proposal Instructions and Form
Y	With Proposal	C	Bid/Proposal Affidavit (see link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/AttachmentC-Bid_Proposal-Affidavit.pdf)
N		D	Minority Business Enterprise (MBE) Forms
N		E	Veteran-Owned Small Business Enterprise (VSBE) Forms
Y		F	Maryland Living Wage Affidavit of Agreement for Service Contracts (see link at

			http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/AttachmentF-LivingWageAffidavit.pdf)
Y	With Proposal	G	Federal Funds Attachments (see link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/AttachmentG-FederalFundsAttachment.pdf)
Y	With Proposal	H	Conflict of Interest Affidavit and Disclosure (see link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/05/AttachmentH-Conflict-of-InterestAffidavit.pdf)
Y	5 Business Days after recommended award – However, suggested with Proposal	I	Non-Disclosure Agreement (Contractor) (see link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/Attachment-I-Non-DisclosureAgreementContractor.pdf)
Y	5 Business Days after recommended award – However, suggested with Proposal	J	HIPAA Business Associate Agreement (see link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/Attachment-J-HIPAABusinessAssociateAgreement.pdf)
N		K	Mercury Affidavit
Y	With Proposal	L	Location of the Performance of Services Disclosure (see link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/Attachment-L-PerformanceofServicesDisclosure.pdf)
Y	5 Business Days after recommended award	M	Sample Contract (included in this RFP)
Y	5 Business Days after	N	Contract Affidavit (see link at http://procurement.maryland.gov/wp-

	recommended award		content/uploads/sites/12/2018/04/Attachment-N-ContractAffidavit.pdf)
Y	5 Business Days after recommended award	O	DHS Hiring Agreement (see link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/Attachment-O-DHSHiringAgreement.pdf)
Appendices			
Applies?	**When to Submit**	**Label**	**Attachment Name**
Y	n/a	1	Abbreviations and Definitions (included in this RFP)
Y	With Proposal	2	Offeror Information Sheet (see link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/Appendix2-Bidder_OfferorInformationSheet.pdf)
Y	N/A	3	MCR laws and Regulations
Y	N/A	4-1	NPCR Program Standards 2022-2027
Y	N/A	4-2	NPCR Logic Model
Y	N/A	4-3	Database System Maintenance and Support
Y	N/A	4-4	NPCR - CSS 2021 Data Release Policy
Y	N/A	4-5	Program Evaluation Instrument (PEI) Overview
Y	N/A	4-6	NPCR Data Modernization Strategy
Y	N/A	4-7	NPCR Success Stories
Y	N/A	4-8	NPCR Education and Training Coordination

Y	N/A	4-9	Data Quality Activities Overview
Y	N/A	4-10	NPCR - CSS Data Submission Specification Overview
Y	N/A	4-11	NPCR Electronic Reporting Guidance
Y	N/A	4-12	Physician Reporting Guidance
Y	N/A	4-13	Electronic Data Exchange Guidance
Y	N/A	4-14	NPCR Hospital, Pathology Laboratory and Physician Progress Report
Y	N/A	5	Maryland Evaluation Plan Performance Measures
Y	N/A	6	Management Reports
Y	With Proposal	7	Labor Resume Form (see link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/05/Appendix-xx-Labor-Resume-Form.dotx)
Y	N/A	8	Corporate Diversity Addendum – Affidavit I & II (https://procurement.maryland.gov/wp-content/uploads/sites/12/2022/09/Corporate-Diversity-Addendum-Version-8.12.2022.docx)

Additional Submissions

Applies?	When to Submit	Label	Attachment Name
Y	5 Business Days after recommended award		Evidence of meeting insurance requirements (see **Section 3.6**); 1 copy
Y	With Proposal		PEP; 1 copy

Y	With deliverables	--	Deliverable Product Acceptance Form (DPAF) (see online at http://doit.maryland.gov/contracts/Documents/_procurementForms/DeliverableProductAcceptanceForm-DPAFsample.pdf

Attachment A. Pre-Proposal Conference Response Form

Solicitation Number OCMP-24-19699

Cancer Surveillance, Operations, and Quality Assurance for the Maryland Cancer Registry

A Pre-Proposal conference will be held on December 4, 2023 via (Google Meet) Teleconference.

Please return this form by December 1, 2023 3:00pm advising whether or not your firm plans to attend.

The completed form should be returned via e-mail to the Procurement Officer (LaCynda Conaway)at the contact information below:

Procurement Officer: Lacynda Conaway

Email: lacynda.conaway@maryland.gov

Please indicate:

____ Yes, the following representatives will be in attendance.

Attendees (Please include Full Name, Name of Organization, Phone Number, eMail Address, and MBE Yes or No):

1.

2.

3.

____ No, we will not be in attendance.

Please specify whether any reasonable accommodations are requested (see RFP § 4.1"Pre-Proposal conference"):

Offeror: _____

Offeror Name (please print or type)

By: _____

Signature/Seal

Printed Name: _____

Printed Name

Title: _____

Title

Date: _____

Date

Attachment B. Financial Proposal Instructions & Form

B-1 Financial Proposal Instructions

In order to assist Offerors in the preparation of their Financial Proposal and to comply with the requirements of this solicitation, Financial Proposal Instructions and a Financial Proposal Form have been prepared. Offerors shall submit their Financial Proposal on the Financial Proposal Form in accordance with the instructions on the Financial Proposal Form and as specified herein. Do not alter the Financial Proposal Form or the Proposal may be determined to be not reasonably susceptible of being selected for award. The Financial Proposal Form is to be signed and dated, where requested, by an individual who is authorized to bind the Offeror to the prices entered on the Financial Proposal Form.

The Financial Proposal Form is used to calculate the Offeror's TOTAL Proposal PRICE. Follow these instructions carefully when completing your Financial Proposal Form:

A) All Unit and Extended Prices must be clearly entered in dollars and cents, e.g., $24.15. Make your decimal points clear and distinct.

B) All Unit Prices must be the actual price per unit the State will pay for the specific item or service identified in this RFP and may not be contingent on any other factor or condition in any manner.

C) All calculations shall be rounded to the nearest cent, e.g., .344 shall be .34 and .345 shall be .35.

D) Any goods or services required through this RFP and proposed by the vendor at **No Cost to the State** must be clearly entered in the Unit Price, if appropriate, and Extended Price with **$0.00**.

E) Every blank in every Financial Proposal Form shall be filled in. Any changes or corrections made to the Financial Proposal Form by the Offeror prior to submission shall be initialed and dated.

F) Except as instructed on the Financial Proposal Form, nothing shall be entered on or attached to the Financial Proposal Form that alters or proposes conditions or contingencies on the prices. Alterations or conditions may render the Proposal not reasonably susceptible of being selected for award.

G) It is imperative that the prices included on the Financial Proposal Form have been entered correctly and calculated accurately by the Offeror and that the respective total prices agree with the entries on the Financial Proposal Form. Any incorrect entries or inaccurate calculations by the Offeror will be treated as provided in COMAR 21.05.03.03.F and may cause the Proposal to be rejected.

H) If option years are included, Offerors must submit pricing for each option year. Any option to renew will be exercised at the sole discretion of the State and comply with all terms and conditions in force at the time the option is exercised. If exercised, the option period shall be for a period identified in the RFP at the prices entered in the Financial Proposal Form.

I) All Financial Proposal prices entered below are to be fully loaded prices that include all costs/expenses associated with the provision of services as required by the RFP. The Financial Proposal price shall include, but is not limited to, all: labor, profit/overhead, general operating, administrative, and all other expenses and costs necessary to perform the work set forth in the solicitation. No other amounts will be paid to the Contractor. If labor rates are requested, those amounts shall be fully loaded rates; no overtime amounts will be paid.

J) Unless indicated elsewhere in the RFP, sample amounts used for calculations on the Financial Proposal Form are typically estimates for evaluation purposes only. Unless stated otherwise in the RFP, the Department does not guarantee a minimum or maximum number of units or usage in the performance of the Contract.

K) Failure to adhere to any of these instructions may result in the Proposal being determined not reasonably susceptible of being selected for award.

The Financial Proposal Form shall contain all price information in the format specified on these pages. Complete the Financial Proposal Form only as provided in the Financial Proposal Instructions. Do not amend, alter or leave blank any items on the Financial Proposal Form. If option years are included, Offerors must submit pricing for each option year. Failure to adhere to any of these instructions may result in the Proposal being determined not reasonably susceptible of being selected for award.

See separate Excel Financial Proposal Form labeled Attachment B – OCMP-24-19692 MDH Cancer Surveillan.xls.

Attachment C. Proposal Affidavit

See link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/AttachmentC-Bid_Proposal-Affidavit.pdf.

Attachment D. Minority Business Enterprise (MBE) Forms

This solicitation does not include a Minority Business Enterprise (MBE) subcontractor participation goal.

Attachment E. Veteran-Owned Small Business Enterprise (VSBE) Forms

This solicitation does not include a Veteran-Owned Small Business Enterprise goal.

Attachment F. Maryland Living Wage Affidavit of Agreement for Service Contracts

See link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/AttachmentF-LivingWageAffidavit.pdf to complete the Affidavit.

A. This contract is subject to the Living Wage requirements under Md. Code Ann., State Finance and Procurement Article, Title 18, and the regulations proposed by the Commissioner of Labor and Industry (Commissioner). The Living Wage generally applies to a Contractor or subcontractor who performs work on a State contract for services that is valued at $100,000 or more. An employee is subject to the Living Wage if he/she is at least 18 years old or will turn 18 during the duration of the contract; works at least 13 consecutive weeks on the State Contract and spends at least one-half of the employee's time during any work week on the State Contract.

B. The Living Wage Law does not apply to:

(1) A Contractor who:

(a) Has a State contract for services valued at less than $100,000, or

(b) Employs 10 or fewer employees and has a State contract for services valued at less than $500,000.

(2) A subcontractor who:

(a) Performs work on a State contract for services valued at less than $100,000,

(b) Employs 10 or fewer employees and performs work on a State contract for services valued at less than $500,000, or

(c) Performs work for a Contractor not covered by the Living Wage Law as defined in B(1)(b) above, or B (3) or C below.

(3) Service contracts for the following:

(a) Services with a Public Service Company;

(b) Services with a nonprofit organization;

(c) Services with an officer or other entity that is in the Executive Branch of the State government and is authorized by law to enter into a procurement ("Unit"); or

(d) Services between a Unit and a County or Baltimore City.

C. If the Unit responsible for the State contract for services determines that application of the Living Wage would conflict with any applicable Federal program, the Living Wage does not apply to the contract or program.

D. A Contractor must not split or subdivide a State contract for services, pay an employee through a third party, or treat an employee as an independent Contractor or assign work to employees to avoid the imposition of any of the requirements of Md. Code Ann., State Finance and Procurement Article, Title 18.

E. Each Contractor/subcontractor, subject to the Living Wage Law, shall post in a prominent and easily accessible place at the work site(s) of covered employees a notice of the Living Wage Rates, employee rights under the law, and the name, address, and telephone number of the Commissioner.

F. The Commissioner shall adjust the wage rates by the annual average increase or decrease, if any, in the Consumer Price Index for all urban consumers for the Washington/Baltimore metropolitan area, or any successor index, for the previous calendar year, not later than 90 days after the start of each fiscal year. The Commissioner shall publish any adjustments to the wage rates on the Division of Labor and Industry's website. An employer subject to the Living Wage Law must comply with the rate requirements during the initial term of the contract and all subsequent renewal periods, including any increases in the wage rate, required by the Commissioner, automatically upon the effective date of the revised wage rate.

G. A Contractor/subcontractor who reduces the wages paid to an employee based on the employer's share of the health insurance premium, as provided in Md. Code Ann., State Finance and Procurement Article, §18-103(c), shall not lower an employee's wage rate below the minimum wage as set in Md. Code Ann., Labor and Employment Article, §3-413. A Contractor/subcontractor who reduces the wages paid to an employee based on the employer's share of health insurance premium shall comply with any record reporting requirements established by the Commissioner.

H. A Contractor/subcontractor may reduce the wage rates paid under Md. Code Ann., State Finance and Procurement Article, §18-103(a), by no more than 50 cents of the hourly cost of the employer's contribution to an employee's deferred compensation plan. A Contractor/subcontractor who reduces the wages paid to an employee based on the employer's contribution to an employee's deferred compensation plan shall not lower the employee's wage rate below the minimum wage as set in Md. Code Ann., Labor and Employment Article, §3-413.

I. Under Md. Code Ann., State Finance and Procurement Article, Title 18, if the Commissioner determines that the Contractor/subcontractor violated a provision of this title or regulations of the Commissioner, the Contractor/subcontractor shall pay restitution to each affected employee, and the State may assess liquidated damages of $20 per day for each employee paid less than the Living Wage.

J. Information pertaining to reporting obligations may be found by going to the Division of Labor and Industry website http://www.dllr.state.md.us/labor/prev/livingwage.shmtl and clicking on Living Wage for State Service Contracts.

Attachment G. Federal Funds Attachments

See link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/AttachmentG-FederalFundsAttachment.pdf.

Attachment H. Conflict of Interest Affidavit and Disclosure

See link at https://procurement.maryland.gov/wp-content/uploads/sites/12/2018/05/AttachmentH-Conflict-of-InterestAffidavit.pdf

Attachment I. Non-Disclosure Agreement (Contractor)

See link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/Attachment-I-Non-DisclosureAgreementContractor.pdf.

Attachment J. HIPAA Business Associate Agreement

See link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/Attachment-J-HIPAABusinessAssociateAgreement.pdf.

Attachment K. Mercury Affidavit

This solicitation does not include the procurement of products known to likely include mercury as a component.

Attachment L. Location of the Performance of Services Disclosure

See link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/Attachment-L-PerformanceofServicesDisclosure.pdf.

Attachment M. Contract

Maryland Department of Health (MDH)

"Cancer Surveillance, Operations, and Quality Assurance for the Maryland Cancer Registry"

OCMP-24-19699

THIS CONTRACT (the "Contract") is made this ____ day of _____, 20___ by and between _____ (the "Contractor") and the STATE OF MARYLAND, acting through the MARYLAND DEPARTMENT OF HEALTH ("MDH" or the "Department").

In consideration of the promises and the covenants herein contained, the adequacy and sufficiency of which are hereby acknowledged by the parties, the parties agree as follows:

1. Definitions

In this Contract, the following words have the meanings indicated:

1.1 "COMAR" means Code of Maryland Regulations.

1.2 "Contractor" means the entity first named above whose principal business address is (Contractor's primary address) and whose principal office in Maryland is (Contractor's local address), whose Federal Employer Identification Number or Social Security Number is (Contractor's FEIN), and whose eMaryland Marketplace Advantage vendor ID number is (eMMA Number).

1.3 "Financial Proposal" means the Contractor's [pick one: Financial Proposal or Best and Final Offer (BAFO)] dated _____(Financial Proposal date or BAFO date).

1.4 Minority Business Enterprise (MBE) – Any legal entity certified as defined at COMAR 21.01.02.01B (54) which is certified by the Maryland Department of Transportation under COMAR 21.11.03.

1.5 "RFP" means the Request for Proposals for Cancer Surveillance, Operations, and Quality Assurance for the Maryland Cancer Registry, Solicitation # OCMP-24-19699 and any amendments, addenda, and attachments thereto issued in writing by the State.

1.6 "State" means the State of Maryland.

1.7 "Technical Proposal" means the Contractor's Technical Proposal dated. _____ (Technical Proposal date), as modified and supplemented by the Contractor's responses to requests clarifications and requests for cure, and by any Best and Final Offer.

1.8 "Veteran-owned Small Business Enterprise" (VSBE) means A business that is verified by the Center for Verification and Evaluation (CVE) of the United States Department of Veterans Affairs as a veteran-owned small business. See Code of Maryland Regulations (COMAR) 21.11.13.

1.9 Capitalized terms not defined herein shall be ascribed the meaning given to them in the RFP.

2. Scope of Contract

2.1 The Contractor shall perform in accordance with this Contract and Exhibits A-D, which are listed below and incorporated herein by reference. If there is any conflict between this Contract and the Exhibits, the terms of the Contract shall control. If there is any conflict among the Exhibits, the following order of precedence shall determine the prevailing provision:

Exhibit A – The RFP

Exhibit B – The Contract Affidavit, executed by the Contractor and dated

Exhibit C – The Technical Proposal

Exhibit D – The Financial Proposal

2.2 The Procurement Officer may, at any time, by written order, make unilateral changes in the work within the general scope of the Contract. No other order, statement, or conduct of the Procurement Officer or any other person shall be treated as a change or entitle the Contractor to an equitable adjustment under this section. Except as otherwise provided in this Contract, if any change under this section causes an increase or decrease in the Contractor's cost of, or the time required for, the performance of any part of the work, whether or not changed by the order, an equitable adjustment in the Contract price shall be made and the Contract modified in writing accordingly. The Contractor must assert in writing its right to an adjustment under this section within thirty (30) days of receipt of written change order and shall include a written statement setting forth the nature and cost of such claim. No claim by the Contractor shall be allowed if asserted after final payment under this Contract. Failure to agree to an adjustment under this section shall be a dispute under the Disputes clause. Nothing in this section shall excuse the Contractor from proceeding with the Contract as changed.

2.3 Without limiting the rights of the Procurement Officer under Section 2.2 above, the Contract may be modified by mutual agreement of the parties, provided: (a) the modification is made in writing; (b) all parties sign the modification; and (c) all approvals by the required agencies as described in COMAR Title 21, are obtained.

3. Period of Performance

3.1 The term of this Contract begins on the date the Contract is signed by the Department following any required prior approvals, including approval by the Board of Public Works, if such approval is required (the "Effective Date") and shall continue for Five (5) years. ("Initial Term").

3.2. The Contractor's performance under the Contract shall commence as of the date provided in a written NTP.

3.3 The Contractor's obligation to pay invoices to subcontractors providing products/services in connection with this Contract, as well as the audit; confidentiality; document retention; patents, copyrights & intellectual property; warranty; indemnification obligations; and limitations of liability under this Contract; and any other obligations specifically identified, shall survive expiration or termination of the Contract.

4. Consideration and Payment

4.1 In consideration of the satisfactory performance of the work set forth in this Contract, the Department shall pay the Contractor in accordance with the terms of this Contract and at the prices quoted in the Financial Proposal. Unless properly modified (see above Section 2), payment to the Contractor pursuant to this Contract, including the Initial Term and any Renewal Term, shall not exceed the Contracted amount.

The total payment under a fixed price Contract or the fixed price element of a combined fixed price – time and materials Contract shall be the firm fixed price submitted by the Contractor in its Financial Proposal.

4.2 For time and materials Contracts, IDIQ Contracts, or Contracts which include either or both a time and materials or IDIQ element(s), total payments to the Contractor pursuant to this Contract for the time and materials and IDIQ portion(s) may not exceed $_____ (the "NTE Amount"), which includes $_____ for the Initial Term.

4.3 Contractor shall notify the Contract Monitor, in writing, at least sixty (60) days before payments reach the NTE Amount. After notification by the Contractor, if the State fails to increase the Contract amount, the Contractor shall have no obligation to perform under this Contract after payments reach the stated amount; provided, however, that, prior to the stated amount being reached, the Contractor shall: (a) promptly consult and work in good faith with the Department to establish a plan of action to assure that every reasonable effort is undertaken by the Contractor to complete State-defined critical work in progress prior to the date the NTE Amount will be reached; and (b) when applicable secure databases, systems, platforms, and applications on which the Contractor is working in an industry standard manner so as to prevent damage or vulnerabilities to any of the same due to the existence of any such unfinished work.

4.4 Unless a payment is unauthorized, deferred, delayed, or set-off under COMAR 21.02.07, payments to the Contractor pursuant to this Contract shall be made no later than 30 days after the Department's receipt of a proper invoice from the Contractor as required by RFP **Section 3.3**.

The Contractor may be eligible to receive late payment interest at the rate of 9% per annum if:

(1) The Contractor submits an invoice for the late payment interest within thirty days after the date of the State's payment of the amount on which the interest accrued; and

(2) A contract claim has not been filed under State Finance and Procurement Article, Title 15, Subtitle 2, Annotated Code of Maryland.

The State is not liable for interest:

(1) Accruing more than one year after the 31st day after the agency receives the proper invoice; or

(2) On any amount representing unpaid interest. Charges for late payment of invoices are authorized only as prescribed by Title 15, Subtitle 1, of the State Finance and Procurement Article, Annotated Code of Maryland, or by the Public Service Commission of Maryland with respect to regulated public utilities, as applicable.

Final payment under this Contract will not be made until after certification is received from the Comptroller of the State that all taxes have been paid.

Electronic funds transfer shall be used by the State to pay Contractor pursuant to this Contract and any other State payments due Contractor unless the State Comptroller's Office grants Contractor an exemption.

4.5 In addition to any other available remedies, if, in the opinion of the Procurement Officer, the Contractor fails to perform in a satisfactory and timely manner, the Procurement Officer may refuse or limit approval of any invoice for payment and may cause payments to the Contractor to be reduced or withheld until such time as the Contractor meets performance standards as established by the Procurement Officer.

4.6 Payment of an invoice by the Department is not evidence that services were rendered as required under this Contract.

5. Rights to Records

5.1 The Contractor agrees that all documents and materials including, but not limited to, Software, reports, drawings, studies, specifications, estimates, tests, maps, photographs, designs, graphics, mechanical, artwork, computations, and data prepared by the Contractor for purposes of this Contract shall be the sole property of the State and shall be available to the State at any time. The State shall have the right to use the same without restriction and without compensation to the Contractor other than that specifically provided by this Contract.

5.2 The Contractor agrees that at all times during the term of this Contract and thereafter, works created as a Deliverable under this Contract (as defined in **Section 7.2**), and services performed under this Contract shall be "works made for hire" as that term is interpreted under U.S. copyright law. To the extent that any products created as a Deliverable under this Contract are not works made for hire for the State, the Contractor hereby relinquishes, transfers, and assigns to the State all of its rights, title, and interest (including all intellectual property rights) to all such products created under this Contract, and will cooperate reasonably with the State in effectuating and registering any necessary assignments.

5.3 The Contractor shall report to the Contract Monitor, promptly and in written detail, each notice or claim of copyright infringement received by the Contractor with respect to all data delivered under this Contract.

5.4 The Contractor shall not affix any restrictive markings upon any data, documentation, or other materials provided to the State hereunder and if such markings are affixed, the State shall have the right at any time to modify, remove, obliterate, or ignore such warnings.

5.5 Upon termination or expiration of the Contract, the Contractor, at its own expense, shall deliver any equipment, Software or other property provided by the State to the place designated by the Procurement Officer.

6. Exclusive Use

6.1 The State shall have the exclusive right to use, duplicate, and disclose any data, information, documents, records, or results, in whole or in part, in any manner for any purpose whatsoever, that may be created or generated by the Contractor in connection with this Contract. If any material, including Software, is capable of being copyrighted, the State shall be the copyright owner and Contractor may copyright material connected with this project only with the express written approval of the State.

6.2 Except as may otherwise be set forth in this Contract, Contractor shall not use, sell, sub-lease, assign, give, or otherwise transfer to any third party any other information or material provided to Contractor by the Department or developed by Contractor relating to the Contract, except as provided for in **Section 8**. **Confidential or Proprietary Information and Documentation**.

7. Patents, Copyrights, and Intellectual Property

7.1. All copyrights, patents, trademarks, trade secrets, and any other intellectual property rights existing prior to the Effective Date of this Contract shall belong to the party that owned such rights immediately prior to the Effective Date ("Pre-Existing Intellectual Property"). If any design, device, material, process, or other item provided by Contractor is covered by a patent or copyright or which is proprietary to or a trade secret of another, the Contractor shall obtain the necessary permission or license to permit the State to use such item or items pursuant to its rights granted under the Contract.

7.2 Except for (1) information created or otherwise owned by the Department or licensed by the Department from third parties, including all information provided by the Department to Contractor;

(2) materials created by Contractor or its subcontractor(s) specifically for the State under the Contract ("Deliverables"), except for any Contractor Pre-Existing Intellectual Property included therein; and (3) the license rights granted to the State, all right, title, and interest in the intellectual property embodied in the solution, including the know-how and methods by which the solution is provided and the processes that make up the solution, will belong solely and exclusively to Contractor and its licensors, and the Department will have no rights to the same except as expressly granted in this Contract. Any SaaS Software developed by Contractor during the performance of the Contract will belong solely and exclusively to Contractor and its licensors. For all Software provided by the Contractor under the Contract, Contractor hereby grants to the State a nonexclusive, irrevocable, unlimited, perpetual, non-cancelable, and non-terminable right to use and make copies of the Software and any modifications to the Software. For all Contractor Pre-Existing Intellectual Property embedded in any Deliverables, Contractor grants to the State a license to use such Contractor Pre-Existing Intellectual Property in connection with its permitted use of such Deliverable. During the period between delivery of a Deliverable by Contractor and the date of payment therefor by the State in accordance with this Contract (including throughout the duration of any payment dispute discussions), subject to the terms and conditions contained herein, Contractor grants the State a royalty-free, non-exclusive, limited license to use such Deliverable and to use any Contractor Materials contained therein in accordance with this Contract.

7.3. Subject to the terms of **Section 10**, Contractor shall defend, indemnify and hold harmless the State and its agents and employees, from and against any and all claims, costs, losses, damages, liabilities, judgments and expenses (including without limitation reasonable attorneys' fees) arising out of or in connection with any third party claim that the Contractor-provided products/services infringe, misappropriate or otherwise violate any third party intellectual property rights. Contractor shall not enter into any settlement involving third party claims that contains any admission of or stipulation to any guilt, fault, liability or wrongdoing by the State or that adversely affects the State's rights or interests, without the State's prior written consent.

7.4 Without limiting Contractor's obligations under **Section 5.3**, if an infringement claim occurs, or if the State or the Contractor believes such a claim is likely to occur, Contractor (after consultation with the State and at no cost to the State): (a) shall procure for the State the right to continue using the allegedly infringing component or service in accordance with its rights under this Contract; or (b) replace or modify the allegedly infringing component or service so that it becomes non-infringing and remains compliant with all applicable specifications.

7.5 Except as otherwise provided herein, Contractor shall not acquire any right, title or interest (including any intellectual property rights subsisting therein) in or to any goods, Software, technical information, specifications, drawings, records, documentation, data or any other materials (including any derivative works thereof) provided by the State to the Contractor. Notwithstanding anything to the contrary herein, the State may, in its sole and absolute discretion, grant the Contractor a license to such materials, subject to the terms of a separate writing executed by the Contractor and an authorized representative of the State as well as all required State approvals.

7.6 Without limiting the generality of the foregoing, neither Contractor nor any of its subcontractors shall use any Software or technology in a manner that will cause any patents, copyrights or other intellectual property which are owned or controlled by the State or any of its affiliates (or for which the State or any of its subcontractors has received license rights) to become subject to any encumbrance or terms and conditions of any third party or open source license (including, without limitation, any open source license listed on http://www.opensource.org/licenses/alphabetical) (each an "Open Source License"). These restrictions, limitations, exclusions and conditions shall apply even if the State or any of its subcontractors becomes aware of or fails to act in a manner to

address any violation or failure to comply therewith. No act by the State or any of its subcontractors that is undertaken under this Contract as to any Software or technology shall be construed as intending to cause any patents, copyrights or other intellectual property that are owned or controlled by the State (or for which the State has received license rights) to become subject to any encumbrance or terms and conditions of any open-source license.

7.7 The Contractor shall report to the Department, promptly and in written detail, each notice or claim of copyright infringement received by the Contractor with respect to all Deliverables delivered under this Contract.

7.8 The Contractor shall not affix (or permit any third party to affix), without the Department's consent, any restrictive markings upon any Deliverables that are owned by the State, and if such markings are affixed, the Department shall have the right at any time to modify, remove, obliterate, or ignore such warnings.

8. Confidential or Proprietary Information and Documentation

8.1 Subject to the Maryland Public Information Act and any other applicable laws including, without limitation, HIPAA, the HI-TECH Act, and the Maryland Medical Records Act and regulations promulgated pursuant thereto, all confidential or proprietary information and documentation relating to either party (including without limitation, any information or data stored within the Contractor's computer systems or cloud infrastructure, if applicable) shall be held in confidence by the other party. Each party shall, however, be permitted to disclose, as provided by and consistent with applicable law, relevant confidential information to its officers, agents, and Contractor Personnel to the extent that such disclosure is necessary for the performance of their duties under this Contract. Each officer, agent, and Contractor Personnel to whom any of the State's confidential information is to be disclosed shall be advised by Contractor provided that each officer, agent, and Contractor Personnel to whom any of the State's confidential information is to be disclosed shall be advised by Contractor of the obligations hereunder, and bound by, confidentiality at least as restrictive as those of set forth in this Contract.

8.2 The provisions of this section shall not apply to information that: (a) is lawfully in the public domain; (b) has been independently developed by the other party without violation of this Contract; (c) was already rightfully in the possession of such party; (d) was supplied to such party by a third party lawfully in possession thereof and legally permitted to further disclose the information; or (e) which such party is required to disclose by law.

9. Loss of Data

9.1 In the event of loss of any State data or records where such loss is due to the act or omission of the Contractor or any of its subcontractors or agents, the Contractor shall be responsible for restoring or recreating, as applicable, such lost data in the manner and on the schedule set by the Contract Monitor. The Contractor shall ensure that all data is backed up and recoverable by the Contractor. At no time shall any Contractor actions (or any failures to act when Contractor has a duty to act) damage or create any vulnerabilities in data bases, systems, platforms, and applications with which the Contractor is working hereunder.

9.2 In accordance with prevailing federal or state law or regulations, the Contractor shall report the loss of non-public data as directed in **RFP Section 3.7**.

9.3 Protection of data and personal privacy (as further described and defined in RFP **Section 3.8**) shall be an integral part of the business activities of the Contractor to ensure there is no inappropriate or unauthorized use of State information at any time. To this end, the Contractor shall safeguard the

confidentiality, integrity and availability of State information and comply with the conditions identified in **RFP Section 3.7**.

10. Indemnification and Notification of Legal Requests

10.1. At its sole cost and expense, Contractor shall (I) indemnify and hold the State, its employees and agents harmless from and against any and all claims, demands, actions, suits, damages, liabilities, losses, settlements, judgments, costs and expenses (including but not limited to attorneys' fees and costs), whether or not involving a third party claim, which arise out of or relate to the Contractor's, or any of its subcontractors', performance of this Contract and (ii) cooperate, assist, and consult with the State in the defense or investigation of any such claim, demand, action or suit. Contractor shall not enter into any settlement involving third party claims that contains any admission of or stipulation to any guilt, fault, liability or wrongdoing by the State or that adversely affects the State's rights or interests, without the State's prior written consent.

10.2. The State has no obligation: (I) to provide legal counsel or defense to the Contractor or its subcontractors in the event that a suit, claim or action of any character is brought against the Contractor or its subcontractors as a result of or relating to the Contractor's obligations or performance under this Contract, or (ii) to pay any judgment or settlement of any such suit, claim or action. Notwithstanding the foregoing, the Contractor shall promptly notify the Procurement Officer of any such claims, demands, actions, or suits.

10.3. Notification of Legal Requests. In the event the Contractor receives a subpoena or other validly issued administrative or judicial process, or any discovery request in connection with any litigation, requesting State Pre-Existing Intellectual Property, of other information considered to be the property of the State, including but not limited to State data stored with or otherwise accessible by the Contractor, the Contractor shall not respond to such subpoena, process or other legal request without first notifying the State, unless prohibited by law from providing such notice The Contractor shall promptly notify the State of such receipt providing the State with a reasonable opportunity to intervene in the proceeding before the time that Contractor is required to comply with such subpoena, other process or discovery request. .

11. Non-Hiring of Employees

No official or employee of the State, as defined under Md. Code Ann., General Provisions Article, § 5-101, whose duties as such official or employee include matters relating to or affecting the subject matter of this Contract, shall, during the pendency and term of this Contract and while serving as an official or employee of the State, become or be an employee of the Contractor or any entity that is a subcontractor on this Contract.

12. Disputes

This Contract shall be subject to the provisions of Md. Code Ann., State Finance and Procurement Article, Title 15, Subtitle 2, and COMAR 21.10 (Administrative and Civil Remedies). Pending resolution of a claim, the Contractor shall proceed diligently with the performance of the Contract in accordance with the Procurement Officer's decision. Unless a lesser period is provided by applicable statute, regulation, or the Contract, the Contractor must file a written notice of claim with the Procurement Officer within thirty (30) days after the basis for the claim is known or should have been known, whichever is earlier. Contemporaneously with or within thirty (30) days of the filing of a notice of claim, but no later than the date of final payment under the Contract, the Contractor must submit to the Procurement Officer its written claim containing the information specified in COMAR 21.10.04.02.

13. Maryland Law Prevails

13.1 This Contract shall be construed, interpreted, and enforced according to the laws of the State of Maryland.

13.2 The Maryland Uniform Computer Information Transactions Act (Commercial Law Article, Title 22 of the Annotated Code of Maryland) does not apply to this Contract or any purchase order, task order, or Notice to Proceed issued thereunder, or any Software, or any Software license acquired hereunder.

13.3 Any and all references to the Maryland Code, annotated and contained in this Contract shall be construed to refer to such Code sections as are from time to time amended.

14. Nondiscrimination in Employment

The Contractor agrees: (a) not to discriminate in any manner against an employee or applicant for employment because of race, color, religion, creed, age, sex, sexual orientation, gender identification, marital status, national origin, ancestry, genetic information, or any otherwise unlawful use of characteristics, or disability of a qualified individual with a disability unrelated in nature and extent so as to reasonably preclude the performance of the employment, or the individual's refusal to submit to a genetic test or make available the results of a genetic test; (b) to include a provision similar to that contained in subsection (a), above, in any underlying subcontract except a subcontract for standard commercial supplies or raw materials; and (c) to post and to cause subcontractors to post in conspicuous places available to employees and applicants for employment, notices setting forth the substance of this clause.

15. Contingent Fee Prohibition

The Contractor warrants that it has not employed or retained any person, partnership, corporation, or other entity, other than a bona fide employee or agent working for the Contractor to solicit or secure the Contract, and that the Contractor has not paid or agreed to pay any person, partnership, corporation, or other entity, other than a bona fide employee or agent, any fee or any other consideration contingent on the making of this Contract.

16. Non-Availability of Funding

If the General Assembly fails to appropriate funds or if funds are not otherwise made available for continued performance for any fiscal period of this Contract succeeding the first fiscal period, this Contract shall be canceled automatically as of the beginning of the Fiscal Year for which funds were not appropriated or otherwise made available; provided, however, that this will not affect either the State's or the Contractor's rights under any termination clause in this Contract. The effect of termination of the Contract hereunder will be to discharge both the Contractor and the State from future performance of the Contract, but not from their rights and obligations existing at the time of termination. The Contractor shall be reimbursed for the reasonable value of any nonrecurring costs incurred but not amortized in the price of the Contract. The State shall notify the Contractor as soon as it has knowledge that funds may not be available for the continuation of this Contract for each succeeding fiscal period beyond the first.

17. Termination for Default

If the Contractor fails to fulfill its obligations under this Contract properly and on time, fails to provide any required annual and renewable bond 30 days prior to expiration of the current bond then in effect, or otherwise violates any provision of the Contract, the State may terminate the Contract by written notice to the Contractor. The notice shall specify the acts or omissions relied upon as cause for termination. All finished or unfinished work provided by the Contractor shall, at the State's option, become the State's property. The State shall pay the Contractor fair and equitable

compensation for satisfactory performance prior to receipt of notice of termination, less the amount of damages caused by the Contractor's breach. If the damages are more than the compensation payable to the Contractor, the Contractor will remain liable after termination and the State can affirmatively collect damages. Termination hereunder, including the termination of the rights and obligations of the parties, shall be governed by the provisions of COMAR 21.07.01.11B.

18. Termination for Convenience

The performance of work under this Contract may be terminated by the State in accordance with this clause in whole, or from time to time in part, whenever the State shall determine that such termination is in the best interest of the State. The State will pay all reasonable costs associated with this Contract that the Contractor has incurred up to the date of termination, and all reasonable costs associated with termination of the Contract. However, the Contractor shall not be reimbursed for any anticipatory profits that have not been earned up to the date of termination. Termination hereunder, including the determination of the rights and obligations of the parties, shall be governed by the provisions of COMAR 21.07.01.12A (2).

19. Delays and Extensions of Time

19.1 The Contractor agrees to prosecute the work continuously and diligently and no charges or claims for damages shall be made by it for any delays or hindrances from any cause whatsoever during the progress of any portion of the work specified in this Contract.

19.2 Time extensions will be granted only for excusable delays that arise from unforeseeable causes beyond the control and without the fault or negligence of the Contractor, including but not restricted to, acts of God, acts of the public enemy, acts of the State in either its sovereign or contractual capacity, acts of another Contractor in the performance of a contract with the State, fires, floods, epidemics, quarantine restrictions, strikes, freight embargoes, or delays of subcontractors or suppliers arising from unforeseeable causes beyond the control and without the fault or negligence of either the Contractor or the subcontractors or suppliers.

20. Suspension of Work

The State unilaterally may order the Contractor in writing to suspend, delay, or interrupt all or any part of its performance for such period of time as the Procurement Officer may determine to be appropriate for the convenience of the State.

21. Pre-Existing Regulations

In accordance with the provisions of Section 11-206 of the State Finance and Procurement Article, Annotated Code of Maryland, the regulations set forth in Title 21 of the Code of Maryland Regulations (COMAR 21) in effect on the date of execution of this Contract are applicable to this Contract.

22. Financial Disclosure

The Contractor shall comply with the provisions of Section13-221 of the State Finance and Procurement Article of the Annotated Code of Maryland, which requires that every business that enters into contracts, leases, or other agreements with the State or its agencies during a calendar year under which the business is to receive in the aggregate, $200,000 or more, shall within 30 days of the time when the aggregate value of these contracts, leases or other agreements reaches $200,000, file with the Secretary of State of Maryland certain specified information to include disclosure of beneficial ownership of the business.

23. Political Contribution Disclosure

The Contractor shall comply with Election Law Article, Title 14, Annotated Code of Maryland, which requires that every person that enters into a procurement contract with the State, a county, or a municipal corporation, or other political subdivision of the State, during a calendar year in which the person receives a contract with a governmental entity in the amount of $200,000 or more, shall file with the State Board of Elections statements disclosing: (a) any contributions made during the reporting period to a candidate for elective office in any primary or general election; and (b) the name of each candidate to whom one or more contributions in a cumulative amount of $500 or more were made during the reporting period. The statement shall be filed with the State Board of Elections: (a) before execution of a contract by the State, a county, a municipal corporation, or other political subdivision of the State, and shall cover the 24 months prior to when a contract was awarded; and (b) if the contribution is made after the execution of a contract, then twice a year, throughout the contract term, on or before: (i) May 31, to cover the six (6) month period ending April 30; and (ii) November 30, to cover the six (6) month period ending October 31. Additional information is available on the State Board of Elections website: http://www.elections.state.md.us/campaign_finance/index.html.

24. Retention of Records

The Contractor and subcontractors shall retain and maintain all records and documents in any way relating to this Contract for (i) three (3) years after final payment by the State hereunder, or (ii) any applicable federal or State retention requirements (such as HIPAA) or condition of award, , whichever is longer, and shall make them available for inspection and audit by authorized representatives of the State, as designated by the Procurement Officer, at all reasonable times. The Contractor shall provide copies of all documents requested by the State, including, but not limited to itemized billing documentation containing the dates, hours spent, and work performed by the Contractor and its subcontractors under the Contract. All records related in any way to the Contract are to be retained for the entire time provided under this section.

25. Right to Audit

25.1 The State reserves the right, at its sole discretion and at any time, to perform an audit of the Contractor's performance under this Contract. An audit is defined as a planned and documented independent activity performed by qualified personnel, including but not limited to State and federal auditors, to determine by investigation, examination, or evaluation of objective evidence from data, statements, records, operations and performance practices (financial or otherwise) the Contractor's compliance with the Contract, including but not limited to adequacy and compliance with established procedures and internal controls over the services performed pursuant to the Contract.

25.2 Upon three (3) Business Days' notice, the State shall be provided reasonable access to Contractor's records to perform any such audits. The Department may conduct these audits with any or all of its own internal resources or by securing the services of a third-party accounting or audit firm, solely at the Department's election. The Department may copy any record related to the services performed pursuant to the Contract. The Contractor agrees to fully cooperate and assist in any audit conducted by or on behalf of the State, including, by way of example only, making records and employees available as, where, and to the extent requested by the State and by assisting the auditors in reconciling any audit variances. Contractor shall not be compensated for providing any such cooperation and assistance.

25.3 The right to audit shall include any of the Contractor's subcontractors including but not limited to any lower tier subcontractor(s). The Contractor shall ensure the Department has the right to audit such subcontractor(s).

26. Compliance with Laws

The Contractor hereby represents and warrants that:

a. It is qualified to do business in the State and that it will take such action as, from time-to-time hereafter, may be necessary to remain so qualified;

b. It is not in arrears with respect to the payment of any monies due and owing the State, or any department or unit thereof, including but not limited to the payment of taxes and employee benefits, and that it shall not become so in arrears during the Term;

c. It shall comply with all federal, State and local laws, regulations, and ordinances applicable to its activities and obligations under this Contract; and

d. It shall obtain, at its expense, all licenses, permits, insurance, and governmental approvals, if any, necessary to the performance of its obligations under this Contract.

27. Cost and Price Certification

27.1 The Contractor, by submitting cost or price information certifies that, to the best of its knowledge, the information submitted is accurate, complete, and current as of the date of its Proposal.

27.2 The price under this Contract and any change order or modification hereunder, including profit or fee, shall be adjusted to exclude any significant price increases occurring because the Contractor furnished cost or price information which, as of the date of its Proposal, was inaccurate, incomplete, or not current.

28. Subcontracting; Assignment

The Contractor may not subcontract any of its obligations under this Contract without obtaining the prior written approval of the Procurement Officer, nor may the Contractor assign this Contract or any of its rights or obligations hereunder, without the prior written approval of the Procurement Officer, each at the State's sole and absolute discretion; provided, however, that a Contractor may assign monies receivable under a contract after written notice to the State. Any subcontracts shall include such language as may be required in various clauses contained within this Contract, exhibits, and attachments. The Contract shall not be assigned until all approvals, documents, and affidavits are completed and properly registered. The State shall not be responsible for fulfillment of the Contractor's obligations to its subcontractors.

29. Limitations of Liability

29.1 Contractor shall be liable for any loss or damage to the State occasioned by the acts or omissions of Contractor, its subcontractors, agents or employees as follows:

(a) For infringement of patents, trademarks, trade secrets and copyrights as provided in **Section 7 "Patents, Copyrights, Intellectual Property"** of this Contract;

(b) Without limitation for damages for bodily injury (including death) and damage to real property and tangible personal property; and

(c) For all other claims, damages, loss, costs, expenses, suits or actions in any way related to this Contract and regardless of the basis on which the claim is made, Contractor's liability shall not exceed two (2) times the total value of the Contract or $1,000,000, whichever is greater. The above limitation of liability is per incident.

(d) In no event shall the existence of a subcontract operate to release or reduce the liability of Contractor hereunder. For purposes of this Contract, Contractor agrees that all subcontractors shall be held to be agents of Contractor.

29.2 Contractor's indemnification obligations for Third party claims arising under **Section 10** ("Indemnification") of this Contract are included in this limitation of liability only if the State is immune from liability. Contractor's indemnification liability for third party claims arising under **Section 10** of this Contract shall be unlimited if the State is not immune from liability for claims arising under **Section 10**.

29.3. In no event shall the existence of a subcontract operate to release or reduce the liability of Contractor hereunder. For purposes of this Contract, Contractor agrees that it is responsible for performance of the services and compliance with the relevant obligations hereunder by its subcontractors.

30. Commercial Nondiscrimination

30.1 As a condition of entering into this Contract, Contractor represents and warrants that it will comply with the State's Commercial Nondiscrimination Policy, as described under Title 19 of the State Finance and Procurement Article of the Annotated Code of Maryland. As part of such compliance, Contractor may not discriminate on the basis of race, color, religion, ancestry, national origin, sex, age, marital status, sexual orientation, sexual identity, genetic information or an individual's refusal to submit to a genetic test or make available the results of a genetic test or on the basis of disability, or otherwise unlawful forms of discrimination in the solicitation, selection, hiring, or commercial treatment of subcontractors, vendors, suppliers, or commercial customers, nor shall Contractor retaliate against any person for reporting instances of such discrimination. Contractor shall provide equal opportunity for subcontractors, vendors, and suppliers to participate in all of its public sector and private sector subcontracting and supply opportunities, provided that this clause does not prohibit or limit lawful efforts to remedy the effects of marketplace discrimination that have occurred or are occurring in the marketplace. Contractor understands that a material violation of this clause shall be considered a material breach of this Contract and may result in termination of this Contract, disqualification of Contractor from participating in State contracts, or other sanctions. This clause is not enforceable by or for the benefit of, and creates no obligation to, any third party.

30.3 As a condition of entering into this Contract, upon the request of the Commission on Civil Rights, and only after the filing of a complaint against Contractor under Title 19 of the State Finance and Procurement Article of the Annotated Code of Maryland, as amended from time to time, Contractor agrees to provide within 60 days after the request a complete list of the names of all subcontractors, vendors, and suppliers that Contractor has used in the past four (4) years on any of its contracts that were undertaken within the State of Maryland, including the total dollar amount paid by Contractor on each subcontract or supply contract. Contractor further agrees to cooperate in any investigation conducted by the State pursuant to the State Commercial Nondiscrimination Policy as set forth under Title 19 of the State Finance and Procurement Article of the Annotated Code of Maryland, and to provide any documents relevant to any investigation that are requested by the State. Contractor understands that violation of this clause is a material breach of this Contract and may result in Contract termination, disqualification by the State from participating in State contracts, and other sanctions.

30.4 The Contractor shall include the language from 30.1, or similar clause approved in writing by the Department, in all subcontracts.

31. Prompt Pay Requirements

31.1 If the Contractor withholds payment of an undisputed amount to its subcontractor, the Department, at its option and in its sole discretion, may take one or more of the following actions:

(a) Not process further payments to the Contractor until payment to the subcontractor is verified;

(b) Suspend all or some of the Contract work without affecting the completion date(s) for the Contract work;

(c) Pay or cause payment of the undisputed amount to the subcontractor from monies otherwise due or that may become due to the Contractor; or

(d) Take other or further actions as appropriate to resolve the withheld payment.

31.2 An "undisputed amount" means an amount owed by the Contractor to a subcontractor for which there is no good faith dispute. Such "undisputed amounts" include, without limitation: (a) retainage which had been withheld and is, by the terms of the agreement between the Contractor and subcontractor, due to be distributed to the subcontractor; and (b) an amount withheld because of issues arising out of an agreement or occurrence unrelated to the agreement under which the amount is withheld.

31.3 An act, failure to act, or decision of a Procurement Officer or a representative of the Department concerning a withheld payment between the Contractor and a subcontractor under this **Section 31**, may not:

(a) Affect the rights of the contracting parties under any other provision of law;

(b) Be used as evidence on the merits of a dispute between the Department and the Contractor in any other proceeding; or

(c) Result in liability against or prejudice the rights of the Department.

31.4 The remedies enumerated above are in addition to those provided under COMAR 21.11.03.13 with respect to subcontractors that have contracted pursuant to the MBE program.

31.5 To ensure compliance with certified MBE subcontract participation goals, the Department may, consistent with COMAR 21.11.03.13, take the following measures:

(a) Verify that the certified MBEs listed in the MBE participation schedule actually are performing work and receiving compensation as set forth in the MBE participation schedule. This verification may include, as appropriate:

i. Inspecting any relevant records of the Contractor;

ii. Inspecting the jobsite; and

iii. Interviewing subcontractors and workers.

Verification shall include a review of:

i. The Contractor's monthly report listing unpaid invoices over thirty (30) days old from certified MBE subcontractors and the reason for nonpayment; and

ii. The monthly report of each certified MBE subcontractor, which lists payments received from the Contractor in the preceding thirty (30) days and invoices for which the subcontractor has not been paid.

(b) If the Department determines that the Contractor is not in compliance with certified MBE participation goals, then the Department will notify the Contractor in writing

of its findings and will require the Contractor to take appropriate corrective action. Corrective action may include, but is not limited to, requiring the Contractor to compensate the MBE for work performed as set forth in the MBE participation schedule.

(c) If the Department determines that the Contractor is in material noncompliance with MBE Contract provisions and refuses or fails to take the corrective action that the Department requires, then the Department may:

i. Terminate the Contract;

ii. Refer the matter to the Office of the Attorney General for appropriate action; or

iii. Initiate any other specific remedy identified by the Contract, including the contractual remedies required by any applicable laws, regulations, and directives regarding the payment of undisputed amounts.

(d) Upon completion of the Contract, but before final payment or release of retainage or both, the Contractor shall submit a final report, in affidavit form under the penalty of perjury, of all payments made to, or withheld from, MBE subcontractors.

32. Living Wage

If a Contractor subject to the Living Wage law fails to submit all records required under COMAR 21.11.10.05 to the Commissioner of Labor and Industry at the Department of Labor, Licensing and Regulation, the Department may withhold payment of any invoice or retainage. The Department may require certification from the Commissioner on a quarterly basis that such records were properly submitted.

33. Use of Estimated Quantities

Unless specifically indicated otherwise in the State's solicitation or other controlling documents related to the Scope of Work, any sample amounts provided are estimates only and the Department does not guarantee a minimum or maximum number of units or usage in the performance of this Contract.

34. Risk of Loss; Transfer of Title

Risk of loss for conforming supplies, equipment, materials and Deliverables furnished to the State hereunder shall remain with the Contractor until such supplies, equipment, materials and Deliverables are received and accepted by the State, following which, title shall pass to the State.

35. Effect of Contractor Bankruptcy

All rights and licenses granted by the Contractor under this Contract are and shall be deemed to be rights and licenses to "intellectual property," and the subject matter of this Contract, including services, is and shall be deemed to be "embodiments of intellectual property" for purposes of and as such terms are used and interpreted under § 365(n) of the United States Bankruptcy Code ("Code") (11 U.S.C. § 365(n) (2010)). The State has the right to exercise all rights and elections under the Code and all other applicable bankruptcy, insolvency and similar laws with respect to this Contract (including all executory statement of works). Without limiting the generality of the foregoing, if the Contractor or its estate becomes subject to any bankruptcy or similar proceeding: (a) subject to the State's rights of election, all rights and licenses granted to the State under this Contract shall continue subject to the respective terms and conditions of this Contract; and (b) the State shall be entitled to a complete duplicate of (or complete access to, as appropriate) all such intellectual

property and embodiments of intellectual property, and the same, if not already in the State's possession, shall be promptly delivered to the State, unless the Contractor elects to and does in fact continue to perform all of its obligations under this Contract.

36. Miscellaneous

36.1 Any provision of this Contract which contemplates performance or observance subsequent to any termination or expiration of this Contract shall survive termination or expiration of this Contract and continue in full force and effect.

36.2 If any term contained in this Contract is held or finally determined to be invalid, illegal, or unenforceable in any respect, in whole or in part, such term shall be severed from this Contract, and the remaining terms contained herein shall continue in full force and effect, and shall in no way be affected, prejudiced, or disturbed thereby.

36.3 The headings of the sections contained in this Contract are for convenience only and shall not be deemed to control or affect the meaning or construction of any provision of this Contract.

36.4 This Contract may be executed in any number of counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument. Signatures provided by facsimile or other electronic means, e,g, and not by way of limitation, in Adobe .PDF sent by electronic mail, shall be deemed to be original signatures.

37. Contract Monitor and Procurement Officer

37.1 The State representative for this Contract who is primarily responsible for Contract administration functions, including issuing written direction, invoice approval, monitoring this Contract to ensure compliance with the terms and conditions of the Contract, monitoring MBE and VSBE compliance, and achieving completion of the Contract on budget, on time, and within scope. The Contract Monitor may authorize in writing one or more State representatives to act on behalf of the Contract Monitor in the performance of the Contract Monitor's responsibilities. The Department may change the Contract Monitor at any time by written notice to the Contractor.

37.2 The Procurement Officer has responsibilities as detailed in the Contract and is the only State representative who can authorize changes to the Contract. The Department may change the Procurement Officer at any time by written notice to the Contractor.

38. Notices

All notices hereunder shall be in writing and either delivered personally or sent by certified or registered mail, postage prepaid, as follows:

If to the State:

Tyler Adamson

Maryland Cancer Registry

Center for Cancer Prevention and Control

Prevention and Health Promotion Administration

201 W. Preston Street, Rm 400

Baltimore, MD 21201

Phone Number: 410-767-5281

E-Mail: tyler.adamson@maryland.gov

With a copy to:

Calvin Johnson

Department of Health (MDH)

Office of Contract Management and Procurement (OCMP)

E-Mail: calvin.johnson@maryland.gov

If to the Contractor:

(Contractor's Name)

(Contractor's primary address)

Attn: _____

[[Delete the following if a parent company guarantee is inapplicable:]]

Parent Company Guarantor

Contact: _____

Attn: _____

<<39.>> Parent Company Guarantee (If applicable)

If a Contractor intends to rely on its Parent Company in some manner while performing on the State Contract, the following clause should be included and completed for the Contractor's Parent Company to guarantee performance of the Contractor. The guarantor/Contractor's Parent Company should be named as a party and signatory to the Contract and should be in good standing with SDAT.

(Corporate name of Contractor's Parent Company) hereby guarantees absolutely the full, prompt, and complete performance by (Contractor) of all the terms, conditions and obligations contained in this Contract, as it may be amended from time to time, including any and all exhibits that are now or may become incorporated hereunto, and other obligations of every nature and kind that now or may in the future arise out of or in connection with this Contract, including any and all financial commitments, obligations, and liabilities. (Corporate name of Contractor's Parent Company) may not transfer this absolute guaranty to any other person or entity without the prior express written approval of the State, which approval the State may grant, withhold, or qualify in its sole and absolute subjective discretion. (Corporate name of Contractor's Parent Company) further agrees that if the State brings any claim, action, lawsuit or proceeding against (Contractor), (Corporate name of Contractor's Parent Company) may be named as a party, in its capacity as Absolute Guarantor.

40. Federal Department of Health and Human Services (DHHS) Exclusion Requirements

The Contractor agrees that it will comply with federal provisions (pursuant to §§ 1128 and 1156 of the Social Security Act and 42 C.F.R. 1001) that prohibit payments under certain federal health care programs to any individual or entity that is on the List of Excluded Individuals/Entities maintained by DHHS. By executing this Contract, the Contractor affirmatively declares that neither it nor any employee is, to the best of its knowledge, subject to exclusion. The Contractor agrees, further, during the term of this Contract, to check the List of Excluded Individuals/Entities prior to hiring or assigning individuals to work on this Contract, and to notify the Department immediately of any identification of the Contractor or an individual employee as excluded, and of any DHHS action or proposed action to exclude the Contractor or any Contractor employee.

42. Compliance with federal Health Insurance Portability and Accountability Act (HIPAA) and State Confidentiality Law

42.1 The Contractor acknowledges its duty to become familiar with and comply, to the extent applicable, with all requirements of the federal Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. § 1320d et seq., and implementing regulations including 45 C.F.R. Parts 160 and 164. The Contractor also agrees to comply with the Maryland Confidentiality of Medical Records Act (MCMRA), Md. Code Ann. Health-General §§ 4-301 et seq. This obligation includes:

(a) As necessary, adhering to the privacy and security requirements for protected health information and medical records under HIPAA and MCMRA and making the transmission of all electronic information compatible with the HIPAA requirements;

(b) Providing training and information to employees regarding confidentiality obligations as to health and financial information and securing acknowledgement of these obligations from employees to be involved in the Contract; and

(c) Otherwise providing good information management practices regarding all health information and medical records.

42.2 Based on the determination by the Department that the functions to be performed in accordance with the scope of work set forth in the solicitation constitute business associate functions as defined in HIPAA, the selected Offeror shall execute a business associate agreement as required by HIPAA regulations at 45 C.F.R. 164.504 and in the form as required by the Department.

42.3 "Protected Health Information" as defined in the HIPAA regulations at 45 C.F.R. 160.103 and 164.501, means information transmitted as defined in the regulations, that is individually identifiable; that is created or received by a healthcare provider, health plan, public health authority, employer, life insurer, school or university, or healthcare clearinghouse; and that is related to the past, present, or future physical or mental health or condition of an individual, to the provision of healthcare to an individual, or to the past, present, or future payment for the provision of healthcare to an individual. The definition excludes certain education records as well as employment records held by a covered entity in its role as employer.

43. Hiring Agreement

43.1 The Contractor agrees to execute and comply with the enclosed Maryland Department of Human Services (DHS) Hiring Agreement (Attachment O). The Hiring Agreement is to be executed by the Offeror and delivered to the Procurement Officer within ten (10) Business Days following receipt of notice by the Offeror that it is being recommended for Contract award. The Hiring Agreement will become effective concurrently with the award of the Contract.

43.2 The Hiring Agreement provides that the Contractor and DHS will work cooperatively to promote hiring by the Contractor of qualified individuals for job openings resulting from this procurement, in accordance with Md. Code Ann., State Finance and Procurement Article §13-224.

44. Maryland's Green Purchasing Reporting Requirements

The State of Maryland reserves the right to request from the Contractor quarterly sales data over the life of this contract. This information must include details about the recycled content, third-party sustainability certifications, and other environmental attributes of products and services sold on this price agreement per the contract specifications.

This information will enable Maryland State agencies to comply with Article §14–405 of the Annotated Code of Maryland and COMAR 21.13.01.14, effective October 1, 2014, which requires Maryland state agencies to report to the Department of General Services on their procurement of environmentally preferable products and services.

To facilitate consistent reporting on targeted contracts, the Contractor will be provided with a VENDOR GREEN SALES REPORT template by the Maryland Department of General Services.

SIGNATURES ON NEXT PAGE

IN WITNESS THEREOF, the parties have executed this Contract as of the date hereinabove set forth.

Contractor	State of Maryland Department of Health (MDH)
By:	By: <<agencyContractSigner>>, <<agencyContractSignerTitle>>
Date	
PARENT COMPANY (GUARANTOR) (if applicable)	By:
_____	_____
By:	Date
_____	
Date	
Approved for form and legal sufficiency this ____ day of _____, 20___. _____ Assistant Attorney General	
APPROVED BY BPW: _____ _____ (Date) (BPW Item #)	

Attachment N. Contract Affidavit

See link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/Attachment-N-ContractAffidavit.pdf.

Attachment O. DHS Hiring Agreement

See link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/Attachment-O-DHSHiringAgreement.pdf.

Appendix 1. – Abbreviations and Definitions

For purposes of this RFP, the following abbreviations or terms have the meanings indicated below:

A. Acceptable Use Policy (AUP) - A written policy documenting constraints and practices that a user must agree to in order to access a private network or the Internet.

B. Access – The ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any Information System resource.

C. AERRO – Advancing E-cancer Reporting and Registry Operations.

D. Application Program Interface (API) – Code that allows two Software programs to communicate with each other.

E. Accession Number – A unique number that is assigned to a tumor by the facility registry in consecutive order.

F. Business Day(s) – The official working days of the week to include Monday through Friday. Official working days excluding State Holidays (see definition of "Normal State Business Hours" below).

G. Cancer Site – A name/code for a specific spot on the body or histology of cancer.

H. Case Finding – The systematic process of checking for additional cancer cases that have not already been reported to the MCR.

I. CCPC – Center for Cancer Prevention and Control.

J. CCR – Central Cancer Registry.

K. CDC – Centers for Disease Control and Prevention.

L. CINA – Cancer in North America.

M. Clinical Document Architecture – A type of electronic file structure for Meaningful Use data.

N. CM – Clinical Modification.

O. CNS – Central Nervous System.

P. COMAR – Code of Maryland Regulations available on-line at http://www.dsd.state.md.us/COMAR/ComarHome.html.

Q. Contract – The Contract awarded to the successful Offeror pursuant to this RFP. The Contract will be in the form of **Attachment M**.

R. Contract Monitor – The State representative for this Contract who is primarily responsible for Contract administration functions, including issuing written direction, invoice approval, monitoring this Contract to ensure compliance with the terms and conditions of the Contract, monitoring MBE and VSBE compliance, and achieving completion of the Contract on budget, on time, and within scope. The Contract Monitor may authorize in writing one or more State representatives to act on behalf of the Contract Monitor in the performance of the Contract Monitor's responsibilities. The Department may change the Contract Monitor at any time by written notice to the Contractor.

S. Contractor – The selected Offeror that is awarded a Contract by the State.

T. Contractor Personnel – Employees and agents and subcontractor employees and agents performing work at the direction of the Contractor under the terms of the Contract awarded from this RFP.

U. CRF – Cigarette Restitution Fund.

V. CRAC – Cancer Registry Advisory Committee.

W. CRS – Central Registry System, a Software program designed by CDC.

X. CSS – Cancer Surveillance System.

Y. CTR – Certified Tumor Registrar.

Z. Data At Rest – Inactive data that is stored physically in any digital form and includes all registry data no matter where it is stored.

AA. Data Breach – The unauthorized acquisition, use, modification or disclosure of State data, or other Sensitive Data.

BB. Data In Motion – Active data which is stored in a non-persistent digital state typically in computer random access memory (RAM), CPU caches, or CPU registers and also includes data in transit.

CC. Data Edits – Computer Software algorithms that check the content of data fields against an encoded set of acceptable codes and subsequently provide feedback on the quality of the data.

DD. DCO – Death Certificate Only cases.

EE. Disease Index- A listing of patients discharged from the hospital organized by disease or diagnosis code. MCR provides a listing of codes to be used for the Disease Index.

FF. Death Clearance - The process of completing the following activities: Death Case Finding and Follow Back, Vital Statistics match and Write Back, Social Security Death Index Write Back, and National Death Index match and Write Back.

GG. Department of Health or (MDH or the "Department").

HH. Eligible Providers – A healthcare provider who has demonstrated their understanding of electronic medical records (EMRs) by implementing criteria based on EMR patient updates and Meaningful Use laws.

II. eMMA – eMaryland Marketplace Advantage (see RFP **Section 4.2**).

JJ. EMRs – Electronic Medical Records.

KK. Enterprise License Agreement (ELA) – An agreement to license the entire population of an entity (employees, on-site contractors, off-site contractors) accessing a Software or service for a specified period of time for a specified value.

LL. ETC – Education and Training Coordinator.

MM. Facility Reporters - Hospitals, radiation therapy centers, freestanding diagnostic laboratories, ambulatory care facilities, physicians, and other individual facilities that report cancer data to the MCR.

NN. FIPS – Federal Information Processing Standard.

OO. Fiscal Year – A 12-month time period that generally begins on July 1st and end June 30th.

PP. Follow Back – Following information back to original source for collection of unknown elements.

QQ. Follow-up Source Central – A field in the MCR database that allows coding of the source of follow-up information.

RR. FY – Fiscal Year (July 1 – June 30th).

SS. Geocoding – Analysis of geo-demographic data such as ZIP codes, counties, regions, census tracts, latitude, longitude, etc.

TT. Go-Live Date – The date, as specified in the Notice to Proceed after the Contract Commencement Date, when the Contractor must begin providing all services required by this solicitation (no later than July 1, 2024. See Attachment M **Section 3.1**

UU. HIPAA – Health Insurance Portability and Accountability Act.

VV. ICD – International Classification of Disease.

WW. IHE – Integrating the Healthcare Enterprise.

XX. IHS – Indian Health Service.

YY. Information System – A discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

ZZ. Information Technology (IT) – All electronic information-processing hardware and Software, including: (a) maintenance; (b) telecommunications; and (c) associated consulting services.

AAA. Key Personnel – All Contractor Personnel identified in the solicitation as such that are essential to the work being performed under the Contract. See RFP **Sections 3.10**.

BBB. LAN – Local Area Network.

CCC. Local Time – Time in the Eastern Time Zone as observed by the State of Maryland. Unless otherwise specified, all stated times shall be Local Time, even if not expressly designated as such.

DDD. MCMRA -- Maryland Confidentiality of Medical Records Act.

EEE. MCR – Maryland Cancer Registry.

FFF. Minority Business Enterprise (MBE) – Any legal entity certified as defined at COMAR 21.01.02.01B (54) which is certified by the Maryland Department of Transportation under COMAR 21.11.03.

GGG. NAACCR – North American Association of Central Cancer Registries.

HHH. National Interstate Data Exchange Agreement – an agreement made between Maryland and other states to exchange cancer cases diagnosed in those states but with a “State of residence at diagnosis” field as Maryland and vice versa.

III. NDI – National Death Index.

JJJ. NIST – National Institute of Standards and Technology.

KKK. Normal State Business Hours - Normal State Business Hours are 8:00 a.m. – 5:00 p.m. Monday through Friday except State Holidays, which can be found at: www.dbm.maryland.gov – keyword: State Holidays.

LLL. Notice to Proceed (NTP) – A written notice from the Procurement Officer that work under the Contract, project, Task Order or Work Order (as applicable) is to begin as of a specified date. The NTP Date is the start date of work under the Contract, project, Task Order or Work Order. Additional NTPs may be issued by either the Procurement Officer or the Contract Monitor regarding the start date for any service included within this solicitation with a delayed or non-specified implementation date.

MMM. NPCR – National Program of Cancer Registries of the CDC.

NNN. NTP Date – The date specified in a NTP for work on Contract, project, Task Order or Work Order to begin.

OOO. Offeror – An entity that submits a Proposal in response to this RFP.

PPP. Personally Identifiable Information (PII) – Any information about an individual maintained by the State, including (1) any information that can be used to distinguish or trace an individual identity, such as name, social security number, date and place of birth, mother's maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.

QQQ. PHINMS – Public Health Information Network Messaging System.

RRR. Procurement Officer – Prior to the award of any Contract, the sole point of contact in the State for purposes of this solicitation. After Contract award, the Procurement Officer has responsibilities as detailed in the Contract (**Attachment M**) and is the only State representative who can authorize changes to the Contract. The Department may change the Procurement Officer at any time by written notice to the Contractor.

SSS. Program Director's Meeting – A meeting of the directors of the NPCR Funded Registries usually in Atlanta, GA.

TTT. Proposal – As appropriate, either or both of the Offeror's Technical or Financial Proposal.

UUU. Protected Health Information (PHI) – Information that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

VVV. QA/QC – Quality Assurance/Quality Control.

WWW. Quarters – Represents a consecutive three month time period of a year generally March, June, September and December.

XXX. Re-abstraction – A formal procedure conducted to check the accuracy of data in the cancer registry against the source document.

YYY. Request for Proposals (RFP) – This Request for Proposals issued by the Department of Health (Department), with the Solicitation Number and date of issuance indicated in the Key Information Summary Sheet, including any amendments thereto.

ZZZ. Reporting Facilities (Facilities)- Hospitals, radiation therapy centers, freestanding diagnostic laboratories, ambulatory care facilities, physicians, and other individual facilities that report cancer data to the MCR.

AAAA. Security Incident – A violation or imminent threat of violation of computer security policies, Security Measures, acceptable use policies, or standard security practices. "Imminent threat of violation" is a situation in which the organization has a factual basis for believing that a specific incident is about to occur.

BBBB. Security or Security Measures – The technology, policy and procedures that a) protects and b) controls access to networks, systems, and data.

CCCC. SEER – Surveillance Epidemiology and End Results.

DDDD. Sensitive Data - Means PII; PHI; other proprietary or confidential data as defined by the State, including but not limited to "personal information" under Md. Code Ann., Commercial Law § 14-3501(e) and Md. Code Ann., St. Govt. § 10-1301(c) and information not subject to disclosure under the Public Information Act, Title 4 of the General Provisions Article; and information about an individual that (1) can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, or biometric records; or (2) is linked or linkable to an individual, such as medical, educational, financial, and employment information.

EEEE. Service Level Agreement (SLA) - Commitment by the Contractor to the Department that defines the performance standards the Contractor is obligated to meet.

FFFF. sFTP – Secure File Transfer Protocol.

GGGG. SQL – Structured Query Language.

HHHH. SSDI – Social Security Death Index.

IIII. Software - The object code version of computer programs licensed pursuant to this Contract. Embedded code, firmware, internal code, microcode, and any other term referring to Software that is necessary for proper operation is included in this definition of Software. Software includes all prior, current, and future versions of the Software and all maintenance updates and error corrections. Software also includes any upgrades, updates, bug fixes or modified versions or backup copies of the Software licensed to the State by Contractor or an authorized distributor.

JJJJ. Software as a Service (SaaS) - A Software licensing and delivery model in which Software is licensed on a subscription basis and is centrally hosted. For the purposes of this RFP, the terms SaaS and PaaS are considered synonymous and the term SaaS will be used throughout this document.

KKKK. Solution - All Software, deliverables, services and activities necessary to fully provide and support the RFP scope of work. This definition of Solution includes all System Documentation developed as a result of this Contract. Also included are all upgrades, patches, break/fix activities, enhancements and general maintenance and support of the Solution and its infrastructure.

LLLL. State – The State of Maryland.

MMMM. Source Code – Executable instructions for Software in its high level, human readable form which are in turn interpreted, parsed or compiled to be executed as part of a computing system.

NNNN. Systems Administration Manual (Manual) – Is the manual which provides guidance for the security and updates to the MCR database.

OOOO. System Availability – The period of time the Solution works as required excluding non-operational periods associated with planned maintenance.

PPPP. System Documentation – Those materials necessary to wholly reproduce and fully operate the most current deployed version of the Solution in a manner equivalent to the original Solution including, but not limited to:

1) Source Code: This includes source code created by the Contractor or subcontractor(s) and source code that is leveraged or extended by the Contractor for use in the Contract;

2) All associated rules, reports, forms, templates, scripts, data dictionaries and database functionality;

3) All associated configuration file details needed to duplicate the run time environment as deployed in the current deployed version of the system;

4) All associated design details, flow charts, algorithms, processes, formulas, pseudo-code, procedures, instructions, help files, programmer's notes and other documentation;

5) A complete list of Third Party, open source, or commercial Software components and detailed configuration notes for each component necessary to reproduce the system (e.g., operating system, relational database, and rules engine Software);

6) All associated user instructions and training materials for business users and technical staff, including maintenance manuals, administrative guides and user how-to guides; and

7) Operating procedures.

QQQQ. Technical Safeguards – The technology and the policy and procedures for its use that protect State Data and control access to it.

RRRR. Third Party Software – Software and supporting documentation that:

1) are owned by a third party, not by the State, the Contractor, or a subcontractor;

2) are included in, or necessary or helpful to the operation, maintenance, support or modification of the Solution; and

3) are specifically identified and listed as Third-Party Software in the Proposal.

SSSS. Total Proposal Price - The Offeror's total price for goods and services in response to this solicitation, included in Financial Proposal **Attachment B** – Financial Proposal Form.

TTTT. Upgrade - A new release of any component of the Solution containing major new features, functionality and performance improvements.

UUUU. Vital Statistics - The death information for a person including date of death, death certificate number, cause of death and place of death.

VVVV. Veteran-owned Small Business Enterprise (VSBE) – A business that is verified by the Center for Verification and Evaluation (CVE) of the United States Department of Veterans Affairs as a veteran-owned small business. See Code of Maryland Regulations (COMAR) 21.11.13.

WWWW. WAN – Wide Area Network.

XXXX. Write Back– When a large amount of information from MDH is sent to the Contractor to be put into the MCR database but is first put into a copy of the database to assure correct placement.

Appendix 2. – Offeror Information Sheet

Offeror Information Sheet (see link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/04/Appendix2-Bidder_OfferorInformationSheet.pdf)

Appendix 3. – MCR Laws and Regulations

Health-General Article
§18-203 and 18-204
Annotated Code of Maryland

§18–203.

Notwithstanding any other provision of law, the Department may provide patient-identifying information for patients treated in this State for cancer to a cancer control agency in another state if:

(1) The patient is a resident of the other state;

(2) The Department determines that the agency will preserve the confidentiality of the information; and

(3) The other state has authority to provide equivalent information on Maryland residents to this State.

§18–204.

(a) (1) In this section the following words have the meanings indicated.

(2) "Cancer report" means a one–time abstract of the medical record of a patient diagnosed or treated for cancer or a central nervous system tumor which contains:

(i) Reasonably obtained patient demographic information, including risk factors;

(ii) Relevant information on the:

1. Initial histologically precise diagnosis;

2. Initial treatment;

3. Extent of the disease by the end of the first hospitalization; and

4. Extent of the disease within 2 months of diagnosis if the information is available to the reporting facility and the reporting facility has a tumor registry; and

(iii) Facility and other provider identification information.

(3) (i) "Central nervous system tumor" means, irrespective of histologic type or behavior, a primary tumor in the following sites:

1. The brain;

2. The caudea equina;

3. A cranial nerve;

4. The craniopharyngeal duct;

5. The meninges;

6. The pineal gland;

7. The pituitary gland; or

8. The spinal cord.

(ii) "Central nervous system tumor" includes a primary intracranial tumor.

(4) "Freestanding ambulatory care facility" has the meaning stated in § 19–3B–01 of this article.

(b) (1) Each hospital that has care of a patient with cancer or a central nervous system tumor, each freestanding laboratory, freestanding ambulatory care facility, or therapeutic radiological center that has care of or has diagnosed cancer or a central nervous system tumor for a nonhospitalized patient, and each physician who has care of or has diagnosed cancer or a central nervous system tumor for a nonhospitalized patient not otherwise reported shall:

1. Submit a cancer report to the Secretary, on the form that the Secretary provides or in a computerized file;

2. Make available to the Secretary, or an agent of the Secretary, at the facility the information necessary to compile a cancer report; or

3. Enter into an agreement with a hospital or other facility or agency that agrees to report to the Maryland Cancer Registry to act as the reporting source for a cancer or central nervous system tumor patient who has been referred to or from that facility, or reported to that agency with regard to cancer or central nervous system tumor screening, diagnosis, or treatment; and

(i) Effective July 1, 1993, submit a cancer report in a computerized file on a quarterly basis to the Secretary, or an agent of the Secretary, for all patients initially diagnosed, treated, or admitted to a facility for cancer or a central nervous system tumor during that calendar quarter.

(2) To assure compliance with this section, the Secretary, or an agent of the Secretary, may inspect upon reasonable notice a representative sample of the medical records of patients diagnosed, treated, or admitted for cancer or a central nervous system tumor at the facility.

(3) (i) Information obtained under this subsection shall be confidential and subject to Title 4, Subtitle 1 of this article.

(ii) This subsection does not apply to a disclosure by the Secretary to another governmental agency performing its lawful duties pursuant to State or federal law where the Secretary determines that the agency to whom the information is disclosed will maintain the confidentiality of the disclosure.

(iii) A cancer report is not a medical record under Title 4, Subtitle 3 of this article, but is subject to the confidentiality requirements of Title 4, Subtitle 1 of this article.

(4) Each hospital, freestanding laboratory, freestanding ambulatory care facility, therapeutic radiological center, or physician who in good faith submits a cancer report to the Secretary is not liable in any cause of action arising from the submission of the report.

(5) The Secretary, after consultation with the Cancer Registry Advisory Committee, the Maryland Hospital Association, and representatives of freestanding laboratories and therapeutic radiological centers, shall adopt regulations to implement the requirements of this section.

(6) The Secretary, in accordance with § 2–1257 of the State Government Article, shall submit an annual report to the Governor and General Assembly on the activities of the cancer registry, including utilization of cancer registry data.

Code of Maryland Regulations (COMAR) 10.14.01

Title 10 MARYLAND DEPARTMENT OF HEALTH

Subtitle 14 CANCER CONTROL

Chapter 01 Cancer Registry

Authority: Health-General Article, §§2-104, 18-104, 18-203 and 18-204, Annotated Code of Maryland; 42 U.S.C. §280(e)

.01 Scope.

This chapter establishes a cancer registry within the Department, defines key terms, details the information to be contained in a cancer report, and specifies requirements of reporting facilities, nursing facilities, assisted living programs, and general hospice care programs. In addition, this chapter identifies requestors authorized to receive confidential data, allows a fee to be charged for data reports, and incorporates by reference the Maryland Cancer Registry Data Use Manual and Procedures (July 2016).

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Assisted living program" has the meaning stated in COMAR 10.07.14.02B.

(2) "Cancer registry" means a computerized system to register all cases of reportable human cancer or reportable human central nervous system (CNS) tumors of Maryland residents and nonresidents diagnosed or treated in Maryland.

(3) "Cancer report" means a one-time abstract from one or more of the following documents maintained by a reporting facility, nursing facility, assisted living program, or general hospice care program of each new case of reportable human cancer or CNS tumor diagnosed or treated, and any other case of reportable human cancer or CNS tumor initially diagnosed or treated for time periods as designated by the Secretary:

(a) Medical record;

(b) Pathology report; and

(c) Radiological report.

(4) Case of a Reportable Human CNS Tumor.

(a) "Case of a reportable human CNS tumor" means an identified human tumor, irrespective of histologic type or behavior, occurring as a primary tumor in any of the following sites or subsites with International Classification of Diseases for Oncology, Third Edition (ICD-O-3) topography codes C70.0—C72.9 and C75.1—C75.3:

(i) The brain;

(ii) The meninges;

(iii) The spinal cord;

(iv) The cauda equina;

(v) A cranial nerve;

(vi) The pituitary gland;

(vii) The pineal gland; or

(viii) The craniopharyngeal duct.

(b) "Case of a reportable human CNS tumor" includes all benign and uncertain behavior tumors of the CNS (ICD-10-CM Codes D18.02, D32.0—D33.9, D35.2—D35.4, D42.0—D43.9, D44.3—D44.5, Q85.00—Q85.09 and D49.6, and all tumors of the CNS of benign and uncertain behavior with ICD-O-3 codes of "0" or "1"), which includes codes from:

(i) The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM); and

(ii) The International Classification of Diseases for Oncology, Third Edition (ICD-O-3).

(5) "Case of reportable human cancer" means the identification of a human cancer from the following list, which includes codes from the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) and the International Classification of Diseases for Oncology, Third Edition (ICD-O-3):

(a) All malignant neoplasms with ICD-10-CM Codes C00—C43.9, C44.00, C44.09, C44.10_, C44.19_, C44.20_, C44.29_, C44.30_, C44.39_, C44.40, C44.49, C44.50_, C44.59_, C44.60_, C44.69_, C44.70_, C44.79_, C44.80, C44.89, C44.90, C44.99, C45._—C96._, or with ICD-O-3 behavior code of "3", including genital skin cancer of the vagina, clitoris, vulva, prepuce, penis, and scrotum and excluding other sites of skin cancer with ICD-O-3 topography codes C44.0—C44.9 with one of the following ICD-O-3 histologies:

(i) M-8000—8005 Neoplasms, malignant, not otherwise specified of skin;

(ii) M-8010—8046 Epithelial carcinomas of skin;

(iii) M-8050—8084 Papillary and squamous cell carcinomas of skin (C44.02, C44.12_, C44.22_, C44.32_, C44.42, C44.52_, C44.62_, C44.72_, C44.82, C44.92); or

(iv) M-8090—8110 Basal cell carcinomas (C44.01, C44.11_, C44.21_, C44.31_, C44.41, C44.51_, C44.61_, C44.71_, C44.81, C44.91);

(b) All malignant neoplasms with the following ICD-10-CM codes where ICD-O-3 behavior is "3" and ICD-O-3 histologies are reported except as follows:

(i) If there is evidence of multiple foci, lymph node involvement, or metastasis, C37—Thymoma (M-8580);

(ii) C7A.020—Malignant carcinoid tumor of the appendix (M-8240);

(iii) C54.1—Endometrial stroma, low grade (M-8931);

(iv) If there is evidence of multiple foci, lymph node involvement, or metastasis, D48.1—Stromal Tumor of the digestive system (GIST 8639);

(v) D48.60—Phylloides tumor (M-9020);

(vi) D45—Polycythema (M-9950);

(vii) D47.Z9—Plasmacytoma (M-9731, M-9734);

(viii) D47.3—Essential thrombocythemia (M-9962), D46.0, D46.1, D46.20, D46.21, D46A, D46B—Low grade myelodysplastic syndrome lesions (M-9980), D46.22—High grade myelodysplastic syndrome lesions (M-9983), D46.C—Myelodysplastic syndrome with 5q deletion (M-9986), D469—Myelodysplastic syndrome, unspecified (M-9975), D47.1—Myelofibrosis

with myeloid metaplasia (primary myelofibrosis) (M-9961), D47.Z1—post-transplant lymphoproliferative disorder (M-9989), C94.40, C94.41, C94.42, D47.9, D47.Z9—lympho and myeloproliferative disease (M-9960, M-9970);

(ix) C88.2—Alpha and gamma heavy chain disease (M-9762) or Franklin disease (M-9763);

(x) C88.0—Waldenstrom macroglobulinemia (M-9761);

(xi) D46.4—Refractory anemia (M-9980); or

(xii) D46.1—Refractory anemia with ringed sideroblasts (M-9982), refractory anemia with excess blasts (M-9983), or refractory anemia with excess blasts in transformation (M-9984);

(c) All cases of carcinoma in situ with ICD-10-CM Codes D00._—D09.9, D47.Z2, D49.511—D49.519, D49.59, D78.31—D78.34, and D89.40—D89.49, or with ICD-O-3 behavior code of "2", including genital skin cancers of the vagina, clitoris, vulva, prepuce, penis, and scrotum and excluding other skin cancers with ICD-O-3 topography codes C44.0_—C44.9_ with one of the following ICD-O-3 histologies:

(i) M-8000—8005 Neoplasms, malignant, not otherwise specified of skin;

(ii) M-8010—8046 Epithelial carcinomas of skin;

(iii) M-8050—8084 Papillary and squamous cell carcinomas of skin; and

(iv) M-8090—8110 Basal cell carcinomas; or

(d) All cases of intraepithelial neoplasia with ICD-O-3 histology code of M-8077/2:

(i) Including squamous intraepithelial neoplasia of the larynx (LIN), vagina (VAIN), vulva (VIN), and anus (AIN) (ICD-10-CM codes D02.0, D07.2, D07.1, and D01.3; and ICD-O-3 topography codes C52, C51, and C21._); and

(ii) Excluding squamous intraepithelial neoplasia of the cervix (CIN III) and glandular intraepithelial neoplasia of the prostate (PIN) (ICD-10-CM codes D06._ and D07.5; and ICD-O-3 topography codes C53 and C61.9).

(6) "Computerized file" means an electronic data file using Software approved for use by the Secretary, containing complete cancer report information transferable to a master electronic database system maintained by the Department.

(7) "Department" means the Maryland Department of Health or a designee.

(8) "Freestanding ambulatory care facility" has the meaning stated in Health-General Article, §19-3B-01, Annotated Code of Maryland.

(9) "Freestanding laboratory" means a facility, place, establishment, or institution which performs a laboratory examination for a person, authorized by law to request the examination, in connection with the diagnosis of a reportable human cancer or CNS tumor, and is licensed by the State pursuant to COMAR 10.10.03, and:

(a) Not under the administrative control of a hospital; or

(b) Under the administrative control of a hospital for a diagnosis of reportable human cancer or CNS tumor of a nonhospitalized patient.

(10) “General hospice care program” has the meaning stated in COMAR 10.07.21.02.

(11) "Hospital" means a facility which is licensed by the State pursuant to COMAR 10.07.01.

(11-1) “Maryland Cancer Registry Data Use Manual and Procedures” means the document that describes the Maryland cancer registry procedures for release of cancer data and that outlines the procedures to obtain both non-confidential aggregate data and confidential individual-level data.

(12) "Nursing facility" has the meaning stated in COMAR 10.07.02.01B.

(13) "Physician" means an individual who:

(a) Practices medicine, as defined in Health Occupations Article, §14-101, Annotated Code of Maryland; and

(b) Diagnoses or treats a case of reportable human cancer or a reportable human CNS tumor at a practice located in Maryland.

(14) "Reporting facility" means any of the following:

(a) A hospital, freestanding laboratory, freestanding ambulatory care facility, or therapeutic radiological center; or

(b) A physician who has care of or has diagnosed a case of reportable human cancer or reportable human CNS tumor for a nonhospitalized patient not otherwise reported.

(15) "Secretary" means the Secretary of Health or a designee of the Secretary.

(16) "Therapeutic radiological center" means a facility or institution:

(a) Performing radiological treatment for a person authorized by law to request the treatment in connection with a reportable human cancer or a reportable human CNS tumor; and

(b) Licensed or registered by the State pursuant to COMAR 10.05.03 and not under the administrative control of a hospital.

.02-1 Incorporation by Reference.

The Maryland Cancer Registry Data Use Manual and Procedures (Maryland Department of Health, July 2016) is incorporated by reference.

.03 Establishment of a Cancer Registry.

There is a cancer registry established within the Department, whose purpose is to collect reportable human cancer data and reportable human CNS tumor data to further the cancer control goals of the State.

.04 Cancer Control Goals of the State.

A. The cancer control goals of the State are to reduce the incidence and mortality of reportable human cancer and reportable human CNS tumors and racial, ethnic, gender, age, and geographic disparities in reportable human cancer and CNS tumor incidence and mortality in Maryland, by:

(1) Advancing the understanding of reportable human cancer and reportable human CNS tumor demographics;

(2) Describing reportable human cancer and reportable human CNS tumor sources, causes, risk factors, preventive measures, diagnostic tests, screening tests, treatment, and survival; and

(3) Evaluating the cost, quality, efficacy, and appropriateness of diagnostic, therapeutic, rehabilitative, and preventive services and programs related to reportable human cancer and reportable human CNS tumors.

B. Research that will further the cancer control goals of the State is research whose protocols have been reviewed by Department staff who have found that the research will:

(1) Advance scientific knowledge or advance knowledge of clinical practice related to cancer;

(2) Have approaches, aims, and methods that will allow the researcher to perform descriptive analyses or test hypotheses;

(3) Have one or more investigators who have training and experience with the approaches and methods; and

(4) Be conducted in a scientific environment likely to contribute to the success of the research.

.06 Reporting Requirements.

A. A reporting facility shall submit a:

(1) Cancer report to the Secretary in a computerized file containing standard information required by the Secretary;

(2) Computerized file not less than quarterly; and

(3) Completed report of any new individual case of a reportable human cancer or reportable human CNS tumor not later than 6 months after diagnosis or treatment.

B. A nursing facility, an assisted living program, or a general hospice care program shall submit a cancer report containing information that is under the control of the facility to the Secretary if the Secretary requests a cancer report on a patient who has been a resident of the nursing facility, assisted living program, or general hospice care program.

.07 Confidentiality of Cancer Reports.

A. Information obtained under this chapter is not a medical record under Health-General Article, §4-301, Annotated Code of Maryland, but is subject to the confidentiality requirements of Health-General Article, §§4-101—4-103, Annotated Code of Maryland.

B. The Secretary may release confidential data to:

(1) An institution or individual researcher for medical, epidemiological, health care, or other cancer-related or CNS tumor-related research approved by the Secretary and the Department's Institutional Review Board (IRB) in order to further the cancer control goals of the State set forth in Regulation .04 of this chapter;

(2) A reporting facility which:

(a) Routinely submits information on cases of reportable human cancer or reportable human CNS tumors to the cancer registry;

(b) Has been formally accepted as a participant in the cancer registry system; and

(c) Requests data relating to patients reported by the facility;

(3) An out-of-State cancer registry or cancer control agency which requests routine data if the:

(a) Patient is a resident of the other state; and

(b) Other state has authority to provide equivalent information on Maryland residents to this State;

(4) Each county health officer and the Baltimore City Commissioner of Health; and

(5) Another governmental agency performing its lawful duties pursuant to State or federal law.

C. The Secretary may release confidential information, subject to:

(1) A determination by the Secretary that a recipient of the information disclosed will maintain the confidentiality of the disclosed information; and

(2) An agreement signed by the Secretary and by the recipient of the confidential information that the recipient of the information will maintain the confidentiality of the disclosed information.

D. The Secretary shall release confidential data to a requestor in response to a written request only, in accordance with Health-General Article, §§4-101 and 4-102, Annotated Code of Maryland.

E. A reporting facility that in good faith submits a cancer report to the Secretary is not liable in any cause of action arising from the submission of the cancer report to the Secretary.

F. The use or publication of any statistics, information, or other material that summarizes or refers to confidential records in the aggregate, without disclosing the identity of any person who is the subject of the confidential record is not subject to the provisions of Health-General Article, §4-102, Annotated Code of Maryland.

G. The Secretary shall release cancer data in accordance with the procedures outlined in the Maryland Cancer Registry Data Use Manual and Procedures.

.08 Authority and Requirements of the Secretary.

A. To assure compliance by a reporting facility, nursing facility, assisted living program, or general hospice care program with Regulation .05 of this chapter, the Secretary may, upon advance notice, inspect a representative sample of medical records, pathology reports, or radiological reports maintained by the facility of cases of reportable human cancer and reportable human CNS tumors.

B. The Secretary may charge a reasonable fee to cover the cost of providing data reports to appropriate requestors, as allowed by COMAR 10.01.08.04. All applicable fees shall be paid in full in advance of filling the request.

C. After receiving all necessary information to support a request to release cancer registry data, the Secretary shall act in a timely manner and decide on the request with one of the following outcomes:

(1) Final approval;

(2) Interim approval, if the request has been accepted with one or more conditions which shall be met before final approval is granted; or

(3) Disapproval.

D. The Secretary, in accordance with State Government Article, §2-1246, Annotated Code of Maryland, shall submit an annual report to the Governor and General Assembly on the activities of the cancer registry, including use of cancer registry data.

E. Nothing in this chapter is intended to limit or otherwise restrict the Secretary from obtaining cancer report information on Maryland residents from sources located either inside or outside the State.

Effective date: September 28, 1992 (19:19 Md. R. 1707)

Regulation .01 amended effective April 21, 1997 (24:8 Md. R. 616)

Regulation .02B amended effective April 26, 1993 (20:8 Md. R. 723); April 21, 1997 (24:8 Md. R. 616); June 23, 2003 (30:12 Md. R. 788)

Regulation .04 amended effective April 21, 1997 (24:8 Md. R. 616)

Regulation .04C amended effective June 23, 2003 (30:12 Md. R. 788)

Regulation .05B amended effective June 23, 2003 (30:12 Md. R. 788)

Regulation .06B, D amended effective June 23, 2003 (30:12 Md. R. 788)

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Chapter revised effective March 22, 2010 (37:6 Md. R. 478)

Regulation .01 amended effective January 13, 2011 (38:1 Md. R. 11); April 15, 2013 (40:7 Md. R. 611); February 27, 2017 (44:4 Md. R. 253)

Regulation .02B amended effective January 13, 2011 (38:1 Md. R. 11); April 15, 2013 (40:7 Md. R. 611); February 27, 2017 (44:4 Md. R. 253)

Regulation .02-1 adopted effective April 15, 2013 (40:7 Md. R. 611)

Regulation .02-1 amended effective February 27, 2017 (44:4 Md. R. 253)

Regulation .05C amended effective January 13, 2011 (38:1 Md. R. 11)

Regulation .06B amended effective January 13, 2011 (38:1 Md. R. 11)

Regulation .07G adopted effective April 15, 2013 (40:7 Md. R. 611)

Regulation .07G amended effective February 27, 2017 (44:4 Md. R. 253)

Regulation .08A amended effective January 13, 2011 (38:1 Md. R. 11)

Appendix 4-1

National Program of Cancer Registries (NPCR) Program Standards 2022–2027

Acronyms

AMP	Award Management Platform
APR	Annual progress report
BRFSS	Behavioral Risk Factor Surveillance
System CCR	Central cancer registry
CHSDA	Contract Health Service Delivery
Area CRCCP	Colorectal Cancer Control
Program CTR	Certified tumor registrar
DER	Data evaluation report
DMP	Data management plan
DQE	Data quality evaluation
EHR	Electronic health records
ETC	Education and training coordinator
FHIR	Fast healthcare interoperability
resources FTE	Full-time equivalent
FTP	File transfer protocol
HL7	Health Level Seven
HPV	Human papillomavirus
IHS	Indian Health Service
IT	Information technology
MOU	Memorandum of understanding
NAACCR	North American Association of Central Cancer
Registries NBCCEDP	National Breast and Cervical Cancer Early
Detection Program NCCCP	National Comprehensive Cancer Control
Program	
NDI	National Death Index
NOFO	Notice of funding opportunity
NPCR	National Program of Cancer Registries
NPCR-CSS	National Program of Cancer Registries Cancer Surveillance
System OM	Operations manager
PD	Program director
PEI	Program evaluation instrument

PI	Principal investigator
QA	Quality assurance
QC	Quality control
SDOH	Social determinants of health
SEER	Surveillance, Epidemiology, and End
Results SES	Socioeconomic status
TA	Technical Assistance
USCS	United States Cancer Statistics

Introduction

The goal of CDC's National Program of Cancer Registries (NPCR) is to collect, report, and disseminate high-quality data on all reportable incident cancer cases in a timely manner for the purpose of cancer prevention and control. The NPCR Program Standards are a set of interrelated expectations and requirements that provide a framework for effective cancer surveillance program implementation, evaluation, and continuous improvement. They build on one another to equip central cancer registries (CCRs) to assess the cancer burden through the collection, use, and dissemination of complete, timely, and high-quality cancer data. They are based on the 10 Essential Public Health Services (www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html) that seek to protect and promote the health of all people in all communities, and are aligned with the Healthy People 2030 cancer objectives.

The NPCR Program Standards also ensure that CCRs fulfill the overarching performance measures listed below, establish priorities and perform activities that funded programs are expected to achieve, provide objective measures of program progress, and improve program processes that drive outcomes.

The 2022–2027 NPCR Program Standards build on progress achieved during the previous notice of funding opportunity (NOFO DP17-1701) to support and strengthen population-based CCRs and promote ongoing registry data use to inform evidence-based decision making.

At a minimum, an NPCR-funded CCR must be able to:

1. Report cancer incidence trends by geographic area and provide cancer data to support cancer control programs.
2. Collect and report incidence, burden, and stage data and use these data to create surveillance reports that can direct targeted interventions, guide research, and evaluate the success of cancer prevention and screening programs.
3. Identify disparities by age, gender, race, ethnicity, and geographic areas in cancer incidence, stage at diagnosis, and mortality.
4. Create and maintain registry and state or territorial policies that support use of cancer registry data for research.
5. Strengthen its capacity to receive electronic reporting from facilities, labs, physician practices, and other data sources.

We organized CDC's 2022–2027 NPCR Program Standards by strategy, standards, corresponding activities, and performance measures. These standards are based on the legal authority provided to CDC under the Public Health Service Act (Title 42, Chapter 6A, Sub-Chapter II, Part M, § 280e) and subsequent amendments, and apply to all reportable cancers as defined in the Act and amendments. The relevant outcomes, as depicted in the NPCR logic model, and performance measures, which quantify progress toward performing activities and achieving outputs, are also included. Program standards may be revised during the 5-year cooperative agreement performance period.

Short-, Intermediate-, and Long-Term Outcomes

The following outcomes are the intended results of activities in the NOFO that awardees are expected to achieve by the end of the 5-year performance period.

Short-Term Outcomes

a. Increased use of NPCR data by recipients, partners, collaborators, and researchers.
b. Achievement of data quality standards by the CCR.
c. Successful adoption of data modernization strategies.
d. Improved timeliness, quality, completeness, and confidentiality of NPCR surveillance data.
e. Increased collaboration among chronic disease and other public health programs.
f. Increased access to cancer screening and preventive services among populations of focus.
g. Increased knowledge about cancer prevention, screening, and survivorship among populations of focus.
h. Increased reporting of high-quality program data to CDC.
i. Increased use of evaluation findings for program improvement.
j. Increased participation in special studies.

Intermediate-Term Outcomes

a) Increased capacity, flexibility, and utility of CCR infrastructure to meet new data needs.
b) Increased data use for cancer prevention and control.
c) Improved health behaviors.
d) More cancer primary prevention resources and screening available for populations of focus.
e) Increased early detection of cancer among populations of focus.

Long-Term Outcomes

a. Reduced cancer risk factors such as tobacco use, overexposure to ultraviolet rays, human papillomavirus (HPV) infections, and overweight and obesity.
b. Better quality of life among cancer survivors.
c. Decreased cancer incidence, morbidity, and mortality.
d. Reduced cancer disparities.
e. Increased health equity.

NPCR will monitor and assess the CCR's progress, results, and overall impact through:

a) The annual National Program of Cancer Registries Cancer Surveillance System (NPCR-CSS) data submissions that monitor data timeliness, quality, and completeness.

b) Regular assessments including recipient quarterly check-in responses, the Program Evaluation Instrument (PEI), and the Data Quality Evaluation (DQE).

c) Annual Progress Reports (APRs).

d) Regular communications with program consultants, such as conference calls and requests for technical assistance.

NPCR Logic Model Outputs

The NPCR logic model outputs correspond to multiple program standards. Since NPCR strategies and outcomes are interconnected, the NPCR Program Standards serve as building blocks that guide cancer registry program implementation and ongoing program improvement.

a. Infrastructure in place for data collection.
b. Reduced staff attrition; critical registry positions filled.
c. Ongoing trainings and educational sessions for registry staff and facility registrars conducted.
d. Cancer data processed and collected.

e. Quality control procedures implemented.
f. Completeness and data quality compliance reports completed.
g. Data confidentiality and security maintained.
h. Disaster plan that includes risk assessments, data breach plan, and security audits created and updated.
i. CCR Operations Manual reviewed and updated.
j. Required and additional data linkage performed.
k. Effective and sustainable multi-sectoral collaborations developed and strengthened.
l. Data modernization projects implemented.
m. De-identified cancer data submitted.
n. Cancer and related data shared with diverse partners and collaborators.

Strategy 1: Enhance NPCR data quality, completeness, use, and dissemination

Standard 1.1: Legislative Authority

Ensure that legislation supports cancer surveillance and has flexibility to meet innovations in the field.

Activities

1.1.1 : Maintain existing law or regulations that provide legal authority for a CCR, as defined in Public Health Services Act Title 42, Chapter 6A, Sub-Chapter II, Part M, 280e, authorizing NPCR.

1.1.2 : Update existing law or regulations as needed to support criteria specified in Public Health Services Act Title 42, Chapter 6A, Sub-Chapter II, Part M, 280e specifically addressing and complying with electronic reporting, data exchange, data modernization and innovation, and data sharing and use requirements.

Performance Measure

PM 1: CCR reviews state or territorial cancer registry legislation **at least once per year**, works with state or territorial public health and policy entities to recommend revisions as needed, and provides an update in the Annual Progress Report (APR) narrative.

Standard 1.2: Administration and Operations

Maintain effective and efficient processes and high-quality staff to operate the registry.

Activities

1.2.1 : Hire or retain staff sufficient in number and expertise to manage, implement, and evaluate the CCR, as well as use and disseminate the data. Core required staff must fill the following roles: program director, project director, or principal investigator (PD/PI) or operations or registry manager (OM), quality assurance or quality control (QA/QC) manager, information technology (IT) staff, and education and training coordinator (ETC). The QA/QC manager and ETC positions must be filled by qualified, experienced certified tumor registrars (CTRs).

a)	PD/PI or OM	1 full-time equivalent (FTE)	100%
b)	ETC	1 FTE	100%
c)	QA/QC manager	1 FTE	100%
d)	IT staff	0.25 FTE	25%

1.2.2 : Ensure policy and procedure manuals are up-to-date and staff are cross-trained in key functional areas to maintain continuity of operations. At a minimum, the CCR Operations Manual contains:

1. The reporting laws and regulations.
2. A list of reportable diagnoses.

3. A list of required data items.
4. Procedures for data processing operations, including:
   a. Monitoring timeliness of reporting.
   b. Receipt of data.
   c. Database management, including a description of the registry operating system software (this may be accomplished by citing a software vendor's website and documentation).
   d. Conducting death certificate clearance.
   e. Implementing and maintaining the quality assurance or quality control program, including procedures for:
      i. Conducting follow-back to reporting facilities on quality issues, including rules for identifying when action or further investigation is needed.
      ii. Conducting record consolidation.
      iii. Maintaining detailed documentation of all quality assurance operations.
      iv. Education and training.
   f. Conducting data exchange, including a list of states and territories with which case-sharing agreements are in place.
   g. Conducting data linkages.
   h. Ensuring confidentiality and data security, including disaster planning.
   i. Data release, including access to and disclosure of information.
   j. Maintaining and updating the operations manual.

5. Management reports that include processes and activities to monitor the registry operations and database.
6. An abstracting and coding manual that is used by reporting sources that abstract and report cancer cases.

1.2.3 : Ensure that adequate hardware and software systems are in place to support the CCR activities, including data collection, database management, interstate data exchange, data linkages, quality assurance, data analysis, and management reporting. Provide the memorandum of understanding with the IT department if IT staff are not embedded in program.

1.2.4 : Develop or use promising practices and tools to strengthen communication with data reporters to improve data quality, completeness, and timeliness.

1.2.5 : Implement promising processes to improve real-time reporting and data quality.

1.2.6 : Ensure the confidentiality and security of CCR data through software and hardware security standards. This includes:

1. Implementing and documenting security policies and procedures.

2. Documenting data release policies and procedures that include both access to and disclosure of information.

3. Developing a disaster plan that includes annual risk assessments, security audits for registry data, and a mechanism to track ongoing security training for staff and telework options. Details are included on the NPCR data security pages at www.cdc.gov/cancer/npcr/tools/security/.

4. Developing, submitting, and implementing a data management plan (DMP) that conforms with CDC requirements and guidelines.

Performance Measures

PM 2: CCR secures necessary registry management and operations staff per NPCR Manual and NOFO requirements (core required positions: PD/PI or OM, 1 FTE 100%; ETC, 1 FTE 100%; QA/QC manager, 1 FTE 100%; and IT staff, 0.25

FTE 25%).

A. Target: At least 75% of required CCR staff positions are filled on an annual basis.

PM 3: CCR reviews Operations Manual **twice per year**, updates sections as needed, and provides an update in the APR narrative.

PM 4: CCR reviews data management plan (DMP) **once per year** and updates as needed.

PM 5: CCR maintains a list of reporting facilities that is verified and updated **once per year.**

Standard 1.3: Data Collection, Content, and Format
Ensure that the registry collects all reportable data in accordance with NPCR requirements.

Activities

1.3.1 : Central cancer registries must collect and submit data for all reportable cancers and benign neoplasms including, at a minimum, primary site, histology, behavior, date of diagnosis, race, ethnicity, age at diagnosis, sex, stage at diagnosis, and first course of treatment, according to CDC specifications and other information required by CDC.

1.3.2 : For all CDC-required reportable cases, the CCR collects or derives all required data items using standard codes prescribed by CDC.

1.3.3 : Regardless of residency, the CCR collects data on patients who were diagnosed or received the first course of treatment in the registry's state or territory.

1.3.4 : The CCR uses a standardized, CDC-recommended data exchange format to transmit data to other central cancer registries and CDC.

Performance Measures

PM 6: CCR conducts bi-weekly or monthly check-ins with reporting facilities to ensure timely reporting of cancer cases.

PM 7: CCR creates a remediation plan to address reporting challenges due to staff turnover, software issues, or other reasons for reporting delays within 60 days and shares its expectations with the reporting facility.

Standard 1.4: Electronic Data Exchange
Use and promote electronic reporting among facilities and data sources.

Activities

1.4.1 : Develop and implement a plan to enhance timely reporting via the expansion of electronic reporting by one or more means such as data modernization activities, electronic health record (EHR) reporting, and ePath reporting, and through data exchanges including interstate data exchange.

1.4.1.1 The CCR is required to adopt and use standardized, CDC-recommended data transmission formats for the electronic exchange of cancer data (see CDC NPCR Electronic Reporting and Data Exchange Guidance). Registries should promote the use of these formats by reporting sources that transmit data to the registry electronically. CDC-recommended data exchange formats include:

1. Hospital reporting: The North American Association of Central Cancer Registries (NAACCR) record layout version specified in year-appropriate *Standards for Cancer Registries Volume II: Data Standards and Data Dictionary.*

2. Anatomic pathology laboratory reports: NAACCR's *Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting* version 5.0 (or newer standards such as HL7 FHIR).

3. Non-hospital sources using electronic medical records: Office of the National Coordinator for Health Information Technology (ONC) Certification Criteria 2015 Edition: Health Level Seven (HL7) Clinical Document Architecture (CDA®) Release 2 Implementation Guide: Reporting to Public Heath Cancer Registries from Ambulatory Healthcare Providers, Release 1, Draft Standard for Trial Use (DSTU) Release 1.1- US Realm, or newer standards such as HL7 Fast Healthcare Interoperability Resources (FHIR).

A. For hospitals reporting to the CCR, increase the percentage reporting electronically every year to meet the standard of all hospitals reporting electronically by the end of the 5-year performance period.

B. For non-hospital facilities reporting to the CCR, increase the percentage reporting electronically every year to meet the standard of at least 80% of these facilities reporting electronically by the end of the 5-year performance period.

C. The CCR uses a secure Internet-based, file transfer protocol (FTP), https, or encrypted e-mail mechanism to receive electronic data from reporting sources.

Performance Measures

PM 8: Percentage of labs reporting data electronically using HL7 2.5.1 or other standard HL7 format (measure for e-path reporting).

1. Target: Increase the percentage of labs reporting data electronically in the designated HL7 format by 3% each year.

PM 9: Percentage of hospitals reporting electronically to the CCR each year.

1. Target: Increase the percentage every year to meet the standard of 100% of hospitals reporting electronically by the end of the 5-year performance period.

PM 10: Percentage of non-hospital facilities reporting electronically to the CCR each year.

1. Target: Increase the percentage every year to meet the standard of at least 80% of these facilities reporting electronically by the end of the 5-year performance period.

Standard 1.5: Data Completeness, Timeliness, and Quality

Cancer data meet NPCR completeness, timeliness, and quality standards.

Activities

1.5.1 : Implement procedures to ensure timeliness, quality, and completeness of data in accordance with CDC data quality standards.

1.5.2 : Inform CDC in a timely manner if barriers to data collection processes or procedures may negatively affect compliance with CDC data quality standards or delay data submission. Work with CDC to resolve and prevent future occurrence.

1.5.3 : Establish interstate data exchange agreements with other central cancer registries to obtain data on residents who have been diagnosed or treated outside of catchment area and perform data exchanges with them at least twice per year. Quarterly data exchange with geographically bordering central cancer registries is strongly encouraged.

1.5.4 : CCR's annual data submission adheres to the National and Advanced National Data Quality Standards.

1.5.5 : Perform linkages with external data sets to improve data completeness and quality.

1.5.6 : Develop and promote good relationships with reporting facilities.

1.5.7 : Develop and implement a plan to monitor status of case reporting and completeness.

1.5.8 : Develop and implement procedures to handle ePath volume effectively.

1.5.9 : Participate in testing of Registry Plus software, which includes:

1. Installing test versions of Registry Plus software on a desktop computer or test server.
2. Testing the application using protocols provided by the Registry Plus support team.
3. Reporting any issues related to bugs or standards.
4. Installing revised test versions and retesting until all issues have been resolved.

Performance Measures

PM 11: CCR creates and routinely uses management reports that monitor data reporting, completeness, and quality, attaches templates with the APR submission, and provides a brief explanation of these tools in the narrative.

PM 12: Interstate data exchange occurs **at least annually** between CCR and designated states or territories and **quarterly** (if feasible) between CCR and neighboring states.

PM 13: CCR's annual data submission adheres to the following data quality criteria for 12- and 24-month data, as measured via the data evaluation report (DER):

1. There are 3% or fewer death-certificate-only cases.
2. There is a 1 per 1,000 or fewer unresolved duplicate rate.
3. The maximum percentage missing for critical data elements are:
   a. 2% age.
   b. 2% sex.
   c. 3% race.
   d. 2% county.
4. 99% pass a CDC-prescribed set of standard edits for 12-month data, and 97% pass a CDC-prescribed set of standard edits for 24-month data.

PM 14: CCR increases case reporting by at least 2% each year for urologists, dermatologists, and gastroenterologists, as required by law, to demonstrate continuing progress and improvement by the end of the 5-year performance period.

PM 15: CCR increases case reporting by at least 2% each year for medical oncologists, radiation oncologists, and hematologists, as required by law, to demonstrate continuing progress and improvement by the end of the 5-year performance period.

Standard 1.6: Linkages

Perform linkages to improve data quality, completeness, and accessibility.

Activities

1.6.1 : Create and employ data linkages as described in the NPCR Program Standards and additional linkages which are necessary for successful registry operations. Linkages include, but are not limited to:

1. State or territory vital statistics (at a minimum, death records) annually.
2. Indian Health Service administrative records (as appropriate).
3. Social Security Administration Death Master File annually.
4. National Death Index annually.
5. Veterans Administration (if feasible).

- The CCR links with state or territory death files at least once every year and incorporates results on vital status and cause of death into the registry database.

- The CCR links with the National Death Index at least once every year and incorporates results on vital status and cause of death into the registry database.

- The CCR links with the state or territory breast and cervical cancer early detection program at least once every year to identify potentially missed cases, reconcile differences between the two systems, and update appropriate data fields to capture post-linkage information.

- The CCR links with the Indian Health Service (IHS) Administrative Database at least once every five years. However, central cancer registries within IHS Contract Health Service Delivery Area counties link their records with patient registration records from IHS at least once every year.

1.6.2 : Perform linkages that assist in addressing other public health issues as they relate to cancer, including tobacco use, human papillomavirus (HPV) and hepatitis B vaccination, physical activity, and overweight and obesity. Linkages may include behavioral risk factor data such as from the Behavioral Risk Factor Surveillance System (BRFSS), socioeconomic status data, and social determinants of health data, including available data on intersectionality.

- The CCR uses linkages to address gaps identified in data quality and completeness or to improve the utility of the data. Potential sources of information include:
  1. Statewide electronic health files for casefinding and completeness of required data items.
  2. Claims data for casefinding and completeness of required data items.
  3. Census data (or similar) for socio-demographic variables.
  4. Birth records for demographic information.
  5. Department of Motor Vehicle records for demographic information.
  6. Voter registration files for demographic information.

- The CCR should strive to conduct at least one additional linkage per year, inclusive of developing needs such as COVID-19.

Performance Measures

PM 16: CCR performs linkage with state or territory death files at least **once every year** and incorporates results on vital status and cause of death into the registry database.

PM 17: CCR links with the National Death Index at least **once every year** and incorporates results on vital status and cause of death into the registry database.

PM 18: CCR links with the state or territory breast and cervical cancer early detection program at least **once every year** to identify potentially missed cases, reconcile differences between the two systems, and update appropriate data fields to capture post-linkage information.

PM 19: CCR links with the Indian Health Service (IHS) Administrative Database at least **once every five years**. However, CCRs within IHS Contract Health Service Delivery Area counties link their records with patient registration records from IHS at least **once every year**.

Standard 1.7: Data Quality Assurance and Education
Establish policies, procedures, and processes for data quality assurance that link with education and training to maintain high-quality data.

Activities

1.7.1 : Develop, implement, and maintain an education and training plan for internal staff and reporting facilities with the goal of improving CCR data quality.

1.7.2 : Conduct internal registry quality control and quality improvement activities by CCR staff.

1.7.3 : Participate in NPCR-defined national data quality assurance activities including Data Quality Evaluation (DQE) projects, ad hoc data evaluation, audits, and other special data quality control and improvement activities. Complete and submit the Program Evaluation Instrument (PEI) by the due date.

1.7.4 : Use available training and educational resources and program's ETC to educate staff and reporters.

1.7.5 : Incorporate findings and results of NPCR Data Evaluation Reports (DER), PEI, and audits into educational and training plans.

1.7.6 : Conduct routine data quality evaluations showing continuous data quality improvement, for example, lower the percentage of records with unknown values.

Performance Measures

PM 11: CCR creates and routinely uses management reports that monitor data reporting, completeness, and quality, attaches templates with the APR submission, and provides a brief explanation of these tools in the narrative.

PM 20: At least once every 5 years, CCR conducts casefinding and re-abstracting audits from a sample of source documents for each hospital-based reporting facility. This is in addition to the CDC-funded and sponsored Data Quality Evaluation (DQE).

PM 21: CCR provides at least four online trainings or continuing education opportunities and one in-person workshop (if possible) or training to CCR staff and reporting partners each year.

PM 22: CCR meets a percentage completeness each year based on observed-to-expected cases (see **PM 13**).

- **Target:** CCR-submitted 12-month data meets 90% completeness.
- **Target:** CCR-submitted 24-month data meets 95% completeness.

Standard 1.8: Data Use and Data Monitoring

Use cancer and related program data and disseminate to partners, collaborators, and researchers to expand use of registry data, promote a common understanding of the state or territorial cancer burden, and inform evidence-based decision making.

Activities

1.8.1 : Within 12 months of the end of the diagnosis year with data that are 90% complete, the CCR produces preliminary pre-calculated data tables in an electronic data file or report of incidence rates, counts, or proportions for the diagnosis year by Surveillance, Epidemiology, and End Results (SEER) site groups to monitor the top cancer sites within the state or territory.

1.8.2 : Within 24 months of the end of the diagnosis year with data that are 95% complete, the CCR, in collaboration with local cancer control programs, produces the following electronic reports:

- Reports on age-adjusted incidence and age-adjusted mortality rates for the diagnosis year using SEER site groups and, where applicable, stratifying by age, sex, race, ethnicity, and geographic area.

- Biennial reports providing data on stage and incidence by geographic area, with an emphasis on screening- amenable cancers and cancers associated with modifiable risk factors such as tobacco use, overweight and obesity, and human papillomavirus (HPV) infection.

1.8.3 : The CCR ensures annual use of cancer registry data for public health and surveillance research purposes in **at least five** of the following ways:

1. Comprehensive cancer control.
2. Detailed incidence and mortality by stage and geographic area.
3. Collaboration with cancer screening programs for breast, colorectal, or cervical cancer.
4. Health event investigations.
5. Needs assessment and program planning, such as Community Cancer Profiles.
6. Program evaluation.
7. Epidemiologic studies.
8. Survivorship programs.

Performance Measures

PM 23: CCR submits a success story to CDC **annually** detailing how registry data have been used to affect public health.

PM 24: Number of cancer surveillance publications, burden reports, presentations, and data briefs created and disseminated to NPCR and other entities **annually.**

- **Target:** CCR creates and disseminates at least one comprehensive cancer surveillance report that includes age- adjusted incidence rates, stage at diagnosis, and age-adjusted mortality rates for the diagnosis year using SEER site groups stratified by age, sex, race, ethnicity, or geographic area.
- **Target:** CCR presents analysis findings to at least two state or territorial groups and one national group each year (NPCR counts as a national group).
- **Target:** CCR collaborates on at least one summary surveillance report outside of the cancer registry, such as environmental health, immunization, nutrition and physical activity, substance abuse (alcohol, marijuana, opioid use), HIV/AIDS, or sexually transmitted infections.
- **Target:** Creates five one-page cancer surveillance data briefs each year.

Standard 1.9: Data Submission

Submit cancer data to CDC each year in accordance with CDC's standards and requirements.

Activities

1.9.1 : Submit electronic data files to the NPCR-CSS according to the timeframe and content established by CDC that meet the reporting requirements outlined in the NPCR-CSS Submission Specifications document. Submitted data should meet the criteria for publication in the United States Cancer Statistics (USCS), the National Data Quality Standard, and the Advanced National Data Quality Standard.

- In appropriate data submission years, when the CCR data file meets specified data completeness and quality standards, the CCR data are included in the *Cancer in Five Continents* publication.

1.9.2 : Participate in all CDC-created and hosted analytic datasets and web-based data query systems as outlined in the annual NPCR-CSS Data Release Policy.

Performance Measures

PM 22: CCR meets a percent completeness each year based on observed-to-expected cases (see **PM 13**).

- **Target:** CCR-submitted 12-month data meets 90% completeness.
- **Target:** CCR-submitted 24-month data meets 95% completeness.

PM 25: Baseline and annual participation in all CDC-created analytic data sets outlined in the NPCR-CSS data release policy.

Standard 1.10: Innovation Projects
As applicable and available, participate in NPCR-funded innovation projects.

Activities

1.10.1 : Plan, implement, and evaluate innovation projects. Engage cancer coalition leadership and task groups to identify potential project topics.

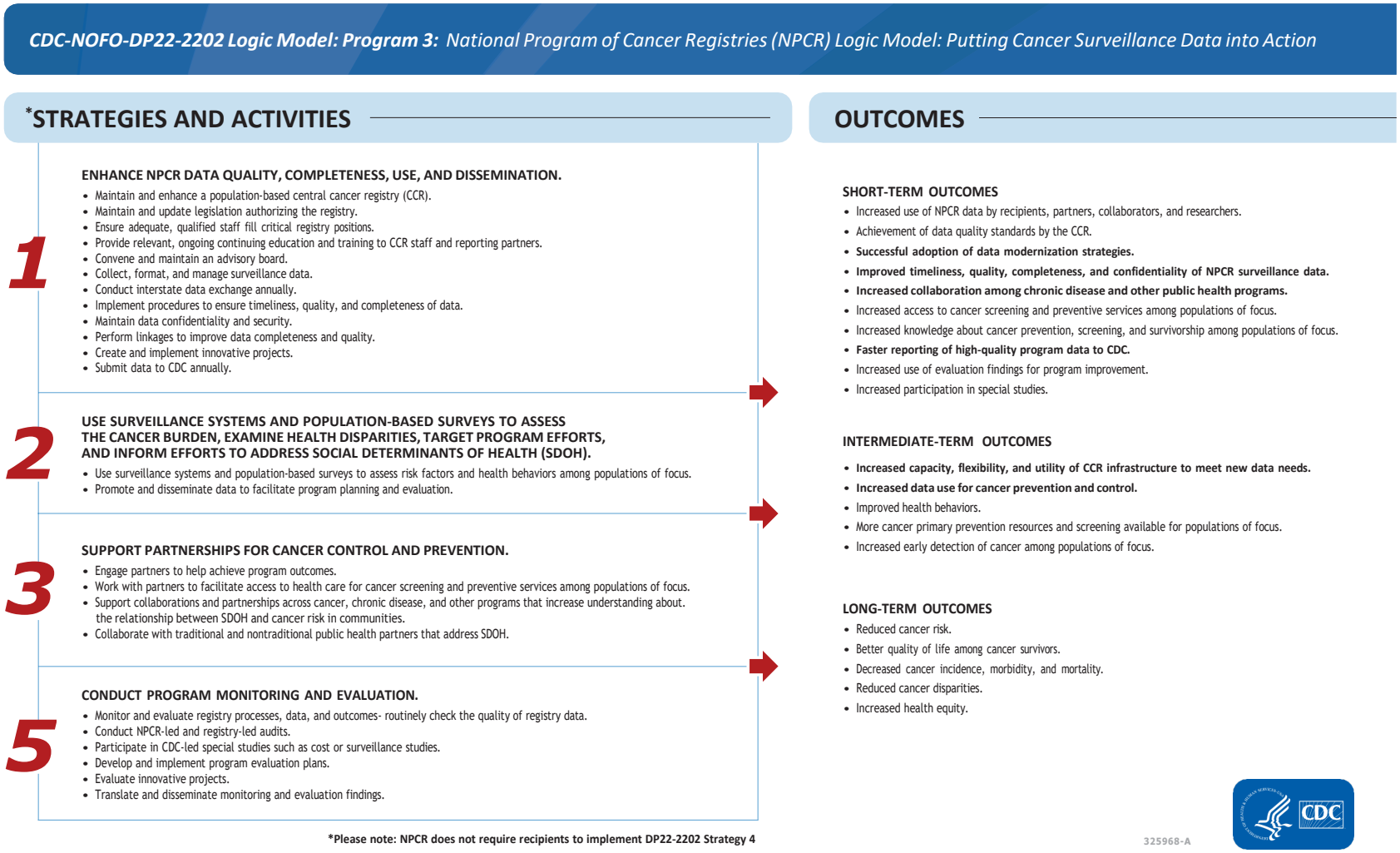
1.10.2 : Share promising practices with partners, cancer coalition, collaborators, and cancer program awardees.

1.10.3 : Participate in CDC sponsored special studies and pilot projects.

Performance Measure

PM 26: Present innovation project findings at one state, territorial, or national conference or meeting **annually** and submit at least one manuscript for publication within the 5-year performance period.

Appendix 4-2. – NPCR Logic Model



Appendix 4-3: Database System Maintenance and Support

1. Software Maintenance Activities

a. Keeping up maintenance and license contracts for all central registry application software.

b. Performing software development activities associated with maintaining existing central registry software, including calculations of upgrade costs and outcome.

c. Maintaining the latest product upgrades, maintenance releases, patches, and documentation.

d. Updating and replacing software to conform to state- or territory-specific standards and improve the scalability of the central cancer registry system.

e. Managing and creating management software maintenance reports.

f. Upgrading applications and databases to conform to changing record layouts and standards used nationally or in the state, territory, jurisdiction, or tribe.

2. Hardware Maintenance Activities

a. Keeping up maintenance contracts for critical central registry hardware

b. Managing and creating management maintenance reports for critical central registry Hardware

c. Identifying and replacing defective hardware devices or identifying hardware improvement, including calculations of upgrade costs.

d. Updating and replacing hardware to conform to state- or territory-specific requirements and improve the scalability of the central registry system.

e. Performing time and material repairs for equipment that is not under a maintenance contract and that needs to be repaired on a per-call basis.

f. Providing remote support and maintenance via the Internet.

g. Maintaining a spare part inventory on site.

3. Information Technology Support Activities

a. Providing database administrator support to maintain central registry databases.

b. Providing network administrator support to maintain central registry networks.

c. Obtaining and applying software patches for specific related operating system concerns.

d. Conducting performance analyses to identify potential problems and optimize the system.

e. Supporting central cancer registry software and platform products, including the operating system, database utilities, backup software and hardware, printers, network utilities, and security, encryption, and disaster recovery products.

f. Storing data backups and media used for backup remotely.

g. Generating data sets for data submissions and ad hoc requests

Appendix 4-4. – NPCR – CSS 2021 Data Release Policy

National Program of Cancer Registries Cancer Surveillance System (NPCR-CSS) 2021 Data Release Policy Diagnosis Years 1995–2020

Policy Revised August 2021

Cancer Surveillance Branch Division of Cancer Prevention and Control
National Center for Chronic Disease Prevention and Health Promotion CDC
4770 Buford Hwy, N.E., Mailstop S107-4 Atlanta, GA 30341-3717
E-mail: uscsdata@cdc.gov (specify "NPCR-CSS" in subject line)

Introduction

This document describes the format and content of data that the Centers for Disease Control and Prevention's (CDC's) National Program of Cancer Registries (NPCR) Cancer Surveillance System (CSS) releases or shares. This multi-year policy updates the July 2020 NPCR-CSS Data Release Policy. This policy applies to data submitted to CDC for the 2021 NPCR-CSS data submission and for all future data submissions until a new policy is provided.

The NPCR-CSS Privacy Steward, as authorized by the Chief of the Cancer Surveillance Branch, clears all releases of state and territory data, ensuring that the data are released according to the terms of this policy.

It is possible that, in future years, data release practices or the content and format of released data may vary from those described in this document. Such changes may occur as a result of improvements in the quality of the data, changes in information technology, and evolving data needs. However, if such variations occur, the data release practices will provide comparable protection (or more protection) for patient confidentiality to that described in this policy. If it is anticipated that any data will be released with less protection (as determined by the NPCR-CSS Privacy Steward) for patient confidentiality than described in this policy, NPCR central cancer registries will be notified and have ample time to respond before the data are released. This policy is reviewed annually by the NPCR-CSS Privacy Steward and other appropriate CDC staff members to determine whether revisions are needed.

Summary of Changes

- Updated the description of the NPCR-CSS institutional review board (IRB) designation. Under the Common Rule, the project is a non-research public health surveillance project and annual IRB review is no longer necessary, page 4.
- Updated the description of the USCS Data Visualizations tool with software used to build the tool and new data shown: stage at diagnosis and survival by stage, page 5.
- Survival data are no longer published in the CDC WONDER tool. WONDER descriptions were updated, page 5.
- Added a description of the new NPCR/SEER Survival dataset, page 9.
- Added a new step of obtaining SEER Research Plus access before accessing USCS databases on pages 25 and 46.
- Clarified the reviewer process for the Restricted-Access Research Dataset,1 0.
- Aligned wording in the Suppression of Rates and Counts section to Table 1 to indicate that the suppression rule of fewer than 6 applies to restricted-access data, page 18.
- Updated the diagnosis years available in Table 1.
- Updated data item lists for NPCR/SEER USCS Incidence Analytic Dataset (Appendix F), NPCR Internal Survival Dataset (Appendix G), and NPCR/SEER USCS Incidence Public-Use Research Dataset (Appendix J).
- Updated text in Appendix H – NPCR-CSS 308(d) Assurance of Confidentiality Statement to match the currently approved Assurance of Confidentiality project description.

Overview of Data

In 1992, Congress established NPCR by enacting the Cancer Registries Amendment Act, Public Law 102-515.[1] The law authorized CDC to provide funds and technical assistance to states and territories to improve or enhance existing cancer registries and to plan for and implement population-based central cancer registries where they did not exist. NPCR's purpose is to assure the availability of more complete local, state, regional, and national cancer incidence data to plan and evaluate cancer control interventions and for research. NPCR adopted reporting requirements and definitions consistent with the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) program;[2,3] required the use of uniform data items, codes, and record layouts as defined by the consensus of members of the North American Association of Central Cancer Registries (NAACCR);[4] and established standards for data management and data completeness, timeliness, and quality similar to those NAACCR recommended.[4,5] In 1994, the first 37 states received funding from CDC.[6] Currently, 46 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the U.S. Pacific Island Jurisdictions are funded by NPCR (Appendix A).[7] NPCR-funded central cancer registries collect data on patient demographics, primary tumor site,

morphology, stage of disease at diagnosis, and first course of treatment. In addition, NPCR central cancer registries conduct follow-up for vital status by linking with state and national death files or active case follow-up.

Invasive and *in situ* cancer case reports are submitted to CDC by population-based central cancer registries in all 46 participating states, the District of Columbia, Puerto Rico, U.S. Virgin Islands, and the U.S. Pacific Island Jurisdictions. In each state or territory, laws and regulations mandate the reporting of cancer cases by facilities and practitioners who diagnose or treat cancer to the state or territory health department or its designee. The central cancer registry receives case reports from facilities and practitioners throughout the state or territory and processes them according to standard data management procedures.[5] Personal identifiers including the patient's name, Social Security number, and street address are removed from the NPCR-CSS submission prior to the encryption and electronic transmission of these case reports to a contractor acting on behalf of CDC. CDC and the contractor adhere to strict data security procedures when receiving, processing, and managing the data (Appendix B). CDC has an Office for Human Research Protections (OHRP)-approved, federal-wide assurance of compliance with rules for the protection of human subjects in research (45 Code of Federal Regulations 46, available at www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/).
NPCR-CSS received formal approval (protocol #2594) from CDC's Institutional Review Board (IRB) in October 1999 and annual approval was approved through 2020. In 2021, under the Common Rule (45 Code of Federal Regulations Part 46, Common Rule 2018), NPCR-CSS was deemed to be a non-research public health surveillance project and annual IRB review is no longer necessary.

Central cancer registries and federal agencies routinely publish cancer incidence data 23 months after the close of each diagnosis year based on data that meet data quality standards.[7,8] However, other versions of the same data, based on the data file as it exists at different time periods, are usually available. For example, some central cancer registries have preliminary data available as soon as 12 months after the close of each diagnosis year. After the publication of official statistics, central cancer registries, as well as CDC and the NCI, continue to update and republish data with new information incorporated. When cancer incidence data are published, it is common practice to document either the data submission date (when the data were submitted to CDC or NCI) or the date that the file was prepared. Changes in central cancer registry incidence data that occur more than 22 months after the close of a diagnosis year are likely to be small; however, delays in reporting are more likely to affect certain cancer sites and may be important for some research studies.[9]

CDC generates multiple data products using NPCR-only data and combined NPCR and SEER data. The combined NPCR and SEER data are referred to as U.S. Cancer Statistics (USCS). USCS is the official federal cancer statistics, providing the most up-to-date information on the U.S. population.

Data Release Activities

Starting with DP17-1701, participation in all CDC-created and hosted analytic datasets and web-based data query systems, as outlined in this policy, is a required strategy.[10] Therefore, the NPCR-CSS Dataset Participation Agreement is no longer provided.

Public Web-based Query Systems

For purposes of this policy, public web-based query systems are defined as datasets that are comprised of aggregated data (not individual case-specific data or microdata) that have been modified according to accepted procedures to block breaches of confidentiality and prevent disclosure of the patient's identity or confidential information. They are stored in a database behind a CDC firewall that is either case-specific microdata or pre-analyzed data tables.[11, 12-17] Users can access only aggregate counts and rates with all confidentiality protections built in. A combination of confidentiality protection measures is employed for each public web-based query system (see Table 1). These systems do not contain information that is identifiable or potentially identifiable according to currently accepted procedures for reducing disclosure risk.[11, 12-17] Before each system is finalized, the aggregate values are analyzed to determine whether there is a need for complementary cell suppression.[11, 12-17] If appropriate, the analysis includes consultation with a statistician with expertise in statistical disclosure limitation techniques. Following the analysis, complementary cell suppression is applied as needed.

There are no restrictions on access to public web-based query systems. A public release disclosure statement (see Public Release Disclosure Statement) cautions users against inappropriate use of the data or inappropriate disclosure of information. Data are released as delimited ASCII files, a web-based query system, or possibly through other data products (see Table 1). As a convenience to NPCR central cancer registries, states and territories may request from CDCa copy of their complete state- or territory-specific analytic database that is used to populate each public web-based query system. The following public web-based query systems are currently being released:

- USCS Data Visualizations tool.
- CDC WONDER – USCS incidence and incidence/mortality rate ratios.

- Federal partners' web-based query systems:
  - NCI's State Cancer Profiles.
  - CDC's Environmental Public Health Program's Tracking Network.
  - Chronic Disease Indicators (CDI) website and data portal.
  - Office on Women's Health's Health Information Gateway.

All NPCR-CSS public web-based query systems consist of cancer incidence data selected from the NPCR/SEER analytic database. This is the same database that provides cancer incidence data for the annual release of USCS data products, including the Data Visualizations tool, public use database and State Cancer Profiles. Data sources, case definitions, basic registry eligibility criteria in terms of required data quality, population denominator sources, methods for calculating incidence rates, and the rationale for specific cell suppression thresholds are as described in the USCS Data Visualizations Tool Technical Notes, available at https://www.cdc.gov/cancer/uscs/technical_notes/, unless noted in separate documentation that accompanies the data.

Separate documentation may accompany each data product that describes its unique features, such as the data submission date, percentage of the U.S. population covered, diagnosis years and cancer sites included, variables included, data suppression rules, any special data quality criteria required for inclusion, and any unique statistical methods employed.

USCS Data Visualizations Tool

The USCS Data Visualizations tool is a web-based application built with D3 Javascript libraries, a React framework, and web application programming interfaces (APIs) that outputs data in hypertext markup language (HTML) containing the aggregate counts and rates for incidence, mortality, prevalence, and survival estimates published annually, along with text documentation and data visualizations. The tool is available at www.cdc.gov/cancer/dataviz. It displays single year and 5- year aggregate counts, crude rates, age-adjusted rates, and 95% confidence intervals by primary site, sex, race, and ethnicity at the county (5-year aggregate), Congressional district (5-year aggregate), state or territory, and national levels. Congressional district estimates (estimated 5-year aggregate counts and age-adjusted rates) are presented by sex, race, and ethnicity (all races/ethnicities, non-Hispanic White, Black, and Hispanic). In addition, cancers grouped by associated risk factors are presented by state, sex, race, and age-group (single year and 5-year aggregate) are presented in Data Visualizations tool. Data by stage at diagnosis and survival by stage for select sites are presented by sex, race/ethnicity, and age at the national level. Stage at diagnosis is categorized as localized, regional, distant, and unknown or unstaged. Preliminary and delay-adjusted incidence rates and counts, as well as other new indicators, may be published in the tool. The Data Visualizations tool's database is behind a CDC firewall with pre-tabulated data created using SEER*Stat queries, which allows for the display of counts and rates that meet suppression and confidentiality protections. Users can access only aggregate counts and rates with all confidentiality protections built in. Downloadable ASCII files with the pre- tabulated data are available from CDC's website. States and territories may request a state- or territory-specific web API.

CDC WONDER – USCS Incidence, Mortality, and Incidence/Mortality Ratios

The USCS dataset available on CDC WONDER (https://wonder.cdc.gov/cancer.html) displays the aggregate incidence and mortality counts, rates, and 95% confidence intervals by primary site, sex, race, and ethnicity at the state, county, regional, metropolitan statistical area (MSA), and national levels. Cancer incidence and mortality rate ratios are also available by year, state, MSA, race, ethnicity, sex, and cancer site. The WONDER database is stored behind a CDC firewall with case-specific microdata. Users can access only aggregate counts and rates with all confidentiality protections built in.

CDC WONDER allows users more flexibility in creating cross-tabulations than the Data Visualizations tool. While the same underlying USCS data are available in both tools, more detailed breakdowns of counts and rates are available through WONDER. The additional values result from variable selections that are not currently available in the Data Visualizations tool (see Table 1) and include results for MSAs that have a population of 50,000 or higher and standard 5- year age groups that the user can combine.

Federal Partners' Web-based Systems

CDC shares aggregated data with federal partners for display in their web-based query systems. The data are generated specifically for the partners' needs and are shared via ASCII files.

Unless otherwise noted below, the data generally consist of aggregate cancer incidence counts, crude rates, and age- adjusted rates for selected primary sites, age groups, and counties in the United States (see Table 1 for more details).

Future versions may contain more detail about cancer at the county level. Beginning in 2008, CDC began routinely publishing county

data averaged over 5 years.

Age-adjusted rates only

State Cancer Profiles (www.statecancerprofiles.cancer.gov/) is a web-based query tool that public health professionals and others can use to prioritize cancer control efforts at the county, state, and national level. Data are released to NCI's Surveillance, Epidemiology, and End Results (SEER) program for the State Cancer Profiles data product, which presents average annual counts and age-adjusted incidence and death rates only.

Age-adjusted and crude rates

Crude and age-adjusted rates are released to the U.S. Department of Health and Human Services' Office of Women's Health. The data are available through their online tool, Health Information Gateway (https://gateway.womenshealth.gov/).

Environmental Public Health Tracking Program

USCS data are provided to CDC's National Center for Environmental Health's Environmental Public Health Tracking Program (https://ephtracking.cdc.gov/) (Tracking Program) for display on the Tracking Network. The Tracking Network displays single-year and 5-year aggregate incidence counts, age-adjusted rates, and 95% confidence intervals for selected primary sites and age groups for selected geographic areas (see Table 1). Single-year data can be viewed at the state level. Data by 5-year average and 5-year summed are available at the county level. Data by 3-, 5-, 7-, and 10-year aggregate are available at the sub-county level.

Maps of incidence counts and incidence rates for select cancers will be displayed for various sub-county geographies. Incidence rates are based on incidence counts stratified by census tract, year of diagnosis, age group (standard 19 groups), sex, and Census-based population estimates. These incidence counts and age-adjusted rates are displayed using aggregation schemas recommended by a sub-county cancer data workgroup: spatial (census tract, geographies with a minimum of 5,000 persons, or geographies with a minimum of 20,000 persons) and temporal (3-, 5-, 7-, or 10-year periods). Rates are age-adjusted to the 2000 US standard population. Counts and rates are suppressed when there are fewer than 16 cases or fewer than 100 persons in the geographic area. Specific to this project, an additional suppression is applied when the relative standard error of the rate is greater than 30%.

The Tracking Program's web-based query system (https://ephtracking.cdc.gov/DataExplorer/#/) uses a database behind a CDC firewall with case-specific microdata, which allows for the calculation of locally weighted smoothed rates, unsmoothed rates, or both:

- Tracking Program Unsmoothed Rates
  Data published are like those on State Cancer Profiles. It includes cancer data from all 50 states.

- Tracking Program Smoothed Rates
  Smoothing is the process of averaging a measure for an area based on information about that area and areas around it. Please note that the main purpose of smoothing is to clarify spatial patterns and to improve the stability of rates, not to prevent disclosure of private information. Back-calculation of case counts from smoothed rates is sometimes possible when the method of smoothing is made known and (non-sensitive) denominator data are available from other sources.

  Through the Tracking Program, users can access only aggregate counts and rates with all confidentiality protections built in.

- Tracking Program National Portal to State Portal
  CDC's Tracking Program has awardees in several NPCR-funded states that are responsible for the state-level public portals. In collaboration with the Tracking Program, upon request, NPCR provides the state-level Tracking Network dataset to the Tracking Program state counterpart.

Data Release to Federal and Trusted Partners

American Cancer Society (ACS)

CDC shares NPCR and USCS data with ACS to promote collaborations on cancer surveillance and epidemiological research efforts. ACS's Surveillance and Health Services Research (SHSR) Program analyzes and disseminates cancer statistics and identifies gaps and opportunities for cancer prevention, early detection, and treatment. The SHSR annually publishes the statistical report, *Facts & Figures*, and peer-reviewed journal articles that are used by public health experts, clinicians, and scientists.

In 2018, a Memorandum of Understanding was implemented with ACS, and ACS staff members must sign a Data Use Agreement form and complete annual Assurance of Confidentiality training before they are given access to the data. Beginning in 2020, due to changes in SEER's data release policy, CDC also obtains approval from SEER before releasing USCS data. CDC provides ACS staff access to the following databases with record-level data through SEER*Stat software: USCS Delay-Adjusted database, NPCR Survival database,

NPCR Prevalence database, and selected variables from the NPCR and SEER Quality Control database. The Quality Control database shared with ACS is restricted to 24- month data, excludes postal code and census tract variables, and excludes "day" fields for date of birth and date of death.

Central Brain Tumor Registry of the United States (CBTRUS)

CBTRUS annually publishes the print and web versions of the statistical report, *Primary Brain Tumors in the United States Statistical Report Supplement*; a previous version of the report is available at: https://www.cbtrus.org/reports. The report includes age-adjusted rates and corresponding 95% confidence intervals on brain and other central nervous system tumors and is presented by state, histology, major histology grouping, primary site, behavior, gender, race, ethnicity, and age at diagnosis. As a trusted partner, CBTRUS is provided access to the NPCR Survival Dataset to include survival estimates in the annual report, conduct in-depth analyses, and respond to queries. CDC provides individual, record-level data to CBTRUS for the publication of this report; Appendix C lists the variables included in this dataset. Only states meeting the USCS publication criteria are included in the dataset.

In addition, CBTRUS uses these data to respond to inquiries that are more specific than those that are provided by the report. For these inquiries, no individual record-level data are released; only aggregated data with the corresponding confidence intervals (if applicable) and appropriate suppression criteria are provided to data inquirers. Attribution to NPCR is provided. CBTRUS signs data use agreements before data are released for their report and future inquiries. For questions, contact CBTRUS staff at cbtrus@aol.com.

International Association of Cancer Registries (IACR)

The International Association of Cancer Registries (http://www.iacr.com.fr/) (IACR) produces the *Cancer Incidence in Five Continents* (CI5) and the *International Incidence of Childhood Cancer* (IICC). The *CI5* series (https://ci5.iarc.fr/) of monographs, published every five years, has become the reference source of data on the international incidence of cancer. The most recent version was published in 2017. The CI5 databases provide access to detailed information on the incidence of cancer recorded by cancer registries (regional or national) worldwide in two formats (CI5 and CI5plus) and the IICC provides access to detailed information on the incidence of pediatric cancers:

- **CI5** presents the basic data published in the CI5 volumes.
- **CI5plus** contains annual incidence for selected cancer registries published in CI5 for the longest possible period.
- **IICC** presents basic pediatric data.

When IACR requests data, the formal Call for Data Submission giving information on the evaluation procedure, likely layout of how data will be presented, and questionnaire on registry operations will be available from the IACR website. NPCR may facilitate the call for data on behalf of awardees. NPCR will provide additional information regarding the CI5 Call for Data as it becomes available. The CI5 Call for Data has two components: the questionnaire and introductory text and data submission.

Data submitted for CI5 may also be used for the IICC publication, making a separate data submission unnecessary. This IACR product requires states to complete a separate questionnaire and introductory text.

States are responsible for completing the online questionnaires and providing introductory text indicating if the CI5 data and introductory text are also used for the IICC product. NPCR will submit aggregated NPCR data for central cancer registries meeting USCS publication criteria.

CONCORD

CONCORD (https://csg.lshtm.ac.uk/research/themes/concord-programme/) is the program for worldwide surveillance of cancer survival, led by the London School of Hygiene & Tropical Medicine and supported by the Union for International Cancer Control (UICC). CONCORD monitors progress toward the UICC's World Cancer Declaration, made in 2013: "major reductions in premature deaths from cancer, and improvements in quality of life and cancer survival".

A call for participation in the CONCORD studies is periodically issued and extends examination of worldwide cancer survival trends for certain cancer sites: stomach, colon, rectum, liver, lung, breast, cervix, ovary, prostate, esophagus, pancreas, and melanoma of skin in adults, as well as leukemias, lymphomas, and brain tumors in adults and children (0 to 14 years). The protocol and dataset specifications are posted to the NPCR-CSS Document Server, CONCORD tab as they become available.

NPCR may facilitate the call for data on behalf of awardees by submitting NPCR data for central cancer registries meeting USCS publication criteria for survival analyses: they meet USCS data quality criteria and have conducted active patient follow-up or linked records with the National Death Index.

Agency for Healthcare Research and Quality (AHRQ)

The U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) is the lead federal agency charged with improving the safety and quality of America's health care system. It develops and disseminates knowledge, tools, and data to improve health care systems and help Americans, health care professionals, and policy makers make informed health decisions. NPCR-CSS data are shared with AHRQ for reports on national health care quality and disparities (https://www.ahrq.gov/research/findings/nhqrdr/).

Analytic Datasets

USCS Analytic Data

Combined NPCR and SEER incidence data are referred to as USCS. CDC creates USCS analytic datasets each year that include data from central cancer registries meeting USCS publication criteria and diagnosis year coverage. CDC, NCI staff members, and contractors analyze USCS data as needed using these internal analytic databases.

The datasets are made available via SEER*Stat software to federal employees, fellows, and contractors in CDC's Division of Cancer Prevention and Control and NCI's SEER program after obtaining SEER Research Plus access, signing an NPCR Analytic Data Use Agreement (Appendix D) and CDC Nondisclosure Agreement (Appendix E) and completing annual Assurance of Confidentiality training. The dataset is also available to approved partnering organizations and state and territory central cancer registries after a Memorandum of Understanding and Data Use Agreements are signed (see Appendix H and Appendix I).

In specially established collaborative relationships, researchers external to CDC, NCI, and ACS may be provided access to the USCS analytic datasets. In these relationships, CDC staff must be included in the analytic project as a co-author, Data Use Agreements must be signed, and Assurance of Confidentiality training must be completed before access is provided. Additionally, access will only be allowed on-site at CDC's Cancer Surveillance Branch offices. See the section "External Data Requests".

Cancer surveillance and epidemiological analyses include assessment of the completeness, timeliness, and quality of cancer incidence data and analyses of the cancer burden and survival as needed to meet national cancer control objectives. Such analyses of state or territory and national data are conducted routinely by federal agencies including CDC and NCI for programmatic or statistical purposes, as needed, to achieve the agencies' mandates.

Five internal analytic datasets are routinely analyzed by CDC and NCI staff members:

NPCR/SEER USCS Incidence Analytic Dataset

CDC and NCI staff members and contractors conduct cancer surveillance and epidemiological research that results in publications, data briefs, and presentations. Examples of research include descriptive analyses by racial and ethnic populations for specific cancers, descriptions of cancer incidence trends, and descriptive analyses of the quality of the data. Appendix F lists the variables available in this dataset.

NPCR Internal Survival Dataset

Cancer survival data are critical for evaluating the progress and effect of early detection and screening programs, comprehensive cancer control plans, and interventions from other sources. CDC's NPCR-CSS calculates and publishes survival estimates on this population at the national, state, and regional levels. Focusing on the entire NPCR-CSS dataset supports analyses of survival estimates for rare cancers that cannot be addressed otherwise and provides data for publication on the USCS Data Visualizations tool. Appendix G lists the variables available in this dataset.

NPCR/SEER Survival Dataset

This database contains data from NPCR- and SEER-funded registries that have completed National Death Index linkages or active patient follow-up for all years included in the database and meet 95% completeness estimates. This dataset will be used to assess Healthy People 2030 cancer objective C-11: Increase the proportion of cancer survivors who are living 5 years or longer after diagnosis. The variables included in the dataset are the same as the NPCR Internal Survival Data, which are listed in Appendix G.

NPCR Internal Prevalence Dataset

This database provides limited-duration prevalence estimates for NPCR registries who meet USCS publication criteria for all years included in the database and that have completed National Death Index linkages or active patient follow-up for all years included in the database. Statistics generated from this dataset are published on the USCS Data Visualizations tool. The list of variables available in this dataset is in Appendix O.

NPCR/SEER USCS Delay-Adjusted Dataset

Case-reporting delay may result in an underestimate of true incidence. Researchers can adjust for this delay using composite delay factors, thus producing more precise cancer incidence trends. The composite delay factors (https://surveillance.cancer.gov/delay/model.html) used in this database were developed by SEER and are used by NPCR, SEER, and NAACCR. The delay-adjustment factors account for cancer site, registry, age, race, ethnicity, and diagnosis year, and are used to estimate delay-adjusted counts and rates. The variables available in this dataset are listed in Appendix P.

4. USCS American Indian and Alaska Native Incidence Analytic Database

CDC uses Indian Health Services (IHS) linkage results for analyses of cancer incidence among American Indian and Alaska Native populations. In addition to improving cancer incidence rates presented in USCS Data Visualizations tool, an employee in CDC's Division of Cancer Prevention and Control assigned to IHS maintains an analytic database, the USCS American Indian and Alaska Native Incidence Analytic Database (AIAD). Access to this database is limited to approved CDC staff.

The data are used to respond to requests for cancer incidence rates for American Indian and Alaska Native populations from tribal organizations. Five-year aggregate incidence counts, age-adjusted rates, and 95% confidence intervals for selected primary sites are displayed in the USCS Data Visualizations tool (see Table 1). These data are limited to non- Hispanic American Indian and Alaska Native people living in IHS Purchased/Referred Care Delivery Areas (PRCDA) counties. Inclusion in the AIAD dataset also allows IHS to provide the state with the date of death obtained through National Death Index (NDI)-IHS linkage or the date the linkage occurred by diagnosis year for registries that complete an NDI supplemental confidentiality agreement for application Y9-0033.

Requirements for Staff

In compliance with the 308(d) Assurance of Confidentiality, CDC and NCI employees and contractors and partner organizations conducting these analyses are required to handle the information in accordance with principles outlined in the CDC Staff Manual on Confidentiality and to follow the specific procedures documented in the NPCR-CSS Confidentiality and Security Statement (appendices B, H, and I).

In addition, CDC, SEER, and partner organization staff members are required to acknowledge state and territory cancer registries whenever NPCR-CSS data are presented, released, or published by making the following (or similar) statement:

> *These data were provided by central cancer registries participating in the National Program of Cancer Registries (NPCR) and submitted to CDC in [Month, Year], and the Surveillance, Epidemiology, and End Results (SEER) program and submitted to NCI in [Month, Year]. The dataset includes data for diagnosis years xxxx–xxxx (excluding SEER-Metro Registry data).*

NPCR/SEER USCS Incidence and Survival Public-Use Research Dataset

For purposes of this policy, the NPCR/SEER USCS Incidence Public-Use Research Dataset (Incidence PUD) and the NPCR Survival Public-Use Research Dataset (Survival PUD) are defined as the version of the full NPCR/SEER USCS microdata (individual case-specific data) that have been modified as needed to minimize the potential for disclosure of confidential information. These datasets contain a subset of data items published in the NPCR/SEER USCS Incidence Analytic dataset. Personal identifiers, such as a patient's name, street address, and Social Security number, are not included in these datasets as this information is not transmitted by central cancer registries to CDC as part of their annual data submission. Certain data items, such as date of birth and reporting-source (death certificate only and autopsy only) cases, may be removed from these research datasets to minimize the potential identification of individuals with a rare cancer in a person of certain age or racial or ethnic group or living in a specific county. The list of the variables included in the NPCR/SEER USCS Incidence Public-Use Dataset is in Appendix J. The NPCR Survival PUD is under development. The NPCR-CSS Data Release Policy will be updated before its release.

The Incidence PUD dataset, previously only available to NPCR registry staff, is now available publicly through SEER*Stat software. Upon completion, the Survival PUD will be made available through the same mechanism. Researchers are given access to the data after obtaining SEER Research Plus access and signing an NPCR and SEER – U.S. Cancer Statistics Research Data Use Agreement (Appendix K). A Public Release Disclosure Statement cautions users against inappropriate use of the data or inappropriate disclosure of information. Cell suppression of fewer than 16 cases is automatic and the SEER*Stat case listing function is disabled as additional data protection measures. This dataset allows authorized users to generate the authorized counts, crude rates, age-adjusted incidence rates, and 95% confidence intervals to meet their specific needs.

Restricted-Access Research Dataset (RDC)

For purposes of this policy, the restricted-access dataset is defined as the version of the full NPCR/SEER USCS analytic dataset, either aggregated data or microdata (individual case-specific data) that has been modified as needed to minimize (but may not remove entirely) the potential for disclosure of confidential information.

CDC uses the National Center for Health Statistics' Research Data Center (NCHS RDC) as a mechanism for researchers outside of the Division of Cancer Prevention and Control (DCPC) to request and gain access to NPCR data for research purposes. The data are available through the NCHS RDC only after the standard data quality reviews that occur as part of the preparation for USCS. The restricted-access dataset is released to researchers through the NCHS RDC after CDC authenticates the requestor's identity and research intent through an extensive proposal review process, and the researcher completes the NCHS RDC's confidentiality and security requirements. The requestor must also comply with the NCHS RDC's confidentiality procedures and data-sharing agreements.

The NCHS RDC has developed and maintains detailed data-sharing agreements and procedures for user authentication and for logging and monitoring data releases. NPCR and NCHS RDC staff review project proposals. Proposals may also be shared for review with central cancer registry staff whose data are included in the proposed project. User documentation includes a data dictionary for every diagnosis year available at the NCHS RDC.

Using the NCHS RDC to manage data access provides the highest level of data security and protection of confidentiality available for data analysis and allows CDC to comply with the Assurance of Confidentiality [308(d)] that was obtained for the NPCR-CSS data. The NCHS RDC is also covered by a separate Assurance of Confidentiality [308(d)]. For further information regarding the NCHS RDC, refer to Appendix L of this policy.

The restricted-access dataset does not contain personal identifiers such as a patient's name, street address, or Social Security number, as this information is not transmitted by central cancer registries to CDC as part of their annual data submission. However, the dataset may contain information that is potentially identifiable especially when linked with other datasets, such as the occurrence of a rare cancer in a person of a certain age or racial or ethnic group or living in a specific county. The data are made available to researchers through a SAS dataset specific to each project created by NCHS RDC staff. Researchers must include a data dictionary in their proposal, and only the requested variables are included in the SAS file.

Data Release Under Controlled Conditions

CDC policy stipulates that a CDC program may consider release data that cannot be released as a public web-based system, a research dataset, or a restricted-access dataset under certain controlled conditions.[18] These controlled conditions may include a CDC-controlled data center such as the NCHS RDC, on-site at CDC's Cancer Surveillance Branch offices, or through special licensing. NPCR-CSS data will not be released except as described above while this policy is in place. Release of data under controlled conditions will be considered in discussions with partners, and a determination will be made as to whether such releases of data will be considered for NPCR-CSS data.

Emergency and Provisional Data Releases

It is not anticipated that CDC will need to release NPCR-CSS data before the files have been modified as needed to protect confidentiality as described in this policy. This is prohibited by the 308(d) Assurance of Confidentiality (appendices B, H, and I).

Provisional data and draft data tables may be shared with CDC employees and contractors, NPCR central cancer registries, and other partners to facilitate data quality reviews. When appropriate, individuals who participate in such reviews sign an NPCR Analytic Data Use Agreement and a CDC Nondisclosure Agreement (when applicable) before accessing the data or tables.

Protection of Data

Assurance of Confidentiality

All data collected and maintained by NPCR-CSS must be managed, presented, published, and released with strict attention to confidentiality and security, consistent with the general principles and guidelines established by CDC for confidential case data[11,18-19] and specific restrictions imposed on NPCR-CSS data (appendices B, H, and I).[1] Special care must be given to cancer incidence data that are not directly identifiable because geographic and small cell data may be indirectly identifying when combined with detailed information in case reports, laboratory reports, medical records, or linkage with other data files.[12-17]

NPCR-CSS has approval for protection under section 308(d) of the Public Health Services (PHS) Act (42 U.S.C. 242m(d)) (appendices B, H, and I). The 308(d) confidentiality assurance protects identifiable and potentially identifiable information from being used for any purpose other than the purpose for which it was collected (unless the person or establishment from which it was obtained has consented to such use). This assurance protects against disclosures under a court order and provides protections that the Privacy Act of 1974 (5

U.S.C. 552a) does not. For example, the Privacy Act of 1974 protects individual participants, but the 308(d) confidentiality assurance also protects institutions. Confidentiality protection granted by CDC promises participants and institutions that their data will be shared only with those individuals and institutions listed in the project's consent form or in its specified policies.

Suppression of Rates and Counts

When the numbers of cases or deaths used to compute rates are small, those rates tend to have poor reliability. Another important reason for using a threshold value for suppressing cells is to protect the confidentiality of patients whose data are included in a report by reducing or eliminating the risk of disclosing their identity.

Therefore, to discourage misinterpretation or misuse of rates or counts that are unstable because case or death counts are small, annual incidence and death rates and counts in publicly available datasets and web-based query systems are suppressed if the case or death counts are below 16. A count of fewer than about 16 results in a standard error of the rate that is approximately 25% or more as large as the rate itself. Similarly, a case count below 16 results in the width of the 95% confidence interval around the rate being at least as large as the rate itself. These relationships were derived under the assumption of a Poisson process with the standard population age distribution assumed to be similar to the observed population age distribution. For aggregated time periods, counts and rates are suppressed for fewer than 16 cases.
However, average annual rates and counts may not be suppressed if the total case count for the time period exceeds 16.

The cell suppression threshold value of 16, which was selected to reduce misuse and misinterpretation of unstable rates and counts, is more than sufficient to protect patient confidentiality.

Per the Data Use Agreements, researchers using restricted-access data files are required to suppress count and statistical results that are based on cells with fewer than 6 cases in publications and presentations. Researchers are advised to use caution when presenting or interpreting results based on fewer than 16 cases.

Complementary cell suppression and suppression of certain race and ethnicity combinations are required as additional measures to assure patient confidentiality and rate stability.

Public Release Disclosure Statement

The following (or similar) public release disclosure statement is prominently displayed for users of all NPCR-CSS public web-based query systems, research datasets, and restricted-access datasets:

> *Data Use Restrictions: Read Carefully Before Using*
>
> ***By using these data, you signify your agreement to comply with the following statutorily based requirements.*** *The National Program of Cancer Registries (NPCR), Centers for Disease Control and Prevention (CDC), has obtained an assurance of confidentiality pursuant to Section 308(d) of the Public Health Service Act, 42 U.S.C. 242m(d). This assurance provides that identifiable or potentially identifiable data collected by the NPCR may be used only for the purpose for which they were obtained unless the person or establishment from which they were obtained has consented to such use. Any effort to determine the identity of any reported cases, or to use the information for any purpose other than statistical reporting and analysis, is a violation of the assurance.*
> *Therefore users will:*
>
> - *Use the data for statistical reporting and analysis only.*
> - *Make no attempt to learn the identity of any person or establishment included in these data.*
> - *Make no disclosure or other use of the identity of any person or establishment discovered inadvertently, and advise the Associate Director for Science, Office of Science Policy and Technology Transfer, CDC, Mailstop D-50, 1600 Clifton Road, N.E., Atlanta, Georgia, 30333, Phone: 404-639-7240 (or NCI's SEER Program if SEER data) and the relevant state, territory, or metropolitan area cancer registry of any such discovery.*

Freedom of Information Act (FOIA) Data Requests

The Freedom of Information Act (FOIA) (www.cdc.gov/od/foia/) generally provides that, upon written request from any person, a federal agency such as CDC must release any agency record unless that record falls (in whole or part) within one of nine exemptions. FOIA applies to federal agencies only and covers only records in the possession and control of those agencies at the time of the FOIA request (except in certain instances involving awardee-held data). Because state- and territory-based data become a federal record in

CDC's possession, such records are subject to disclosure in response to a FOIA request. The FOIA exemptions that may be available to protect some aspects of state and territory data from public disclosures in response to a FOIA request are:

- Exemption 3, which specifically exempts information from disclosure by statute; in this instance, pursuant to an Assurance of Confidentiality under Section 308(d) of the Public Health Service Act.

- Exemption 6, which exempts from disclosure personnel and medical files and similar files, which would constitute an unwarranted invasion of personal privacy.

In general, non-FOIA requests to CDC from the public, media, and other government agencies for local cancer incidence data are referred to the state health department for a reply for three reasons:

1. The state health departments can release cancer incidence data in accordance with local policies and procedures and consistent with provisions of the Cancer Registries Amendment Act (Public Health Service Act, (42 USC 280e-280e-4), as amended).[1]

2. The relative infrequency of data submission to federal agencies assures that the state or territory health department or its designated central cancer registry will have the most complete, accurate, and up-to-date information.

3. The central registry may be able to provide more detailed data that can better meet the needs of the requestor.

When the request is for data regarding cancer incidence involving more than one state or territory, CDC will refer the requestor to published reports or to NPCR-CSS datasets that are released in accordance with practices described in this document, if relevant.

External Data Requests

Individuals, agencies, or organizations outside CDC may request data not available from a public web-based query system or research dataset. When the requests do not identify a state or territory, CDC staff members or contractors tabulate the data for the inquirer. For requests that identify a state or territory, CDC staff members may seek states' or territories' permission regarding use. See Appendix N for additional details.

Researchers may submit data query or study proposal requests for the NPCR/SEER USCS Incidence Analytic Dataset to CDC. These requests must include:

- Names of individuals who will need access to the data.
- Purpose and public health significance of the investigation.
- Research question(s).
- Variables required beyond those in the freely available research data.
- Subset of cases needed (specific cancer type, data years, registries).
- Planned use of data, such as a manuscript, poster, or presentation.

After CDC authenticates the requestor's identity and research intent and verifies that confidentiality is maintained, a CDC analyst will process the data query and provide results to the researcher. The requestor must comply with all confidentiality and data suppression procedures outlined in the NPCR-CSS Assurance of Confidentiality [308(d)].

In circumstances where the researcher requires access to the USCS Analytic Datasets:

- CDC staff must be included in the analytic project as a co-author.
- Data Use Agreements must be signed.
- Assurance of Confidentiality training must be completed.
- Access is only allowed on-site at CDC's Cancer Surveillance Branch offices.

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Table 1: Comparison of the National Program of Cancer Registries-Cancer Surveillance System Datasets

Overview						
	Public Web-Based Query Systems				Analytic Datasets	
	USCS Data Visualizations Tool	**USCS WONDER[i]**	**USCS Data for Partners[ii]**	**NCEH's Tracking Network**	**USCS Public-Use Research Database**	**USCS Restricted-Access Dataset**
Format	Database of aggregate counts and rates, with text documentation	Database of aggregate counts and rates, with text documentation. The database behind the CDC firewall is case- specific microdata.	Database of aggregate counts and rates, with text documentation	Database of aggregate counts and rates, with text documentation. The database behind the CDC firewall is case-specific microdata.	Customized, analytic database. The database behind the SEER*Stat firewall is case-specific microdata with enforced cell suppression and case listing disabled.	Customized, analytic database available through proposal process
Mode of Access	Web-based query system with downloadable ASCII files	Web-based query system	Flat ASCII file, web-based query system, and separate brief text documentation	Web-based query system	SEER*Stat client- server mode only after receipt of signed Data Use Agreement	On-site at CDC or through CDC staff assistance
Web Address or Contact Information	Website www.cdc.gov/cancer/dataviz	CDC WONDER https://wonder.cdc.gov/cancer.html	Request from uscsdata@cdc.gov (specify "USCS County" in subject line)	National Environmental Public Health Tracking Program https://ephtracking.cdc.gov/	www.cdc.gov/cancer/public-use	Application process available at www.cdc.gov/rdc
Contains Potentially Identifiable Information?	No	No	No	No	No	Yes
Registry Eligibility Criteria for Data Completeness and Quality	USCS publication criteria	USCS publication criteria	USCS publication criteria; data meet criteria for unknown county	USCS publication criteria; data meet criteria for unknown county	USCS publication criteria	USCS publication criteria; data meet criteria for unknown county
When Available	Updated 2022	Updated 2022	Updated 2022	Updated 2022	Updated 2022	Updated 2022

[i] This data file is also shared with OWH.
[ii] This data file is shared with CDI and AHRQ.

Table 1 continued

Cases Included						
	Public Web-Based Query Systems				Analytic Datasets	
	USCS Data Visualizations Tool	**USCS WONDER**	**NPCR/SEER USCS County**	**NCEH's Tracking Network**	**USCS Public-Use Research Database**	**USCS Restricted-Access Dataset**
States/ Territories	NPCR/SEER states and territories meeting eligibility criteria		NPCR/SEER states and territories meeting eligibility criteria	NPCR states and territories meeting eligibility criteria	NPCR/SEER states and territories meeting eligibility criteria	NPCR states and territories meeting eligibility criteria
Diagnosis Years	1999; 2000; 2001; 2002; 2003; 2004; 2005; 2006; 2007; 2008; 2009; 2010; 2011; 2012; 2013; 2014; 2015; 2016; 2017; 2018; 2019; 2015-2019; 2020 preliminary results	1999; 2000; 2001; 2002; 2003; 2004; 2005; 2006; 2007; 2008; 2009; 2010; 2011; 2012; 2013; 2014; 2015; 2016; 2017; 2018; 2019	2015 –2019	Individual years 2001 through 2019 for state level; 5-year increments for county level; 10-year increments for DCPC melanoma dashboard; 3-, 5-, 7- and 10-year increments for sub-county level	2001; 2002; 2003; 2004; 2005; 2006; 2007; 2008; 2009; 2010; 2011; 2012; 2013; 2014; 2015; 2016; 2017; 2018; 2019	1999; 2000; 2001; 2002; 2003; 2004; 2005; 2006; 2007; 2008; 2009; 2010; 2011; 2012; 2013; 2014; 2015; 2016; 2017; 2018; 2019
Cancer Sites	All reportable invasive cancers; *in situ* female breast, *in situ* male and female breast, and benign and borderline primary intracranial and central nervous system tumors (diagnosis year 2004)	All reportable invasive cancers; *in situ* female breast, *in situ* male and female breast, and benign and borderline primary intracranial and central nervous system tumors (diagnosis year 2004)	All reportable cancer sites combined; female breast; *in situ* female breast; cervix uteri; colon and rectum; lung and bronchus; melanoma; bladder; prostate; oral cavity and pharynx; brain and other nervous system; thyroid; kidney and renal pelvis; stomach; ovary; corpus and uterus, not otherwise specified; leukemias; non-Hodgkin lymphoma; liver and intrahepatic bile duct; pancreas, esophagus; and childhood cancers	Female breast; late- stage female breast; lung and bronchus; bladder; brain and other nervous system; thyroid; leukemias (all types; acute myeloid leukemia; chronic lymphocytic leukemia); non-Hodgkin lymphoma; all childhood cancers combined (state or territory level only); childhood leukemias (state or territory level only); childhood central nervous system and miscellaneous intercranial and intraspinal neoplasms (state or territory level only); mesothelioma (state or territory level only); kidney and renal pelvis; prostate; melanoma of skin; liver and intrahepatic bile duct; pancreas; oral cavity and pharynx; esophagus; larynx; testis; colon and rectum	All reportable invasive cancers; *in situ* female breast, and benign and borderline primary intracranial and central nervous system tumors (diagnosis year 2004)	All reportable invasive and *in situ* cancers and benign and borderline primary intracranial and central nervous system tumors (diagnosis year 2004)

Table 1 continued

Variables Included						
	Public Web-Based Query Systems				Analytic Datasets	
	USCS Data Visualizations Tool	USCS WONDER	USCS Data for Partners	NCEH's Tracking Network	USCS Public-Use Research Database	USCS Restricted-Access Dataset
Geographic Levels	All areas combined; NPCR/SEER state, territory, congressional districts, county; SEER metropolitan area, IHS regions (AI/AN data only)	All areas combined; NPCR and SEER state or territory; county; region; MSA for cities of ≥500,000 (additional levels may be added)	NPCR and SEER state or territory; county	NPCR and SEER state; county; sub-county (to include census tract, 5,000, and 20,000 aggregations)	All areas combined; U.S. census region; NPCR and SEER state or territory	NPCR and SEER state or territory; county for approved requests only
Race/Ethnicity	All races combined; White; Black; Asian/Pacific Islander (A/PI); American Indian/Alaska Native (AI/AN); Hispanic; White Hispanic; White non-Hispanic; Black Hispanic; Black non-Hispanic		All races combined; White; Black; AI/AN; A/PI; Hispanic; White Hispanic; White non-Hispanic; Black Hispanic; Black non-Hispanic	All races combined; White; Black; AI/AN; A/PI; Hispanic; White non-Hispanic; White-Hispanic. (Sub- county displayed for all races combined)	All races combined; White; Black; A/PI; AI/AN; Hispanic; White Hispanic; White non-Hispanic; Black Hispanic; Black non-Hispanic	All races reported; Hispanic; White Hispanic; White non-Hispanic; Black Hispanic; Black non-Hispanic
Age Groups	All ages combined and standard 5-year age groups for adults and <15, <20, and 5-year age groups for childhood cancers	All ages combined and standard 5- year age groups that can be combined by the user	Childhood cancers: <15 and <20; all other cancers: <50, 50–64, 65+	Childhood cancers: <15 and <20 Breast cancer: <50, 50+	All ages combined, standard 5-year age groups	Standard 5-year age groups and individual ages. Month and day of birth are not provided for confidentiality reasons. If the age at diagnosis is >99, then grouped into one category. Year of birth is also grouped.
Summary Stage	Yes (localized, regional, distant, and unknown or unstaged)	Yes	No	Yes (late-stage screening-amenable cancers)	Yes	Yes
Histology	International Classification of Childhood Cancers, Third Revision (all geographic areas combined), mesothelioma (national and state or territory level), Kaposi sarcoma (national and state or territory level), Consensus Conference on Cancer Registration of Brain, and central nervous system tumors (all geographic areas combined)	Same as USCS Data Visualizations tool	No	No	Same as USCS Data Visualizations tool	Yes

Table 1 continued

Confidentiality Protection and Disclosure Limitation Measures Employed					
	Public Web-Based Query Systems			Analytic Datasets	
	USCS Data Visualizations Tool and USCS WONDER	NPCR/SEER USCS County	Tracking Network	USCS Public-Use Research Database	USCS Restricted-Access Dataset
Direct or Record-Level Identifiers?	No	No	No	No	Yes, but not in output which will be reviewed by CDC staff for confidentiality
Aggregation	Yes	Yes	Yes	No	No
Limited Number of Variables?	Yes	Yes	Yes	Yes	Yes
Grouping or Collapsing of Variables or Response Codes such as race and age recode	Yes	No	Yes	Yes	Yes
(1) Average Annual Counts Rounded to the Nearest Whole Number **(2) Average Annual Rates** **(3) Annual Averages Are Based on At Least 5 Years of Data**	No	Yes	Yes	No	No
Cell Suppression	Yes: Counts and rates: count of fewer than 16	Yes: Counts and rates: 5-year total count of <16	Yes: Counts and unsmoothed rates: count of few than 16 or RSE greater than the limit (25% for state or territory and county- level, 30% for sub-county level) Smoothed rates: RSE greater than the limit (25% for state or territory and county-level, 30% for sub-county level)	Yes: Counts and rates: count of fewer than 16 enforced, case listing disabled	Yes (output reviewed by CDC analyst to ensure counts of fewer than 6 are suppressed)
Complementary Cell Suppression	As needed	As needed	As needed	As needed	As needed
Public Release Disclosure Statement	Yes	Yes	Yes	Yes	Yes
Data Sharing Agreement and IRB Approval	No	No	No	Yes	Yes
User Authentication	No	No	No	No	Yes
Logging and Monitoring	Limited	Limited	Limited	Yes, monitoring databases used, session type and date only	Yes

Appendix A: State and Metro Area Cancer Registries

State, Metropolitan Area, and Territory Cancer Registries by Federal Funding Source, and First Diagnosis Year* for Which Cancer Cases Were Reportable to CDC's NPCR or NCI's SEER Program

State, Metropolitan Area, or Territory	First Diagnosis Year for Which Cancer Cases Were Reportable to NPCR or SEER*	Federal Funding Source
Alabama	1996	NPCR
Alaska	1996	NPCR
Arizona	1995	NPCR
Arkansas	1996	NPCR
California	1995/2000	NPCR and SEER
Los Angeles	1992	SEER
San Francisco-Oakland	1973	SEER
San Jose-Monterey	1992	SEER
Colorado	1995	NPCR
Connecticut	1973	SEER
Delaware	1997	NPCR
District of Columbia	1996	NPCR
Florida	1995	NPCR
Georgia	1995/2010	NPCR and SEER
Atlanta	1975	SEER
Hawaii	1973	SEER
Idaho	1995/2018	NPCR and SEER
Illinois	1995/2022	NPCR and SEER
Indiana	1995	NPCR
Iowa	1973	SEER
Kansas	1995	NPCR
Kentucky	1995/2000	NPCR and SEER
Louisiana	1995/2000	NPCR and SEER
Maine	1995	NPCR
Maryland	1996	NPCR
Massachusetts	1995/2018	NPCR and SEER
Michigan	1995	NPCR
Detroit	1973	SEER
Minnesota	1995	NPCR
Mississippi	1996	NPCR
Missouri	1996	NPCR
Montana	1995	NPCR
Nebraska	1995	NPCR
Nevada	1995	NPCR
New Hampshire	1995	NPCR

State, Metropolitan Area, or Territory	First Diagnosis Year for Which Cancer Cases Were Reportable to NPCR or SEER*	Federal Funding Source
New Jersey	1995/2000	NPCR and SEER
New Mexico	1973	SEER
New York	1996/2018	NPCR and SEER
North Carolina	1995	NPCR
North Dakota	1997	NPCR
Ohio	1996	NPCR
Oklahoma	1997	NPCR
Oregon	1996	NPCR
Pennsylvania	1995	NPCR
Puerto Rico	1998	NPCR
Rhode Island	1995	NPCR
South Carolina	1996	NPCR
South Dakota	2000	NPCR
Tennessee	1999	NPCR
Texas	1995/2022	NPCR and SEER
U.S. Pacific Island Jurisdictions	2007	NPCR
Utah	1973/2016	SEER and NPCR
Vermont	1996	NPCR
Virginia	1996	NPCR
U.S. Virgin Islands	2016	NPCR
Washington	1995	NPCR
Seattle-Puget Sound	1974	SEER
West Virginia	1995	NPCR
Wisconsin**	1995	NPCR and SEER
Wyoming	1996	NPCR

* Diagnosis year is the year during which a reported cancer case was first diagnosed.

** Wisconsin receives research support from SEER but is not under contract to submit data. CDC = Centers for Disease Control and Prevention

NCI = National Cancer Institute

NPCR = National Program of Cancer Registries

SEER = Surveillance, Epidemiology, and End Results Program

Appendix B: NPCR-CSS Overview of Data Security

The NPCR-CSS project data reside on a dedicated server maintained by the NPCR-CSS contractor. To ensure the security and confidentiality of project data, the following provisions have been incorporated into the NPCR-CSS Security Plan in accordance with the requirements of the Assurance of Confidentiality.

The NPCR-CSS server is housed in a secure facility with a guard on duty 24 hours a day. Only authorized staff are allowed to access the facility. Support people are escorted by an authorized staff member if needed. The server resides on its own local area network (LAN) behind the NPCR-CSS contractor's firewall. NPCR-CSS contractor project staff access the server via a virtual private network (VPN) from their primary office location. Elevator and stairwell access is controlled by card key 24 hours. During business hours, an attendant is always present at the reception desk to guide visitors.

- Access to the NPCR-CSS server is limited to authorized NPCR-CSS contractor project staff. It is password- protected on its own security domain. No one else is allowed access to the NPCR-CSS data.
- All NPCR-CSS contractor project staff must sign a confidentiality agreement before passwords and keys are assigned. All staff must pass background checks appropriate to their responsibilities for a public trust position.
- NPCR-CSS data that are submitted electronically are encrypted during transmission from awardees. They arrive on a document server behind the NPCR-CSS contractor's firewall. Each state or territory has its own directory location so that no state or territory has access to another state or territory's data. The data are moved automatically from the document server to the NPCR-CSS server.
- Receipt and processing logs are maintained to document data receipt, file processing, and report production. All reports and electronic storage media containing NPCR-CSS data are stored under lock and key when not in use and will be destroyed when they are no longer needed.
- The NPCR-CSS contractor's security team has developed a comprehensive security plan. The security team consists of the Project Director, Project Manager, Systems Lead and Security Officer, Database Administrator, and LAN/WAN Security Steward. All project staff receive annual security awareness training covering security procedures. The security team oversees operations to prevent unauthorized disclosure of the NPCR-CSS data.
- Periodic (currently quarterly, but at least once per year) reviews and updates of the NPCR-CSS contractor's security processes are conducted to adjust for rapid changes in computer technology and to incorporate advances in security approaches. The security plan is amended as needed to maintain the continued security and confidentiality of NPCR-CSS data.

Appendix C: Data Items for CBTRUS

The dataset for CBTRUS includes individual case-specific data from the NPCR-CSS dataset. The data items included are listed below.

*Diagnosis years 1995 through 2003 invasive cases only, 2004 or later invasive, benign, and borderline cases

Item Name	NAACCR Data Item Number	Comments
Patient ID (unique)	20	
NAACCR Record Version	50	
State of Residence at Diagnosis	80	
County at Diagnosis-Analysis	89	Results presented as 5-year average annual rates as the smallest time period with <16 cell and complementary cell suppression required
Rural/Urban Continuum/Beale Code 2003	3310	
Rural/Urban Continuum/Beale Code 2013	3312	
NPCR Race Recode	Derived based on [160], [161], and [192]	Same as race for USCS
NHIAv2 Derived Hispanic Origin (Results of NAACCR Hispanic/Latino Identification Algorithm)	191	
NAPIIA	193	
Sex	220	
Age at Diagnosis	230	Single year up to age 84; 85+ grouped into one category
Sequence Number—Central	380	
Date of Diagnosis (*YEAR portion only*)	390	Day and month of diagnosis not requested
Date of Diagnosis (full date)	390	Full date
Primary Site	400	
Laterality	410	
Grade	440	
Diagnostic Confirmation	490	
Type of Reporting Source	500	
Histologic Type (ICD-O-3)	522	
Behavior (ICD-O-3)	523	
SEER Summary Stage 1977	760	
SEER Summary Stage 2000	759	
Derived Summary Stage 2000	3020	
NPCR Cancer Stage		Based on 759 and 3020
RX Summ--Surgery Primary Site	1290	≥2003 diagnosis years
Reason for no surgery	1340	≥2001 diagnosis years
RX Summ—Radiation	1360	≥2003 diagnosis years
RX Summ--Chemo	1390	2006–2011, ≥2015 diagnosis years
RX Summ--BRM	1410	Prior to 2006, reported as available
Rad–Regional RX Modality	1570	≥2003 diagnosis years
Merged Radiation		Based on 1360 and 1570 1 = had radiation 2 = did not have radiation 3 = patient or guardian refused radiation 4 = radiation recommended but unknown if received Applied only for selection below: **8000**≤I522_HistTypeICDO3≤**9049** | **9056**≤I522_HistTypeICDO3≤**9139** | **9141**≤I522_HistTypeICDO3≤**9589**
EDITS overrides	1990–2074	

Item Name	NAACCR Data Item Number	Comments
CS Site-Specific Factor 1	2880	WHO Grade
Date of Last Contact	1750	
Vital Status	1760	Diagnosis years 2001–2018 for states included in the NPCR RSA file. Cause of Death items (1910, 1914, 1915) are not included when review has determined that high-quality cause of death information is not available for specific states or territories.
Vital Status Recode	1762	
Record Number Recode	1775	
Surv-Date Active Followup	1782	
Surv-Flag Active Followup	1783	
Survival Months Active Followup	1784	
Surv-Date Presumed Alive	1785	
Surv-Flag Presumed Alive	1786	
Survival Months Presumed Alive	1787	
Surv-Date Dx Recode	1788	
Follow-Up Source	1790	
Follow-Up Source Central	1791	
Cause of Death	1910	
SEER Cause-Specific COD	1914	
SEER Other COD	1915	
ICD Revision Number	1920	

Appendix D: NPCR/SEER USCS Analytic Data Use Agreement

U.S Cancer Statistics Analytic Data

Submitted [Month, Year] (diagnosis years 1998–xxxx)

To protect the confidentiality of the individuals represented within the National Program of Cancer Registries – Cancer Surveillance System (NPCR-CSS) data, the Centers for Disease Control and Prevention (CDC) has obtained an Assurance of Confidentiality under Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)), which provides that these data can only be used for the purpose for which they were obtained.

When using NPCR and U.S. Cancer Statistics analytic data for research purposes, it is necessary to ensure, to the extent possible, that use of the data will be limited to research or public health purposes. In accordance with applicable federal law, there must be no attempt to determine the identity of individuals represented by reported cases, or to use the information for any purpose other than for health statistical reporting and analysis.

CDC's Division of Cancer Prevention and Control (DCPC) takes every possible measure to ensure that the identity of data subjects cannot be determined. All direct identifiers, as well as characteristics that might lead to identification of individuals, are omitted from the dataset. Certain demographic and clinical information have been included for research purposes; thus, all results must be presented or published in a manner that ensures that no individual can be identified. In addition, there must be no attempt to identify individuals from any computer file or to link with a computer file containing patient identifiers.

Data users must agree to the following provisions before receiving access to U.S. Cancer Statistics Incidence, U.S. Cancer Statistics Delay-Adjusted, NPCR Prevalence, and NPCR Survival Analytic Data. *Please initial after each statement to indicate agreement.*

As the recipient of the U.S. Cancer Statistics Incidence (diagnosis years {year}–{year}), U.S. Cancer Statistics Delay-Adjusted (diagnosis years {year}–{year}), NPCR Prevalence (diagnosis years {year}–{year}), and NPCR Survival Analytic Data (diagnosis years {year}–{year}):

- I will adhere to the requirements of the Data Use Agreement and understand that my access to the data will be revoked if these requirements are violated. **Initials:** _____
- I understand that NPCR data belong to the states and territories. The states' and territories' agreement to use of the data are obtained through the activities outlined in the general NPCR-CSS Data Release Policy and by specific requests to the states and territories through the management team of DCPC's Cancer Surveillance Branch. **Initials:** _
- I will not use or permit others to use the datasets in any way other than for statistical reporting and analysis.
  5. **Initials:** _____
- I will not release or permit others to release the datasets or any part of them to any person except with DCPC's written approval. **Initials:** _____
- I will not attempt to link or permit others to link the datasets with individually identifiable records from any other dataset without DCPC's approval. **Initials:** _____
- I will not access nor permit others to access (directly or remotely) the data outside the United States.
  6. **Initials:** _____
- I will not attempt to use the datasets or permit others to use them to learn the identity of any person or establishment included in any dataset. **Initials:** _____
- I will protect the data file(s) I receive with a password or encryption. In addition, any temporary or permanent analysis files, such as those produced with analytic software, will be protected in the same manner(s).
  7. **Initials:** _____
- I will take the following actions if the identity of any person or establishment is discovered inadvertently:
  - Make no use of this knowledge.
  - Notify DCPC's Internal Data Users Group by emailing npcridug@cdc.gov.
  - As requested by DCPC, safeguard or destroy the information that identifies an individual or establishment.
  - Inform no one else of the discovered identity. **Initials:** _____

- In addition, I will make every effort to release all statistical information in such a way as to avoid inadvertent disclosure. In order to do this:
  - I agree that all oral or written reports will contain only aggregate data and I will not report counts of fewer than 6 cases or statistics generated from fewer than 6 cases. **Initials:** _____
  - I understand that calculating rates or other statistics based on small numbers can raise statistical issues concerning stability and confidentiality. I will use appropriate caution when presenting and interpreting results based on fewer than 16 cases. **Initials:** _____
  - I will use complementary cell suppression to ensure that no data on an identifiable case can be derived through subtraction or other calculation from the combination of tables in all oral and written presentations. **Initials:** __
- I have completed the Assurance of Confidentiality Overview Course (https://intranet.cdc.gov/os/osi/pcu/aoc/training/) available through HHS Learning Portal and have e-mailed my certificate of completion to npcridug@cdc.gov. **Initials:** _____
- I have added my project to the NPCR Internal Analysis SharePoint table and, if applicable, I will notify and obtain permission from the Internal Data Users Group to analyze state- and county-level data. **Initials:** _____
- I will acknowledge central cancer registries whenever data are presented, released, or published by including the following (or similar) statement:

  These data were provided by central cancer registries participating in the National Program of Cancer Registries (NPCR) and submitted to CDC in November {year}, and the Surveillance, Epidemiology and End Results (SEER) program and submitted to NCI in November {year}. The U.S. Cancer Statistics Incidence Analytic dataset includes diagnosis years {year}–{year} (excluding SEER-Metro Registry data);
  U.S. Cancer Statistics Delay Adjusted Analytic dataset includes diagnosis years {year}–{year} (excluding SEER-Metro Registry data), NPCR Prevalence Analytic dataset includes diagnosis years {year}–{year} and the NPCR Survival Analytic dataset includes diagnosis years {year}–{year}. **Initials:** _____
- As appropriate, I will cite the data:

  *National Program of Cancer Registries SEER*Stat Database: {Database file name} – {year}–{year}. United States Department of Health and Human Services, Centers for Disease Control and Prevention. Released {date}, based on the November {year} submission.* **Initials:** _____
- I understand that if I require technical assistance in analyzing or interpreting the data and when such assistance goes beyond providing non-manipulated data, IDUG members reserve the right to request to be considered as a research collaborator or co-author in any resulting publications or presentations. **Initials:** _____
- I will provide a courtesy copy of papers or abstracts to the NPCR Internal Data Users Group at npcridug@cdc.gov as they are entered into eClearance. **Initials:** _____
- I am familiar with the use of **SEER*Stat** in analyzing data or will complete the needed training. **Initials:** _____

If you are requesting access to a U.S. Cancer Statistics database, you must first set-up SEER Research Plus (https://seer.cancer.gov/data/access.html) access as the database includes SEER data.

After you have access to SEER Research Plus, complete the fields below, sign and date the agreement, and e- mail all pages to npcridug@cdc.gov.

The e-mail address you provide must be the same one used during the SEER Research Plus verification process.

My signature below indicates that I agree to comply with all the above stated provisions.

_____

Signature Date

Name:_____

Title_____

Branch_____

Telephone_____ E-mail:_____

Appendix E: CDC Non-Disclosure Agreement

Nondisclosure Agreement for Data Covered by an Assurance of Confidentiality

For use with CDC employees involved in activities with information covered by a Section 308(d) Assurance of Confidentiality

The success of CDC's operations depends upon the voluntary cooperation of establishments, including states and territories, and of persons who provide information requested by CDC programs under an assurance that such information will be kept confidential and be used only for epidemiological or statistical purposes.

When confidentiality is authorized, CDC operates under the restrictions of Section 308(d) of the Public Health Service Act (42 U.S.C. §242m(d)), which provides in summary that no information obtained in the course of its activities may be used for any purpose other than the purpose for which it was supplied, and that such information may not be published or released in a manner in which the establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented. As a CDC employee granted access to information covered by Section 308(d), I understand and acknowledge that I am bound to comply with the restrictions provided to the information under Section 308(d).

I am aware that unauthorized disclosure of information covered by Section 308(d) of the Public Health Service Act may subject me to disciplinary action.

"I am aware that unauthorized disclosure of confidential information is punishable under Title 18, Section 1905 of the U.S. Code, which reads, in relevant part:

'Whoever, being an officer or employee of the United States or of any department or agency thereof…publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined not more than $1,000, or imprisoned not more than one year, or both; and shall be removed from office or employment.'

"I understand that unauthorized disclosure of confidential information is also punishable under the Privacy Act of 1974, Subsection 552a (i) (1), which reads:

'Any officer or employee of any agency, who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by this section or by rules or regulations established thereunder, and who knowing that disclosure of the specific material is so prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000.'

These provisions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by existing statute or Executive order relating to (1) classified information, (2) communications to Congress, (3) the reporting to an Inspector General of a violation of any law, rule, or regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, or (4) any other whistleblower protection. The definitions, requirements, obligations, rights, sanctions, and liabilities created by controlling Executive orders and statutory provisions are incorporated into this agreement and are controlling.

'My signature below indicates that I have read, understood, and agreed to comply with the above statements.

Typed/Printed Name	Signature	Date

Center/Institute/Office

Non-Employee 308(d) Pledge of Confidentiality

For use when non-CDC employees are provided access to data covered by a 308(d) Assurance of Confidentiality

I, as a non-CDC Employee (e.g., Guest Researcher, Visiting Fellow, Student, Trainee, employee of a federal agency other than CDC, etc.) may be given access to information that is identifiable or potentially identifiable to a person and that is covered by Section 308(d) of the Public Health Service Act (42 U.S.C. §242m(d)), or an Assurance of Confidentiality. As a condition of this access, I am required to comply with the following safeguards for the protection of this covered data.

1. I agree to be bound by the following assurance:

   In accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. §242m(d)), I agree that no information obtained in the course of the activity described in the Assurance of Confidentiality will be used for any purpose other than the purpose for which it was supplied, unless I am informed in writing that such person has consented to its use for such other purposes. Further, I agree that no information obtained in the course of the activity described in the Assurance of Confidentiality will be disclosed in a manner in which the establishment or person supplying the information or described in it is identifiable, unless I am informed in writing that the establishment or person has consented to such disclosure, to anyone other than authorized staff of CDC or staff covered under this 308(d) Assurance.

2. I agree to maintain the following safeguards to assure that confidentiality is protected and to provide for the physical security of the records:

   To preclude observation of confidential information by persons not authorized to have access to the information on the project, I shall maintain all records that I am provided access to that identify establishments or persons covered by this Assurance of Confidentiality or from which establishments or persons covered by this Assurance of Confidentiality could be identified in locked containers or protected computer files when not under immediate supervision by me or another authorized member of the project. The keys or means of access to these containers or files are not to be given to anyone other than those authorized to have access. I further agree to abide by any additional requirements imposed by CDC for safeguarding the identity of establishments or persons covered by this Assurance of Confidentiality.

My signature below indicates that I have carefully read and understand this agreement and the Assurance of Confidentiality, which pertains to the confidential nature of this project. As a(n) _____ (for example, visiting scientist, guest researcher, fellow, trainee, employee of a federal agency other than CDC), I understand that I am prohibited from disclosing any such confidential information that has been obtained under this project to anyone other than authorized staff of CDC or persons covered under this Section308(d) Assurance of Confidentiality. I understand that any disclosure in violation of this Confidentiality Pledge may lead to termination of my employment, fellowship, training experience, or scientific collaboration, as well as other penalties.

_____

Printed Name

_____

Signature

_____

Date

Agreement of CDC Contractors for Safeguards Against Invasions of Privacy for Certain Establishments or Persons Covered by an Assurance of Confidentiality

For use when contractors or subcontracts have access to information covered by a 308(d) Assurance of Confidentiality

Access to data covered by an Assurance of Confidentially, titled Assurance of Confidentiality for the National Program of Cancer Registries Cancer Surveillance System, ("Assurance") as provided by Section 308(d) of the Public Health Service Act (42 U.S.C. §242m(d)), is necessary for certain projects funded through contract task order number _____. Consistent with Section 308(d), the contractor is required to give an assurance of confidentiality and to provide for safeguards to assure that confidentiality of the data covered by the Assurance is maintained.

To provide this assurance and these safeguards in performance of the contract, the contractor shall

1. Be bound by the following assurances:

   a. No information that is identifiable or potentially identifiable to an establishment or person covered by the Assurance and obtained in the course of this activity may be used for any purpose other than the purpose for which it was supplied, unless CDC informs contractor in writing that such establishment or person has consented to its use for such other purposes.

   b. No information that is identifiable or potentially identifiable to an establishment or person covered by the Assurance and obtained in the course of this activity may be disclosed to anyone other than authorized staff of CDC or others noted in the Assurance, unless CDC informs contractor in writing that such establishment or person has consented to its disclosure to such other persons.

   c. No preliminary data from studies or projects that identifies or potentially identifies an establishment or person covered by the Assurance may be disclosed to anyone other than authorized staff of CDC or others noted in the Assurance of Confidentiality statement, unless this information is otherwise in the public domain or CDC has provided written permission for use of this information to be made public. For example, if CDC clears an abstract for a scientific presentation, this constitutes permission for public presentation.

   d. New research study ideas that are not already funded through the above-referenced contract task order may be discussed or presented during calls/meetings as part of normal communications and coordination between CDC and the contractor; should these ideas lead to further activities with information covered by this Assurance, these protections will extend to those activities only if agreed to in writing by CDC.

2. Maintain the following safeguards to assure that the confidentiality provided by Section 308(d) and the Assurance is protected by the contractor and to provide for the physical security of the records:

   a. After having read the above Assurance, each employee of the contractor participating in this project is to sign the following pledge of confidentiality:

      I have carefully read and understand the CDC assurance, which pertains to the confidential nature of identifiable or potentially identifiable data covered by the Assurance of Confidentiality to be handled in regard to these studies and reviewed as part of activities under task order _____. As an employee of the contractor, I understand that I am prohibited by law from disclosing any such confidential information that identifies or potentially identifies an establishment or person covered by the Assurance of Confidentiality, which has been obtained under the terms of this contract, to anyone other than authorized staff of CDC and that I may use this information only for the purposes for which it was obtained and consistent with the task order.

   b. To preclude observation of confidential information that identifies or potentially identifies an establishment or person covered by the Assurance by persons not employed on the project, the contractor shall maintain all confidential records that identify establishments or persons or from which establishments or persons could be identified under lock and key.

      Specifically, at each site where these items are processed or maintained, all confidential records that will permit identification of establishments or persons are to be kept in locked containers when not in use by the contractor's employees.

The keys or means of access to these containers are to be held by a limited number of the contractor staff at each site. When confidential records that will permit identification of establishments or persons are being used in a room, admittance to the room is to be restricted to employees pledged to confidentiality and employed on this project. If at any time the contractor's employees are absent from the room, it is to be locked.

c. The contractor and his professional staff will take steps to ensure that the intent of the pledge of confidentiality is enforced at all times through appropriate qualifications standards for all personnel working on this project and through adequate training and periodic follow-up procedures.

3. Flow down all requirements set forth in this Agreement to all subcontracts and all subcontract employees.

_____
(Typed/printed Name)

_____
(Signature)

_____
(Date)

CONFIDENTIALITY AGREEMENT for Access to Information Technology Resources at the Centers for Disease Control and Prevention and Limitation on Disclosure of Sensitive Information Under

Contract Number _____, Task Order

As an employee or subcontractor of _____, **THE PARTICIPANT** requires a wide range of access to confidential information and Federal information technology (IT) resources and information maintained by the Centers for Disease Control and Prevention (**CDC**), an agency of the U.S. Department of Health and Human Services.

In consideration for the following mutual covenants, the parties agree as follows:

1. Within the context of CDC Contract Number _____, Task Order _____, and in accordance with the terms of this agreement, **CDC** grants limited access to the following:
   a. The Federal information technology (IT) resources generally described in Table 1.

   b. Datasets and public use data tapes derived from information collected under an Assurance of Confidentiality authorized by Section 308(d) of the Public Health Service Act, also listed in Table 1.

2. **THE PARTICIPANT** acknowledges that within the CDC environment, a variety of restricted access information is held, the vast bulk of which is categorized as "Sensitive but Unclassified", and that in the performance of CDC Contract Number ___, Task Order _____, the participant may require access to such limited access information. Categories of limited access information include the following:
   - Health & health-related data on individuals, groups, entities, some of which identify individuals
   - Federal Privacy Act "systems of records"
   - Information exempted from release under Freedom of Information Act
   - Proprietary data
   - National Defense-related information
   - Information subject to contractual restrictions on access
   - Information covered by a Certificate or Assurance of Confidentiality [P.H.S. Act, Sects. 301(d) & 308(d)]
   - Data collected under other specific legislative mandates (i.e. tobacco, transfer of biological, etc.)
   - Data identified as pre-release, internal working papers, etc., of federal agency

Therefore, **THE PARTICIPANT** further agrees to not attempt to identify any person contained in contract data and to make no use of the identity of any person or establishment discovered inadvertently and advise **CDC** of any such discovery.

3. **THE PARTICIPANT** acknowledges the sensitive and confidential nature of the information covered by this agreement and agrees to employ all reasonable efforts to maintain such information secret and confidential, such efforts to be no less than the degree of care employed by ICF Incorporated to preserve and safeguard ICF Incorporated's own information.

4. **THE PARTICIPANT** agrees to utilize any information accessed through the performance of CDC Contract Number _____, Task Order _____ solely for the purpose of performing that Contract;

5. **THE PARTICIPANT** has read and agrees to be bound by CDC policies and standards regarding confidentiality and use of Federal IT resources. Further, **THE PARTICIPANT** agrees to attend one hour of training by **CDC** on information security and the use of IT resources at **CDC**.

6. **THE PARTICIPANT** agrees to refrain from any of the following prohibited uses:
   a. Disclosing, revealing, or giving to anyone information accessed under CDC Contract Number _____, Task Order _____ except to employees of ICF Incorporated who have a need for the information and who are bound to it by like obligation as to confidentiality, without the express written permission of **CDC**.

   b. Attempting to override or avoid security and integrity procedures and devices established by **CDC**, or its components, to control access to federal IT resources.

   c. Attempting to override or avoid security and integrity procedures and devices established by outside organizations to control access to their information systems and IT resources.

d. Using hardware or software or downloading software within the scope of the project that is not specifically authorized in writing by the Project Officer.

e. Violating copyrights or software licensing agreements.

f. Using CDC's name or logos to misrepresent, as falling under CDC auspices, personal materials, or materials one produces on behalf of an approved group.

7. Upon expiration of this Agreement or CDC Contract Number _____, Task Order _____, **THE PARTICIPANT** agrees to destroy or return to CDC any information accessed through the performance of contract that falls under one or more of the categories listed under paragraph 2 above and that was copied, printed, or otherwise duplicated.

8. **CDC** has the capability and the authority to audit its federal IT resources, and under appropriate circumstances, monitor their use.

9. **CDC** may terminate this access with or without cause at any time without advance notice.

10. **THE PARTICIPANT'S** authorized access automatically expires at the end of the contract period, or sooner if so indicated in the space at the top of Table 1. A written renewal request must be submitted *two months* prior to the termination, with appropriate justification for each access to be continued. A new Agreement for Access and Limitation on Disclosure is required for each renewal.

11. The construction, interpretation, and performance of this Agreement shall be governed by U.S. Federal law.

    Violations of this agreement or misuse of CDC's federal IT resources may subject **THE PARTICIPANT** to criminal penalties in accordance with Federal law (attached). In addition, **THE PARTICIPANT** understands that other Federal laws and regulations govern CDC's maintenance and operation of these Federal IT resources and may apply to **THE PARTICIPANT**.

12. I have read, understood, and agree to comply with the above statements.

_____	_____
Print Name: Last, First, Middle Initial (Person Requesting Access)	Print Name: Last, First, Middle Initial (Contractor's Official Witness)
_____	_____
Position	Position
_____	_____
Signature	Signature
_____	_____
Date (month, day, and year)	Date (month, day, and year)

CDC Point of Contact (Technical Monitor or Project Officer):

_____
Print Name: Last, First, Middle Initial

_____
Position

_____
Signature

_____
Date (month, day, and year)

Copies of the following CDC policy statements are to be provided to each person requesting access.

Laws, Policies and Procedures Governing Use of Electronic Mail, Intranet, Internet and Other Information Technology (IT) ADP Security Policy (Manual Guide-Information Resources Management, No. CDC-3, 3/15/89) 18 U.S.C. Sections 641 and 1030.

Table 1. Federal Information Resources Authorized

Federal IT Resource Name or Description	Location	Authorizing Official(s)
Main point of entry to CDC IT resources: Information Resources Management Office		None authorized
Other LAN account(s)		None authorized
CDC mainframe account		None authorized
CDC e-mail account		None authorized
Internet access		None authorized
CDC Intranet access		None authorized
Cancer incidence data from awardees funded by CDC's Program Announcement DP17-1701 for a cooperative agreement under for the National Program of Cancer Registries		CDC Contracting Officer's Representative CDC Project Officer
Mortality data from the National Center for Health Statistics (NCHS)[1]		NCHS
Population data from the U.S. Census Bureau		Data publicly available on Internet

[1]By signing this agreement, THE PARTICIANT agrees to abide by the conditions stipulated by NCHS in the NCHS Data Use Agreement.

Access to a specific resource does not imply access to any other resource.

Appendix 8

Access to additional resources may be granted upon written request, as described below.

A written request shall be provided to _____, who will forward the request with a statement of support of the justification provided, to _____, the CDC Contracting Officer's Representative (COR) for Contract Number _____, Task Order _____ in the _____ Branch, Centers for Disease Control and Prevention (CDC).

If the requested access involves a physically separate or limited-access device or dataset, the appropriate steward of that device or dataset shall be provided with a copy of the request for review and authorization.

Upon acceptance of the request by all appropriate parties, an amendment to the Agreement for Access and Limitation on Disclosure will be executed, and a copy of any appropriate limitations on access and use will be provided. When this has been done, access will be provided.

If effective access not contained in Table 1 is recognized, or if another relationship is established with a CDC organization that may lead to additional access to federal IT resources at CDC, written notice of such shall be provided to _____, and _____, the CDC COR for Contract Number _____, Task Order _____ Branch, CDC.

Appendix F: Data Items for NPCR/SEER USCS Incidence Analytic Dataset

SEER*Stat Category	SEER*Stat Variable Name	Restrictions
Age at Diagnosis	Age recode with <1 year olds	
Race, Sex, Year Dx, Registry, County	Sex	
	Year of diagnosis	
	Addr at DX – state	
	*County at DX Analysis	Kansas and Minnesota data unavailable
	*State-county	Kansas and Minnesota data unavailable
	USCS standard	
	USCS9819	
	USCS9919	
	USCS1019	
	USCS1519	
	Race recode for USCS	
	Program	
	*Econ status	
	*Region/Division	
	Region	
	Origin recode NHIA (Hispanic, Non-Hisp)	
Site and Morphology	Primary Site – labeled	
	*Primary Site	
	Histologic Type ICD-O-3	
	*Behavior Code ICD-O-3	
	Grade	
	Grade clinical	
	Grade pathological	
	Grade post therapy	
	Diagnostic confirmation	
	ICD-O-3 Hist/behavior, labeled	
	*ICD-O-3 Hist/behavior, malig, labeled	
	Site recode ICD-O-3/WHO 2008	
	ICCC site recode ICD-O-3/WHO 2008	
	ICCC site rec extended ICD-O-3/WHO 2008	
	AYA site recode 2020	
	Lymphoid neoplasm recode 2021 revision	
	Behavior recode for analysis derived/WHO2008	
Stage – LRD [Summary and Historic]	*Derived SS2000	
	*SEER Summary Stage 2000	
	*SEER Summary Stage 1977	
	*SEER Summary Stage 2018	
	Merged Summary Stage	
Therapy	*RX summ – surg prim site	Diagnosis years ≥2003
	*RX summ – chemo	Female and male breast only, diagnosis years ≥2003, and NPCR CCRs† only
	Phase I Radiation Treatment Modality	Female and male breast and colorectal only, diagnosis years ≥2018
	*Merged radiation	Female and male breast and colorectal only, diagnosis years ≥2003, and NPCR CCRs only
Extent of Disease – CS	*CS site-specific factor 1	Brain and other CNS and diagnosis years 2011–2017
	Merged estrogen receptor	Female and male breast only and diagnosis years ≥2004

SEER*Stat Category	SEER*Stat Variable Name	Restrictions
	Merged progesterone receptor	Female and male breast only and diagnosis years ≥2004
	Merged HER2 receptor	Female and male breast only and diagnosis years ≥2010
	Laterality	
Multiple Primary Fields	Sequence number - central	
Race and Age (case data only)	Age at Diagnosis	
	Race 1	
	*IHS Link	
Geographic Locations	Ruralurban continuum 2013	
	*Census Tract Poverty Indicator	Diagnosis years ≥2014, NPCR CCRs only
Dates	Year of Birth	
	Month of diagnosis	
Other	Type of Reporting Source	
Merged System-Supplied	Alcohol-related cancers	
	HPV-related cancers	
	Obesity-related cancers	
	Physical inactivity-related cancers	
	Tobacco-related cancers	
	State race eth suppress	

*Variable is available only in the internal incidence database; it is not available in the NPCR/SEER U.S. Cancer Statistics Public Use Database.

Appendix G: Data Items for NPCR Internal Survival Dataset

SEER*Stat Category	SEER*Stat Variable Name	Restrictions
Age at Diagnosis	Age recode with single ages and 85+	
Race, Sex, Year Dx, Registry, County	Sex	
	Year of diagnosis	
	Addr at DX – state	
	County at DX Analysis	
	State-county	
	Rural-urban continuum 2013	
	NPCR project flag	
	Economic status	
	Race and origin recode (NHW, NHB, NHAIAN, NHAPI, Hispanic)	
	Race recode (White, Black, Other)	
Site and Morphology	Primary Site – labeled	
	Histologic Type ICD-O-3	
	Behavior Code ICD-O-3	
	Grade	
	Diagnostic confirmation	
	ICD-O-3-Hist/behavior, labeled	
	ICD-O-3-Hist/behavior, malig, labeled	
	Site recode ICD-O-3/WHO 2008	
	ICCC site recode ICD-O-3/WHO 2008	
	Behavior recode for analysis derived/WHO2008	
Stage – LRD [Summary and Historic]	Derived SS2000	
	SEER Summary Stage 2000	
	Merged Summary Stage 2000	
Therapy	RX summ – surg prim site	Diagnosis years ≥2003
	Merged radiation	Female breast and colorectal only, diagnosis years ≥2003, and NPCR CCRs only
Extent of Disease – CS	CS Site-Specific Factor 1	Brain/CNS and diagnosis years 2011–2017
	Merged estrogen receptor	Female and male breast only and diagnosis years ≥2004
	Merged progesterone receptor	Female and male breast only and diagnosis years ≥2004
	Merged HER2 receptor	Female and male breast only and diagnosis years ≥2010
	Laterality	
Cause of Death (COD) and Follow-up	Survival months – presumed alive	
	Survival months flag – presumed alive	
	Cause of death (ICD-10)	
	ICD revision number	
	Vital status	
	Follow-up source central	
	COD exclusion flag	
	Original vital status	
	Vital status recode (study cutoff used)	
	Cause of death recode	
	COD recode with Kaposi and mesothelioma	
Multiple Primary Fields	Sequence number - central	

SEER*Stat Category	SEER*Stat Variable Name	Restrictions
Race and Age (case data only)	Age at Diagnosis	
	Race 1	
	NHIA derived Hispanic origin	
	Age recode with <1 year olds	
Dates	Presumed alive year of last contact recode	
	Presumed alive month of last contact recode	
	Presumed alive day of last contact recode	
	Year of birth	
	Month of diagnosis	
	Day of diagnosis	
	Original day of last contact	
	Original month of last contact	
	Original year of last contact	
	Original year of diagnosis	
	Original day of diagnosis	
	Original month of diagnosis	
Other	Type of Reporting Source	
User-Specified	EDPMDE LinkVar	

Appendix H: NPCR-CSS 308(d) Assurance of Confidentiality Statement

A public health surveillance system of population-based cancer incidence data received from cooperative agreement holders for the National Program of Cancer Registries is being conducted by the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) of the Centers for Disease Control and Prevention (CDC), an agency of the U.S. Department of Health and Human Services, and ICF Incorporated, a contractor of CDC. The information to be received by CDC is a subset of a standard set of data items that the central cancer registry routinely receives from hospitals, pathology labs, clinics, private physicians, and other mandated reporters on all cancer cases diagnosed in the state. This information includes patient demographics and cancer diagnosis, treatment, and outcome data.

Each year, CDC requests cumulative data from central cancer registries. The variables reported to CDC may vary from year to year. The data submitted to CDC do not contain any direct identifiers, such as name or Social Security Number. Though project data do not contain direct identifiers, central cancer registries do report indirect identifiers such as patient demographic data items (e.g., a unique identifier, birth date, sex, race, ethnicity, birthplace, county of residence, census tract, zip code) and information about the type of cancer (e.g., date of diagnosis, stage at diagnosis, treatment). The cancer registries maintain these data permanently in longitudinal databases that are used for public health surveillance, program planning and evaluation, and data analyses. CDC updates its longitudinal database each year with data received from central cancer registries. NCCDPHP, recognizing the sensitivity of the data being furnished by states and territories, has applied for and obtained an Assurance of Confidentiality to provide a greater level of protection for the data while at CDC and at the contractor site.

Individual record-level data received by CDC or its contractors as part of this public health surveillance system that could lead to direct or indirect identification of cancer patients is collected and maintained at CDC under Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k) with an assurance that it will be held in strict confidence in accordance with Section 308(d) of the PHS Act (42 U.S.C. 242m). It is used only for purposes stated in this assurance and are not otherwise disclosed or released, even following the death of cancer patients in this surveillance system. These data are used by CDC scientists for routine cancer surveillance, program planning and evaluation, and to provide data for cancer- related research questions that support the purpose of this public health surveillance program, e.g., monitoring the frequency and distribution of disease, evaluating cancer prevention and control activities, program planning and evaluation.

Researchers within CDC, including contract employees and qualified organizations, will be able to access individual, record-level data (i.e., data that do not directly identify individuals but that could lead to identification when combined with other information) for legitimate cancer-related research questions and reporting purposes through the full NPCR CSS analytic dataset, a less restricted dataset with information not included in the restricted-access datasets but one that does not contain all data submitted by the CCRs. A separate complete dataset (i.e., all information submitted by the CCRs) is available for data quality assessments only. “Qualified organizations” are defined as organizations with staff qualified to undertake the proposed analyses by means of specific academic training or demonstrable, related experience in cancer epidemiologic, medical, biomedical, or statistical research and the organization is identified in the NPCR CSS Data Release Policy. These individuals and organizations will be required to adhere to a strict security and confidentiality protocol.

Restricted access will be provided to researchers outside of the CDC, its contractors, or qualified organizations through the National Center for Health Statistics Research Data Centers (NCHS RDC) or, in limited instances, an aggregated data file for federal and trusted partners. A restricted-access dataset is defined as the version of the full NPCR CSS analytic dataset, either aggregated data or individual, record-level data that have been modified as needed to minimize the potential for disclosure of confidential information. For restricted-access datasets, some variables such as county at diagnosis will only be released in a modified format. The unique identifying number assigned to each individual by the central cancer registry is replaced by a random number assigned at CDC to reduce the possibility of linkage to other
state- or territory-level files with indirect identifiers. This restricted access will be controlled in such a way as to limit the researchers’ ability to publish or otherwise provide others access to data that could lead to identification of an individual (i.e., small numbers of cases, unique cancer types in a small geographic area, or aggregated in a way that a case could be identified).

Information collected by CDC is used without personal identifiers for publication in statistical and analytic summaries and for release in restricted release datasets for research. Information that could lead to direct or indirect identification of cancer patients is not made available to any group or individual that have not met the qualifications established by CDC and are not described in the NPCR CSS Data Release Policy. In particular, such information is not disclosed to insurance companies, any party involved in civil, criminal, or administrative litigation, agencies of federal, state, or local government, or any other member of the public.

Collected information that could lead to direct or indirect identification of cancer patients is kept confidential and—with the exception

of CDC employees, their contractors, and qualified researchers—no one is allowed to see or have access to the information. CDC employees and contractors are required to handle the information in accordance with principles outlined in the CDC Staff Manual on Confidentiality and to follow the specific procedures documented in the Confidentiality Security Statement for this project. Qualified researchers are required to sign the NCHS RDC data sharing agreements and abide by the NCHS RDC confidentiality procedures. Access to data released through public-use datasets requires the user to complete and return a signed data use agreement acknowledging confidentiality requirements. Qualified organizations (e.g., the North American Association of Central Cancer Registries, American Cancer Society, National Cancer Institute, and the Central Brain Tumor Registry of the United States) are required to sign a detailed data release agreement to have access to restricted release data.

Appendix I: Frequently Asked Questions About the NPCR-CSS 308(d) Assurance of Confidentiality

Background

The Centers for Disease Control and Prevention (CDC) is responsible for public health surveillance in the United States. CDC collects, compiles, and publishes a large volume of personal, medical, epidemiologic, and statistical data. The success of CDC's operations depends, in part, on the agency's ability to protect the confidentiality of these data. While it is a matter of principle for CDC to guard sensitive information, and federal statutes such as the Privacy Act of 1974 provide a degree of protection for personally identifiable data, Section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) enables CDC to provide the highest level of confidentiality protection for sensitive and mission-significant research and surveillance data.

CDC received a formal delegation of authority from the National Center for Health Statistics (NCHS) to grant 308(d) confidentiality protection in 1983. Section 308(d) of the Public Health Service Act ensures the confidentiality of data collected under Sections 304 and 306 of the Public Health Service Act. These special legislative authorities were the provisions under which NCHS collects and safeguards most of its survey data, along with the mortality data in the National Death Index. CDC was required to establish a stringent application process and continues to use the authority sparingly. The agency has granted confidentiality assurances to projects deemed significant to CDC's mission, such as surveillance of hospital infections, AIDS and HIV infections, pregnancy-related mortality, and congenital defects. Fewer than 65 projects have received 308(d) protection since CDC received this authority, and about 25 active projects have 308(d) confidentiality assurances now. As a testament to the importance of this project to CDC's mission, its National Program of Cancer Registries (NPCR) has been afforded this special data protection.

What is stated in Public Health Service Act, Section 308(d)?

The first clause of Section 308(d) states that CDC must explain the purpose for collecting data to persons or agencies supplying information, and it guarantees that CDC will be limited to those specified uses unless an additional consent is obtained. Moreover, the information obtained may be used only by CDC staff or CDC's contractors in the pursuit of such stated purposes. The second clause states that CDC may never release identifiable information without the advance, explicit approval of the person or establishment supplying the information or by the person or establishment described in the information.

What process did NPCR undertake to obtain 308(d) confidentiality protection?

NPCR staff worked with CDC's Office of General Counsel and CDC's Confidentiality and Privacy Officer to prepare the application for the NPCR-Cancer Surveillance System (CSS) project. The application contained the following four components:

- A Justification Statement summarizing the NPCR-CSS project's programmatic purpose, the type of data to be collected, and the uses to be made of the information. This statement also included an assurance that a) the requested data would not be furnished without the guarantee of a confidentiality assurance, b) confidentiality assurance is important to protect the individuals described in the data and to reassure the institutions submitting data, c) the information cannot reliably be obtained from other sources, d) the information is essential to the project's success, e) granting the confidentiality assurance would not prohibit CDC from fulfilling its responsibilities, and f) the advantages of assuring confidentiality outweigh the disadvantages.

- An Assurance of Confidentiality Statement delineating anticipated data uses and those with whom identifiable data would be shared, along with general advisements regarding the confidentiality protection.

- A Confidentiality Security Statement detailing the stringent safeguarding measures in place to ensure that the promise of confidentiality would not be jeopardized by practices of staff handling the data.

- An Institutional Review Board (IRB) Review Status Statement verifying NPCR-CSS's exemption from CDC IRB approval. (The Human Subjects Administrator at the National Center for Chronic Disease Prevention and Health Promotion determined that as of 2021, NPCR-CSS activities are routine surveillance and not research on human subjects. Therefore, protocol review by CDC IRB was deemed unnecessary.)

The application was submitted to the CDC Confidentiality Officer for review and modification, prepared for presentation to the CDC Confidentiality Review Group (CRG), and in May 2000 NPCR received 308(d) confidentiality protection approval for NPCR-CSS data, including authorization for retroactive confidentiality protection beginning with diagnosis year 1995. NPCR must file for continuation

every 5 years to maintain the assurance.

What makes 308(d) confidentiality assurance the best protection for NPCR-CSS data?

The 308(d) confidentiality assurance is the only confidentiality protection that covers routine surveillance activities such as those conducted by NPCR-CSS. The assurance specifies that data protected by 308(d) may be used only for statistical or epidemiological purposes and not released further in identifiable form without consent. Another exclusive advantage of 308(d) is that it also protects indirectly identifiable data. Operationally, this means that NPCR may never release a directly identifiable variable such as a Social Security number or any combination of variables that could be used to identify an individual indirectly. Finally, 308(d) provides protection for information on both living and deceased individuals.

Are there any disadvantages to individuals or institutions protected by the 308(d) confidentiality assurances?

A 308(d) confidentiality assurance does not pose a disadvantage for individuals or institutions submitting data to CDC. In fact, 308(d) provides an added benefit because it prevents CDC from freely releasing data to researchers and any other persons or entities that could request access to the data. With the confidentiality assurance protecting NPCR-CSS data, NPCR staff members are prohibited from sharing data except for the purposes stated at the time of data collection, unless consent from those who provided the assurance is obtained.

Does NPCR's 308(d) confidentiality assurance protect the data from subpoena and Freedom of Information Act (FOIA) requests?

The 308(d) assurance is the strongest protection against compulsory legal disclosure that CDC can offer. Although CDC receives FOIA requests, the FOIA (b)(6) exemption enables CDC to withhold sensitive, individually identified data that would constitute a "clearly unwarranted invasion of personal privacy." It is CDC's firm position that all projects covered by a 308(d) confidentiality assurance, including NPCR-CSS, meet this exemption.

Has a case involving 308(d) been tested in court?

Yes. CDC's ability to protect data submitted to the agency was upheld in court. The case involved a National Institute for Occupational Safety and Health project collecting death certificate information, which is widely accepted as the least sensitive data protected by 308(d). The court's ruling in favor of the non-release of these data establishes an effective precedent for restricting access to more sensitive data, such as those collected by a cancer registry.

How long are confidential data submitted to NPCR-CSS protected?

NPCR-CSS data are covered by the 308(d) confidentiality assurance forever. Individual records in the NPCR-CSS are protected even following the death of the cancer patients.

Will NPCR release CSS data to persons or agencies outside of CDC?

An assurance of confidentiality protects NPCR-CSS data held at CDC and by its contractor. The 308(d) confidentiality protection does not go with the data whether released publicly or through restricted means, and any data CDC releases to qualified researchers are subject to the limits of any coverage afforded by the requesting agency. However, it is important to note that NPCR's confidentiality assurance prohibits the release of any data that are directly or indirectly identifiable.
Therefore, CDC would not release highly sensitive NPCR-CSS data. Restricted access data that are released to external researchers are done so in accordance with the NCHS RDC proposal process and confidentiality procedures, prohibiting attempts to identify subjects within the record system. Under the 308(d), NPCR is permitted to release NPCR-CSS data to qualified researchers and organizations, such as the North American Association of Central Cancer Registries (NAACCR), American Cancer Society (ACS), and National Cancer Institute (NCI). This is so because these entities were specifically mentioned in the NPCR-CSS confidentiality assurance as anticipated recipients of identifiable data. Prior to the restricted release of NPCR-CSS data to qualified organizations, a detailed data use agreement must be signed by the requesting party. Information that could lead to the identification of cancer patients, through direct or indirect methods, cannot be made available to any other group or individual. In particular, NPCR cannot disclose information to insurance companies; any party involved in civil, criminal, or administrative litigation; agencies of federal, state, or local government; or any other member of the public.

Are there penalties for violating the confidentiality assurance?

NPCR employees and NPCR-CSS contractor staff working on the NPCR-CSS project may be subject to fine, imprisonment, and termination of employment for unauthorized disclosure of confidential information. To assure that all NPCR employees are aware of their responsibilities to maintain and protect NPCR-CSS records and the penalties for failing to comply, CDC employees must read and sign a data use agreement. Contract employees with access to NPCR- CSS data are required to sign a confidentiality agreement.

The research use NPCR/SEER USCS Incidence Public Use dataset contains individual case-specific data from the USCS dataset with enforced fewer than 16 case cell suppression and case listing disabled.

Appendix J: Data Items for NPCR/SEER USCS Incidence Public Use Research Dataset

SEER*Stat Category	SEER*Stat Variable Name	Restrictions
Age at Diagnosis	Age recode with <1 year olds	
Race, Sex, Year Dx, Registry	Sex	
	Year of diagnosis	
	Addr at DX – state	
	USCS standard	
	Race recode for USCS	
	Program	
	Region	
	USCS0119	
	USCS1019	
	USCS1519	
	Origin recode NHIA (Hispanic, Non-Hisp)	
Site and Morphology	Primary site – labeled	
	Histologic type ICD-O-3	
	Grade	
	Grade clinical	
	Grade pathological	
	Diagnostic confirmation	
	ICD-O-3 hist/behavior, labeled	
	Site recode ICD-O-3/WHO 2008	
	ICCC site recode ICD-O-3/WHO 2008	
	ICCC site rec extended ICD-O-3/WHO 2008	
	AYA site recode 2020	
	Lymphoid neoplasm recode 2021 revision	
	Behavior ICD-O-3	
Stage – LRD [Summary and Historic]	Merged summary stage 2000	
Therapy	RX summ – surg prim site	Female breast only and diagnosis years ≥2003
Extent of Disease – CS	CS site-specific factor 1	Brain and other CNS and diagnosis years 2011–2017
	Merged estrogen receptor	Female and male breast only and diagnosis years ≥2004
	Merged progesterone receptor	Female and male breast only and diagnosis years ≥2004
	Merged HER2 receptor	Female and male breast only and diagnosis years ≥2010
	Laterality	
Multiple Primary Fields	Sequence number – central	
Geographic Locations	Ruralurban continuum 2013 calc	Grouped into 3 categories: metro (RUCC 1–3); nonmetro (RUCC 4–9); unknown
Dates	Year of birth	
	Month of diagnosis	
Merged System-Supplied	Alcohol-related cancers	
	HPV-related cancers	
	Obesity-related cancers	
	Physical inactivity-related cancers	
	Tobacco-related cancers	
	State race eth suppress	

Appendix K: NPCR/SEER – U.S. Cancer Statistics Public Use Research Database Data Use Agreement

National Program of Cancer Registries (NPCR) and Surveillance, Epidemiology, and End Results (SEER) Incidence – U.S. Cancer Statistics

Public Use Research Database Data Use Agreement

For data submitted November, {year}

The Centers for Disease Control and Prevention (CDC) and the National Cancer Institute (NCI) make NPCR and SEER data available to the public and researchers through various data release activities. The NPCR and SEER Incidence – U.S. Cancer Statistics Public Use Research Databases are an unrestricted subset of data submitted to CDC and NCI and made available only through the National Cancer Institute's SEER*Stat statistical software.

CDC has obtained an assurance of confidentiality for NPCR pursuant to Section 308(d) of the Public Health Service Act, 42 U.S.C. 242m(d). Any effort to determine the identity of any reported case, or to use the information for any purpose other than statistical reporting and analysis, is a violation of the assurance. All direct identifiers, as well as characteristics that might easily lead to identifying individuals, are omitted from the NPCR and SEER Incidence – U.S. Cancer Statistics Public Use Research Databases. Certain demographic information has been included for research purposes; thus, all SEER*Stat results must be presented or published in a manner that ensures that no individual can be identified. In addition, there must be no attempt to identify individuals from any computer file or to link with a computer file containing patient identifiers.

Data users must agree to the following provisions before receiving access to the NPCR and SEER Incidence – U.S. Cancer Statistics {year}–{year} and {year}–{year} Public Use Research Databases. ***Please initial after each statement to indicate agreement.***

As the recipient of access to NPCR and SEER Incidence – U.S. Cancer Statistics Public Use Research Databases:

- I will adhere to the requirements of the Data Use Agreement and understand that my access to the data will be revoked if these requirements are violated. **Initials:** _____
- I understand that all NPCR data are owned by the states and territories. The states and territories have established agreements with CDC regarding the use and dissemination of the data. **Initials:** _____
- I will not use or permit others to use the analytic results in any way other than for statistical reporting and analysis.
  8. **Initials:** _____
- I will use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this agreement. **Initials:** _____
- I will ensure all members of the research team who have access to the NPCR and SEER Incidence – U.S. Cancer Statistics Public Use Research Database through SEER*Stat have signed this agreement. **Initials:** _____
- I will not attempt to link or permit others to link NPCR and SEER Incidence – U.S. Cancer Statistics Public Use Research Data with individually identifiable records from any other dataset without CDC approval.
  9. **Initials:** _____
- I will not attempt to use the analytic results or permit others to use them to learn the identity of any person or establishment included in any dataset. **Initials:** _____
- I will take the following actions if the identity of any person or establishment is discovered inadvertently:
  - Make no use of this knowledge.
  - Notify CDC by sending an e-mail to uscsdata@cdc.gov.
  - As requested by CDC, safeguard or destroy the information that identifies an individual or establishment.
  - Inform no one else of the discovered identity. **Initials:** _____
- I will make every effort to release all statistical information in such a way as to avoid inadvertent disclosure by:

- Ensuring that no data on an identifiable case can be derived through subtraction or other calculation from the combination of tables in the given publication. **Initials:** _____
- Ensuring that no data permit disclosure when used in combination with other known data. **Initials:** _____
- Not disclosing or otherwise making public data on any unit smaller than 16. If the total number of cases in a cell is fewer than 16, the cell data will be suppressed in oral and written presentations. **Initials:** _____

- I have read the data documentation file and have an understanding of the data available in the database and the restrictions related to their use. If I have questions regarding my analytic approach, I will contact CDC NPCR (uscsdata@cdc.gov) for assistance. **Initials:** _____
- I am familiar with the use of **SEER*Stat** in analyzing data or will complete the needed training. **Initials:** _____
- I understand that I am responsible for the results of my own analysis. The findings and conclusions resulting from the analysis of these data are those of the authors and do not necessarily represent the official position of CDC. **Initials:** _____
- I will acknowledge central cancer registries whenever data are presented, released, or published by including the following (or similar) statement:

  These data were provided by central cancer registries participating in CDC's National Program of Cancer Registries (NPCR) and NCI's Surveillance, Epidemiology, and End Results (SEER) Program and submitted to CDC and NCI in November {date}. **Initials:** _____

- As appropriate, I will cite the data –

  For the {date}-{date}*database:* National Program of Cancer Registries and Surveillance, Epidemiology, and End Results SEER*Stat Database: NPCR and SEER Incidence – U.S. Cancer Statistics Public Use Research Database, November {year} submission ({year}–{year}), United States Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute.
  Released {date}, based on November {year} submissions. Available at www.cdc.gov/cancer/public-use.

  For the {year}-{year} *database:* National Program of Cancer Registries and Surveillance, Epidemiology, and End Results SEER*Stat Database: NPCR and SEER Incidence – U.S. Cancer Statistics Public Use Research Database with Puerto Rico, November {year} submission ({year}–{year}, United States Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute. Released {date}, based on November {year} submissions. Available at www.cdc.gov/cancer/public-use.

  Initials: _____

Users cannot be given access to the U.S. Cancer Statistics databases until SEER Research Plus access is set up.

When you have access to SEER Research Plus, complete the fields below, sign and date the agreement, and e- mail both pages to uscsdata@imsweb.com.

The e-mail address you provide must be the same one used to obtain access to SEER Research Plus.

_____ _____

Signature **Date**

Name: _____

Title and organization: _____

Telephone number: _____ E-mail address: _____

Appendix L: NPCR Data at the NCHS RDC Questions and Answers

Can you summarize the data access process?

CDC uses the National Center for Health Statistics' (NCHS) Research Data Center (RDC) as a mechanism for researchers outside of the Division of Cancer Prevention and Control (DCPC) to request and gain access to the Restricted-Access NPCR/SEER data for research purposes. The data are available through the NCHS RDC only after the standard data quality reviews that occur as part of the preparation for USCS.

The use of the NCHS RDC to manage data access provides the highest level of data security and protection of confidentiality that is available for analysis of data. Any researcher must submit a proposal that is reviewed and approved by CDC and may be reviewed by representatives from the participating central cancer registries (CCRs) before any data analysis begins. Trained data analysts at the NCHS RDC create a dataset that is customized to each analysis. The researcher can run his or her own statistical analysis or have the NCHS RDC analyst run the analysis. The NCHS RDC analyst reviews all output from statistical analysis to ensure that the researcher only conducts analyses relevant to the approved protocol and that small cell sizes are suppressed. Absolutely no individual-level data leave the NCHS RDC facilities. The data can only be accessed onsite; the NCHS RDC remote option is not available for the Restricted-Access NPCR/SEER data.

What is National Center for Health Statistics (NCHS)?

NCHS is one of the national centers at CDC and is located in Hyattsville, Maryland. As the nation's principal health statistics agency, it compiles statistical information to guide actions and policies to improve the health of the population. More information about NCHS is available at www.cdc.gov/nchs/about.htm.

What is the Research Data Center (RDC)?

The NCHS RDC began in 1998 and has a long history of managing access to health and vital statistics data through a rigorous proposal review process as well as review of the statistical output. Its mission is to give public access to a full range of health and vital statistics data, while protecting the confidentiality of the respondents and institutions that collected the information. There have been no breeches of confidentiality for data access through the NCHS RDC.

The NCHS RDC houses sensitive, but not classified, data. It allows access to individual data without the possibility of disclosure of identifying information. The NCHS RDC offers statistical, programming, and consulting expertise to facilitate the data analysis for research.

The NCHS RDC is a data hosting center, not a data repository. The data extracts that are hosted on the NCHS RDC are tailored specifically to the proposal and have a research life cycle. When the analysis is completed, the data extract is archived for 2 years and then destroyed. More information about the NCHS RDC is available at www.cdc.gov/rdc/.

Why does CDC use the NCHS RDC?

Maintaining confidentiality is the primary objective of the NCHS RDC. Its staff have statistical expertise to address confidentiality and disclosure risk. Using the NCHS RDC allows CDC to comply with the Assurance of Confidentiality [308(d)] that was obtained for the NPCR-CSS data. All researchers must take a confidentiality orientation, complete confidentiality forms, and review the disclosure manual, all of which outline practices that are essential to protecting the data and preventing disclosure of confidential information. Additionally, data housed at the NCHS RDC are not subject to the Freedom of Information Act (FOIA). More information about confidentiality is available at www.cdc.gov/rdc/B4ConfiDisc/CfD400.htm.

The use of the NCHS RDC to host the NPCR data provides confidence in knowing that the data are used correctly and safely by external researchers. In addition, this approach will not overtax resources in CDC's DCPC or in the CCRs. The NCHS RDC provides a level of data control beyond that of any other data access system used for registry data.

What is the research proposal process?

The NCHS RDC has a rigorous review process for analyses proposed by any researchers wanting to use RADS data. All proposals will be evaluated by a Review Committee consisting of the NCHS RDC Director, the Confidentiality Officer, the assigned NCHS RDC analyst, and NPCR representatives. The iterative review and comment process may take 6 to 8 weeks.

Through this process, the NCHS RDC staff, the NPCR staff, and the CCR staff will fully understand the intended analysis and will be able to provide any needed direction or restrictions on the analysis and describe any limitations in what is proposed. It will be possible for CDC and participating registries to disapprove a proposal. However, guidance and re- direction as needed should be the norm. More Information about the review process is available at www.cdc.gov/rdc/leftbrch/userestricdt.htm.

Once a proposal has been approved, the NCHS RDC offers a secure environment for data analyses and has processes in place to review data output for small cell sizes. This will ensure that the NPCR suppression rules are properly applied.
Through the NCHS RDC, the user can conduct analyses and have remote access to data but cannot download the individual record level data or obtain counts for inappropriately small cell sizes.

Who has access to the data and at what level?

The NCHS RDC analysts can access the individual record-level data, since it is easier to create an analytic dataset using these data. The NCHS RDC analysts are bound by the same data use agreements that CDC staff sign annually.
Researchers with approved proposals can conduct analyses through the NCHS RDC on the created dataset or have an NCHS RDC analyst do the analysis for them. However, they cannot download any part of the data from the NCHS RDC. Any additional variables that were not included in the original analysis proposal will need a separate approval process.

Note that this is different from the process that NPCR has used in the past, where researchers with approved proposals had direct access to the dataset, including the ability to download the data and create a list of individual record-level data and all variables in the dataset.

Researchers have several possible modes of access to the dataset created for their specific research proposal. More information is available at www.cdc.gov/rdc/B2AccessMod/ACs200.htm.

When a researcher conducts an analysis, what type of output will he or she get?

If a researcher is on-site at the NCHS RDC, he or she can save the results on the hard drive of the NCHS RDC computer. The NCHS RDC analyst will review the output for disclosure then either load the output onto a flash drive supplied by the researcher or e-mail the output files to the researcher. If a researcher is accessing the NCHS RDC remotely, he or she will send program by e-mail and, after disclosure review by the NCHS RDC analyst, will receive the output files by e-mail. No individual record level data are released to the researcher.

Can CCRs decide whether their data are available through the NCHS RDC?

Participation in all CDC-created and hosted analytic datasets and web-based data query systems, as outlined in the annual NPCR-CSS Data Release Policy, is a required strategy. Therefore, data from all CCRs meeting eligibility requirements are included. Data use is important to NPCR and for continued support of the registries.

Will the CCRs be able to decide if their county-identifying variable (County at Dx [NAACCR#90]) is to be available for use in the NCHS RDC?

Participation in all CDC-created and hosted analytic datasets and web-based data query systems, as outlined in the annual NPCR-CSS Data Release Policy, is a required strategy. [DP17-1701, 2. CDC Project Description, a. Approach, iii. Strategies and Activities, Program 3: National Program of Cancer Registries (NPCR) – Component 1, Strategy 3 Cancer Data and Surveillance (Domain 1), Data Submission (page 19)]. Therefore, data from all CCRs meeting eligibility requirements are included. Data use is important to NPCR and for continued support of the registries. County data will be used only in approved analyses and in the following ways:

- As a linkage variable (to census data, for example) only by the NCHS RDC analyst. The county variable will not be available to the researcher. The NCHS RDC analyst uses it to create a linked dataset and then removes it.
- As a confounder or other control variable, but no data are presented by county. The NCHS RDC analyst creates dummy variables to mask the actual county name.
- In geographically aggregated form such as large metropolitan statistical areas (those with a population of 1 million or larger), multi-county regions, or geographic areas such as Appalachia or IHS Contract Health Services Delivery Areas (CHSDA) counties. The county data make it possible for the NCHS RDC analyst to create these areas for the researcher.

Previous data release policies indicate that the project proposals for RADS would be reviewed by the RADS working group, facilitated by CDC with representation by the CCRs. Does this procedure change now that the NCHS RDC is used?

The CCRs will still have input on the RADS proposals. The NCHS RDC review process includes the NCHS RDC analyst and the confidentiality officer, who are responsible mainly for disclosure review to ensure that we abide by the 308(d) assurance of confidentiality obtained for NPCR-CSS. More information about the NCHS RDC review process is available at: https://www.cdc.gov/rdc/b1datatype/rdc-Output.htm.

Will SEER data be included for analysis, or will the data be limited to NPCR data?

Yes. Both NPCR and SEER data may be accessed through the NCHS RDC.

Will the NCHS RDC staff have access to SEER*Prep and SEER*Stat?

No. NPCR previously provided a SEER*Stat file to the NCHS RDC but found that researchers only used the SAS file. Therefore, the SEER*Stat file is no longer provided.

What suppression rules will be used for the RADS?

RADS use the same suppression rules that are used for *United States Cancer Statistics.* More detailed information is available at www.cdc.gov/cancer/npcr/uscs/technical_notes/stat_methods/suppression.htm.

The suppression rules for Asian and Pacific Islander (A/PI) people and American Indian and Alaska Native (AI/AN) people will also apply.

CDC doesn't collect personal identifiers like name or Social Security number. Wouldn't it be better for researchers to contact CCRs directly for linkage studies?

Yes, it would be best for researchers to contact CCRs directly for linkage studies that require individual identifiers. However, valuable public health research can be conducted with access to county-level data. Examples include linkage with U.S. Census data for socioeconomic analyses, or to examine regional differences in the prevalence of a specific cancer.

Will IRB review be required for each proposal? If not, will NCHS require researchers to obtain IRB approval before they submit their proposal?

The NCHS RDC has an umbrella ethics review board (ERB) protocol that covers CDC employees and can be extended to external researchers. The principal investigator and all research team members who come in contact with the data must take the confidentiality orientation and complete the confidentiality forms. One of the confidentiality forms is the designated agent form (www.cdc.gov/rdc/Data/B4/DesignatedAgent.pdf [PDF-41KB]), which extends the ERB to cover external researchers.

Note that the ERB protocol serves the same function as an institutional review board (IRB) protocol. At CDC, one office coordinates the submission and tracking of human research protocols. However, other centers such as NCHS and the National Institute of Occupational Safety and Health have different names for these review boards: Research Ethics Review Board (ERB) at NCHS and Human Subjects Review Board (HSRB) at NIOSH.

Researchers may choose to obtain an IRB protocol from their own institution, but it will not be required.

Does access to the RADS cost anything?

No. CDC covers the cost of analyzing RADS through the NCHS RDC.

As more researchers become aware of the RADS, they may want access to additional variables that CCRs submit to CDC. How will this process be handled?

The addition of new variables in RADS will be discussed with CCRs prior to their inclusion in the data release policy, which is updated annually.

How is access to the comparative effectiveness research (CER) dataset managed?

Access to the CER dataset is managed through the same NCHS RDC process. The proposal process will not differ except that staff from the specialized registries funded for CER data collection will review these proposals.

Appendix M: Data Items for Restricted-Access Dataset (RDC)

The restricted-access dataset consists of individual case-specific data derived from the NPCR-CSS dataset. The data are available to researchers at NCHS' Research Data Center (RDC) as a SAS file. SAS files are created specifically for each project's needs. The data items that researchers may request are listed below.

Variable Name

- Alternate Patient ID Number
- Address at Diagnosis – State
- Address at Diagnosis – County at Analysis*
- USCS Standard
- USCS9919
- USCS1519
- USCS9819
- USCS1019
- Address at Diagnosis – Census Region
- Race 1
- Race 2
- Race Recode
- Economic Status
- State race eth suppress
- Spanish/Hispanic Origin
- IHS Link
- Sex
- Age at Diagnosis**
- Age Recode
- Birth Date***
- Rural-urban continuum 2013
- Sequence Number – Central
- Date of Diagnosis****
- Primary Site
- Laterality
- Grade
- Grade Clinical
- Grade Pathological
- Grade Post Therapy
- Diagnostic Confirmation
- Type of Reporting Source
- Histologic Type ICD-O-3
- Behavior Code ICD-O-3
- Behavior Recode for Analysis Derived/WHO 2008
- Primary Site Recode
- SEER International Classification of Childhood Cancer (ICCC) Recode Extended ICD-O-3/WHO 2008
- AYA Site Recode 2020
- Lymphoma Neoplasm Recode 2020 Revision
- SEER Summary Stage 2000
- SEER Summary Stage 1977
- Derived SS2000
- Summary Stage 2018
- Merged Summary Stage
- RX Summ – Surg Prim Site
- Merged radiation
- CS Site-Specific Factor 1

- Merged Estrogen Receptor
- Merged Progesterone Receptor
- Merged HER2 Receptor
- Over-ride Age/Site/Morph
- Over-ride SeqNo/DxConf
- Over-ride Site/Lat/Sequence Number
- Over-ride Site/Type
- Over-ride Histology
- Over-ride Report Source
- Over-ride Ill-define Site
- Over-ride Leuk, Lymphoma
- Over-ride Site/Behavior
- Over-ride Site/Lat/Morph
- Alcohol-related cancers
- HPV-related cancers
- Obesity-related cancers
- Physical activity-related cancers
- Tobacco-related cancers

* County data will be used only in approved analyses and in the following ways: a) as a linkage variable (linkage to census data, for example) only by the NCHS RDC analyst; b) as a confounder or other control variable, but no data are presented by county; c) in geographically aggregated form such as large metropolitan statistical areas (those with a population of 1 million or larger), multi-county regions, or geographical areas such as Appalachia or IHS Contract Health Services Delivery Areas (CHSDA) counties.

**Age over 99 is recoded.

***Only year is provided; if age is over 99, year of birth is recoded.

****Day of diagnosis is not provided.

Appendix N: NPCR-CSS Levels of Data Access

Internal Analytic Datasets

Includes: Record-level information, Survival dataset, Prevalence dataset, and Delay-Adjusted dataset

Criteria: USCS criteria met, <6 cases cell suppression, complementary cell suppression

Availability: NPCR, SEER, IHS researchers and contractors

Access: Signed Data Use Agreement and Non-Disclosure Agreement, assurance of confidentiality training

If a state, territory, or county is used and identified, the awardee should be notified of the study results. Otherwise, no additional permission is needed, but researchers should document its use and include the proper acknowledgment.

Federal Agencies and Trusted Partners

Includes: Record-level information; may include Survival dataset, Prevalence dataset, and Delay-Adjusted dataset

Criteria: USCS criteria met, <16 cases cell suppression, complementary cell suppression **Availability:**

ACS, CBTRUS, IACR, CONCORD, AHRQ, OWH, CDI, CDC's Tracking Program **Access:** Signed Data

Use Agreement and Non-Disclosure Agreement; may include MOU **External Restricted-Access**

Dataset

Includes: Includes record-level information

Criteria: USCS criteria met

Availability: Researchers outside DCPC through NCHS RDC

Access: Proposal submitted to NCHS RDC, signed Data Use Agreement and Non-Disclosure Agreement NPCR and RDC

review; may include state and territory

NPCR-CSS Levels of Data Access for Public Use Datasets

No additional permission needed; users should document its use and include the proper acknowledgment.

USCS Data Visualizations tool

Includes: State, territory, county, region, and Congressional district levels, no record-level information

Criteria: USCS criteria met, permission provided on Dataset Participation Agreement, <16 cases cell suppression enforced

Availability: Public

CDC WONDER

Includes: State, territory, county, region, and MSA levels, no record-level information

Criteria: USCS criteria met, permission provided on Dataset Participation Agreement, <16 cases cell suppression enforced

Availability: Public

State Cancer Profiles

Includes: State and county levels, no record-level information

Criteria: USCS criteria met, permission provided on Dataset Participation Agreement, <16 cases cell suppression enforced

Availability: Public

NPCR/SEER USCS Public Use Dataset

Includes: State and territory record-level information, no case listing

Criteria: USCS criteria met, permission provided on Dataset Participation Agreement, <16 cases cell suppression enforced

Availability: Public after signed Data Use Agreement and Non-Disclosure Agreement, annual agreements required

Appendix O: Data Items for NPCR/SEER USCS Delay-Adjusted Database

SEER*Stat Category	SEER*Stat Variable Name
Age at Diagnosis	Delay age Age recode with single ages and 85+
	Age recode with <1 year olds
Race, Sex, Year Dx, Registry, County	Sex
	Year of diagnosis
	Addr at DX – state
	County at DX Analysis
	State-county
	Origin recode NHIA (Hispanic, Non-Hispanic)
Required Delay Fields	Delay factor
	Delay site
	Race and origin recode (NHW, NHB, NHAIAN, NHAPI, Hispanic)
	Delay race (All, Race recode (White, Black, AIAN, CHSDA, API, Hisp, Non-Hisp)
Site and Morphology	Behavior recode for analysis derived/WHO2008
Multiple Primary Fields	Sequence number - central

Appendix P: Data Items for NPCR Prevalence Database

SEER*Stat Category	SEER*Stat Variable Name
Age at Prevalence Date	Age at Prevalence Data (Calculated)
Age at Diagnosis	Age recode with single ages and 85+
Race, Sex, Year Dx, Registry, County	Sex
	Year of diagnosis
	Addr at DX – state
	County at DX Analysis
	State-county
	NPCR project flag
	Economic status
	Race and origin recode (NHW, NHB, NHAIAN, NHAPI, Hispanic)
	Race and origin recode (NHW, NHB, NHAIAN, NHAPI, Hispanic)
	State
	County
	Race recode (White, Black, Other)
Site and Morphology	Primary Site – labeled
	Histologic Type ICD-O-3
	Behavior Code ICD-O-3
	Grade
	Diagnostic confirmation
	ICD-O-3-Hist/behavior, labeled
	ICD-O-3-Hist/behavior, malig, labeled
	Site recode ICD-O-3/WHO 2008
	ICCC site recode ICD-O-3/WHO 2008
	Behavior recode for analysis derived/WHO2008
Stage – LRD [Summary and Historic]	Derived SS2000
	SEER Summary Stage 2000
	Merged Summary Stage 2000
Extent of Disease – CS	CS Site-Specific Factor 1
	CS Site-Specific Factor 2
	CS Site-Specific Factor 15
	Laterality
Cause of Death (COD) and Follow-up	Survival months – presumed alive
	Survival months flag – presumed alive
	Cause of death (ICD-10)
	ICD revision number
	Vital status
	Follow-up source central
	COD exclusion flag
	Original vital status
	Vital status recode (study cutoff used)
	Cause of death recode
	COD recode with Kaposi and mesothelioma
Multiple Primary Fields	Sequence number - central
Race and Age (case data only)	Age at Diagnosis
	Race 1

	NHIA derived Hispanic origin
Dates	Presumed alive year of last contact recode
	Presumed alive month of last contact recode
	Presumed alive day of last contact recode
	Year of birth
SEER*Stat Category	**SEER*Stat Variable Name**
	Month of diagnosis
	Day of diagnosis
	Original day of last contact
	Original month of last contact
	Original year of last contact
	Original year of diagnosis
	Original day of diagnosis
	Original month of diagnosis
Other	Type of Reporting Source
User-Specified	EDPMDE LinkVar

Appendix 4-5. – Program Evaluation Instrument (PEI) Overview

Appendix 4-5: Performance Evaluation Instrument (PEI) Overview

Purpose

The NPCR Program Evaluation Instrument (PEI) is a biennial online survey that assesses NPCR-funded registries' operational attributes and progress towards meeting NPCR Program Standards.

Based on CDC's Updated Guidelines for Evaluating Public Health Surveillance Systems, the PEI monitors the integration of surveillance, registry operations, and health information systems, use of established data standards, and electronic exchange of health data.

The PEI provides a uniform approach to assessing NPCR-funded central cancer registries (CCRs). Knowledge about NPCR-funded registries' operations and activities provides key insight into factors contributing to overall successes and challenges of the NPCR. Results of this survey are used to guide program planning and evaluation, assist with strategic planning, direct technical assistance to NPCR- funded registries, and continuously improve and enhance the NPCR.

Overview
Content

The survey instrument is comprised of about 50 questions organized into sections: staffing, legislative authority, administration, reporting completeness, data exchange, data content and format, data quality assurance, data use, collaborative relationships, advanced activities, and survey feedback.

Survey questions are closely aligned with NPCR Program Standards to facilitate monitoring and measuring registries' progress over time.

Timing

The time required to complete the survey depends on the registry's resources and readiness. Estimated time of completion is 2 hours. This includes reviewing instructions, identifying data sources, gathering data, responding to survey questions, and carefully reviewing entered information.

A 30-day turnaround is given to complete the survey and return it to NPCR.

Frequency

NPCR intends to administer the PEI every other year. Within the 5-year Notice of Funding Opportunity (NOFO), it is projected that the PEI will be conducted in 2022 and 2024. Administration frequency may subject to change per Office of Management and Budget (OMB) approval or other circumstances.

Security

CCR staff access the online survey using NPCR-CSS document server (DocServer) login credentials. Survey responses are encrypted before transmission to a dedicated secure web server.

Responsibilities

Program-assigned NPCR-funded CCR staff complete the PEI. The program director or principal investigator is responsible for final review and approval of survey responses.

An NPCR contractor is responsible for collecting PEI surveys, analyzing data, reporting results to CCRs and NPCR, and maintaining the PEI Data Collection and Reporting Portal.

Results

CCR staff may view individual and aggregated survey results. Individual results are uploaded to the NPCR-CSS DocServer. CCR staff may also generate individual, regional, and national reports using the PEI Reporting Portal. Registry program officials are notified when results may be viewed and provided instructions on accessing the PEI Reporting Portal.

Appendix 4-6: NPCR Data Modernization Strategy

Over the next five years, NPCR will invest in data modernization initiatives that consolidate many services for data reporters and central cancer registries (CCRs). These services will be performed using the Cancer Surveillance Cloud-Based Computing Platform (CS-CBCP). The CS-CBCP will have an honest data broker relationship with data reporters and CCRs based on data governance standards. The data governance standards will be developed and updated by stakeholders such as CCRs, data reporters, standard setters, and other cancer surveillance organizations.

Over time, the CS-CBCP will benefit data reporters and CCRs in the following ways:

1. **Cost Savings:** By consolidating information technology (IT) services, data reporters and CCRs are likely to experience significant savings. The CS-CBCP may provide substantial advantages for disaster recovery, loss prevention, application installation, server optimization, and system configuration.

2. **Security:** By using the latest Federal Information Security Modernization Act (FISMA) and Federal Risk and Authorization Management Program (FedRAMP) standards, we can meet a standard of security not achieved by most data centers.

3. **Automatic Software Updates:** When patches, standards, or enhancements need to be updated, the CS-CBCP will allow for a single update. CCRs' IT support staff will not be required to make these updates.

4. **Real-Time, Actionable Data:** As data reporters send data to the platform, CCRs will have direct access to these reports.

5. **Automation of Manual Activities:** By pooling resources, many services can be developed to automate the processing and quality control of data reports.

6. **Interactive Data Visualization Dashboards:** Data reporters and CCRs will be able to review data reporting and processing using a visual interactive interface. Users will be able to drill down to individual record reports to understand what is being reported and processed more clearly.

These are just a few of the many advantages of the CS-CBCP. NPCR awardees will be given opportunities to contribute to the platform's data governance and functionality. By supporting its development and implementation, CCRs should be able to improve their productivity, quality, and data use for cancer control efforts.

Appendix 4-7. – NPCR Success Stories

National Program of Cancer Registries (NPCR) Success Stories

CDC's Cancer Surveillance Branch (CSB) collects and promotes success stories from National Program of Cancer Registries (NPCR)-funded awardees as an annual requirement of NOFO DP22-2202. Success stories provide a record of innovative activities in which each registry has been engaged in the past year, focusing on operations or public health effects. Success stories may include ways in which cancer registry data have been used, publications and journal citations, or other activities of interest to registries, NPCR, and the public.
Registries can use compelling success stories, rich with in-the-field experiences, to promote their progress, value, and impact. These stories engage and inform stakeholders, increase program visibility, demonstrate the value of cancer data, and share best practices.

Promoting these stories is critical to describe the role cancer registries play in reducing the burden of cancer. Registry success stories are collected annually in the fall, edited and cleared by CDC, and posted on CSB's internal and external SharePoint sites. They have been promoted in many ways, including:

- At the national NPCR program review meeting.
- As part of peer-to-peer learning by registries.
- As part of continuing education.
- At national meetings, conferences, and webinars.
- On websites for CDC, NPCR partners, and registries.
- In newsletters, blog posts, and cancer awareness month promotions.
- In communications for CDC leaders and members of Congress.

The benefits of creating and distributing registry success stories include:

- Capturing program progress over time.
- Illustrating a problem being addressed.
- Showcasing a specific achievement.
- Describing the effects of specific activities and strategies.
- Facilitating peer-peer support and development of new technical assistance resources.
- Demonstrating responsible use of resources for stakeholders, partners, and members of the public.
- Educating decision makers about the program's impact.
- Broadening understanding of the value of registries.
- Attracting new partners for collaboration.

Appendix 4-8: NPCR Education and Training Coordination

Tips for a Successful Education Program

CDC's NPCR Program requires awardees to have an Education and Training Coordinator (ETC) who works with quality control staff to maintain the highest level of data quality. Below are some ideas and tips for how to maximize your educational and training efforts and improve the data that are reported to your central cancer registry.

1. What are the educational and training needs in your jurisdiction? Review existing resources including policy and procedure manuals, coding manuals, and training materials to ensure you have a good grasp of the information available and the requirements for your staff. Identify performance, skill level, knowledge, and goals upon successful completion of your education program or training session.

2. Participate in the National Education and Training Coordinators (NET-C) Forum and the annual NPCR Education and Training Workshop. These are great ways to share resources and opportunities for education and training with those who have many levels of experience and knowledge in cancer registration.

3. Provide feedback and educational opportunities through multiple channels of communication, such as webinars, newsletters, or face-to-face. Everyone learns and retains information differently, so it is important to know that your designed trainings are meeting the needs of your audience.

4. Review NPCR's Data Quality Evaluation (DQE) and the Data Evaluation Results (DER) reports for more insight into your registry's specific challenges and areas for improvement. These evaluations assess data quality, including coding accuracy and completeness.

5. Another good way to identify problem areas is by conducting routine audits. Routine audits are discussed in detail in our NPCR NET Module Series on Quality Assurance at https://fcds.med.miami.edu/inc/flccsc.shtml. Audits also provide assurance about the education program's effectiveness by providing measurable feedback from priority problem areas. If the audit results show improvement, the education program is operating effectively.

6. Measure pre-training performance levels and get feedback after the training or meeting. It is a good idea to develop a short evaluation or assessment to get a baseline of staff skills and accuracy and post-training assessment. These will help define your education goals and assess how effective the training

was.

7. Here are some questions to help your registry plan a successful education program:

   - Who are the intended recipients of your education efforts? Will you educate seasoned staff or new registrars?
   - What challenges does your registry face related to education and training?
   - What educational resources are available?
   - What types of errors are consistent? Can trends be identified? Are errors from the central registry or reporting facility?

Appendix 4-9: NPCR Data Quality Activities Overview

For more than 25 years, NPCR data have served as one of the cornerstones to monitor the cancer burden, priority goals, and measure progress toward cancer prevention and control activities in the United States. High-quality population-based surveillance systems, including NPCR, depend on the completeness of case reporting, timeliness, and data accuracy. NPCR emphasizes that central cancer registries (CCRs) collect and report high-quality data by implementing the NPCR Program Standards and data assessments. These procedures and assessments ensure that cancer data available for public health surveillance research are of the highest quality. Below is a brief description of NPCR's data quality activities.

Data Quality Evaluation (DQE)

All NPCR awardees are required to participate in NPCR-sponsored independent DQE conducted by CDC or a CDC-approved organization or entity on the regular basis, usually every 3 years. The DQE assesses the data quality of NPCR-funded cancer registries, identifies best practices and challenges, and determines training needs. The DQE has two components: validation and completeness.

The validation evaluation assesses the quality of select data items for specific primary sites in the CCR database. The validation results compare the CCR's performance with NPCR program standards so NPCR can offer recommendations to improve the CCR's data accuracy.

The completeness evaluation reviews the count and proportion of cases coded to unknown or some variation of unknown for selected data items. This includes a follow-back activity to complete unknown data. The purpose of the follow-back is to understand the reasons for unknown values for selected data items, assess the burden to collect and complete unknown values, and assess the feasibility of collecting high-quality treatment data.

These components and the cancer sites are subject to change.

Central Cancer Registry (CCR) Internal Audits

In addition to the DQE, CCRs should conduct their own internal case finding and re-abstracting audits from a sample of source documents for each hospital-based reporting facility at least every 5 years. These audits may include a manual review of source documents, as well as data linkages of electronic files from submitting facilities with the CCR database. Internal audits standardize interpretation and abstracting of the medical record, estimate rates of agreement, and identify problems in data collection and interpretation.

Data Evaluation Report (DER)

The NPCR-Cancer Surveillance System (NPCR-CSS) DER shows the completeness, accuracy, and timeliness of the CCR's data submission. The following data quality criteria are included in the report: percent completeness adjusted for duplicates, unresolved duplicate rate, percent death certificate only cases, percent missing critical data elements (age, sex, race, and county), and percent passing edits. The report also provides information related to registry operations, such as distribution of reported cases by behavior, percentage of cases with override flags, and distribution of missing or unknown data quality indicators.

Internal Data Quality Analysis of Selected Data Items

NPCR staff routinely evaluate the quality of selected data items. Extensive descriptive and trend analyses are performed for data items of interest by demographics including sex, age group, race and ethnicity, and state or territory of diagnosis. The focus is on the distribution of cases with unknown values for specific data items across cancer sites.

NPCR Quality Control Workgroup

This CDC workgroup discusses data quality projects and activities. It meets monthly and includes representatives from the DCPC's Cancer Surveillance Branch. Its activities include in-depth analysis of CCRs meeting NPCR's 12- and 24-month standards, development of briefs describing operational success and challenges, and CCR-specific data quality presentations for program consultants to use during site visits or conference calls with CCRs.

Data Quality Collaborations with Other Partners

As an additional process to ensure high-quality data are available in USCS, NPCR collaborates with the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program on projects designed to establish a consistent set of quality benchmarks for evaluating various data items. Common benchmarks prevent duplication of work, improve communication about data quality, and raise awareness that CCRs provide high-quality data for public health surveillance research and cancer control. Recent work includes quality evaluations of cancer grade and staging data.

Appendix 4-10. – NPCR – CSS Data Submission Specification Overview

Appendix 4-10: 2023 NPCR-CSS Data Submission Specification Overview

1. Use ICD-O-3 codes

2. Diagnosis years
   a. Submit to CDC by November 30, 2023:
      i. NPCR reference year through December 31, 2011
      ii. January through December 31, 2022 strongly encouraged

   b. Submit to CDC by January 31, 2024:
      i. Submit January through December 31, 2022

   c. **Do not** resubmit any diagnosis year data
      i. Unless CDC instructs you to do so

3. Reportable diagnoses
   a. Report all histologies with:
      i. Behavior of /2 or /3
      ii. Pilocytic astrocytoma [9421]: convert behavior to /3 except optic nerve (C723) diagnosed on January 1, 2018 or later
      iii. Non-malignant primary intracranial/CNS, behavior /0, /1 diagnosed on or after January 1, 2004
      iv. Behavior /0 or /1 reported as /3 by a pathologist

   b. Exclude:
      i. Primary site and histology combinations noted in NAACCR Vol II
      ii. Squamos and intraepithelial neoplasia grade III (8077/2)
         1. Anus (C21.0–C21.1, AIN III)
         2. Vagina (C52.9, VAIN III)
         3. Vulva (C51, VIN III)
         4. Cranial bones behavior /0 or /1 (C41.0)
      iii. Histologies 8442/1, 8451/1, 8462/1, 8472/1, and 8473/1 diagnosed before January 1, 2001

4. Include all required data items in Attachment 2
   a. Bold indicates a new data item
   b. Data items **not collected**
      i. Leave blank
      ii. Note reason in submission form
   c. Data items **collected but not reported for confidentiality, or State law prohibits**
      i. Note reason in submission form
      ii. Data of Diagnosis, Date of Last Contact must be reported in full.
      iii. Do no convert others dates to unknown, submit partial dates/
      iv. Include confidential/restricted data items in input file. Select confidential/restricted data to be excluded from output file.

d. **Do not include** data items from the Patient-Confidential Section

e. Diagnosis year-appropriate stage data
   i. Summary Stage 1977 diagnosis years 1995 through 2000
   ii. Summary Stage 2000 diagnosis years 2001 through 2003 and 2015 through 2017
   iii. Derived Summary Stage 2000 diagnosis years 2004-2014
      1. May submit directly-coded Summary Stage 2000
      2. Diagnosed on/after January 1, 2012
      3. Diagnosed in 2004-2011 if the Type of Reporting Source is 3, 4, 5, 6, or 7
      4. Over-Ride CS 20 set to 1
   iv. Summary Stage 2018 diagnosis year 2018 and later

f. Early Detection Program link variables
   i. Link through 2022 diagnosis year
   ii. Link variable to indicate linkage results
   iii. Link date to indicate date records matched on linkage
g. Primary payer at diagnosis variable - as available, but strongly encouraged

5. Run edits shown in Attachment 3
   a. No separate edit set for diagnosis year 2022
      i. Diagnosis year 2022 is not required to be error-free
   b. Bold indicates a new edit

6. Perform duplicate assessment protocol
   a. Identify duplicate records using updated NAACCR protocol
   b. Perform 100% patient-level deduplication
      i. Self-report results
         1. NPCR reference year-2021
         2. 2021
         3. 2022
   c. Initiate tumor-level deduplication
      i. Self-report results
         1. 2017-2021
         2. 2021
   d. Create Match*Pro archive file (CSV-format) and upload at submission.

7. Report linkage and algorithm results
   a. Indian Health Service linkage is required for all registries
   b. Use NAACCR*Prep,
      i. Select NPCR-CSS configuration rile
      ii. Determine appropriate suppressions
      iii. Derive and include linkage results in submitted data. The derived data items are noted in Appendix 2.

8. Record format
   a. NAACCR Record Layout version 23
   b. Submit XML file format

9. Submission due date
      i. 11/1-30/23
         1. **Deadline is 6 p.m. EST, 11/30/23**

b. 1/1-31/24
   i. **Deadline is 6 p.m. EST, 1/31/24**

c. Allow sufficient time for file review to determine acceptability
d. Extensions that were approved in advance for unusual and compelling circumstances only
   i. **Requests deadline 10/16/23.**

e. **Do not resubmit any diagnosis year data**
   i. Unless instructed to do so by CDC

10. Prepare and transmit file
    a. Use attachment 5, NPCR-CSS Checklist provided

11. Attachment 6, File Transfer Instructions provided
    a. Include both the XML data file and the NAACCR*Prep output user dictionary in compressed file
    b. Naming convention (XX represents the state or territory abbreviation)
       i. XX9521V23
       ii. XX22V23

12. Attachment 7, Data Security Overview provided

13. Complete online Data Submission Form

14. Questions
    a. See Attachment 9 for answers to frequently asked questions
    b. Technical questions
       i. E-mail support@npcrcss.org (preferred)
       ii. Help line 301-572-0502

    c. Submission deadlines, requirements, and submission form
       i. E-mail Red Wilson (rwilson1@cdc.gov) and Mary Elizabeth O'Neil (dbi8@cdc.gov) (preferred)
          1. Copy your program consultant
       ii. 770-448-3245

15. Data Evaluation
    a. Advanced National Data Standard
       i. ≥90% completeness
       ii. ≤3% missing or unknown
          1. Age
          2. Sex
          3. county
       iii. ≤5% missing/unknown
          1. Race
       iv. ≤2 duplicates/1,000
       v. ≥97% pass edits

    b. National Data Standard
       i. ≥95% completeness
       ii. ≤2% missing or unknown
          1. Age
          2. Sex

3. County

iii. ≤3% missing or unknown
1. Race

iv. ≤3% Death certificate only (DCO)
v. ≤1 duplicate per 1,000 records
vi. ≥99% pass edits

c. USCS/USCS County Public-Use File publication criteria
i. ≤3% missing or unknown
1. Age
2. Sex

ii. ≤5% missing or unknown
1. Race

iii. ≤5% DCO

d. NPCR Survival File
i. National Death Index linkage performed ***or***
ii. Current follow-up date ≥80% of alive cases ***and***
iii. Trend in number or percent deceased records
iv. Completeness of Date of Last Contact

Appendix 4-11: NPCR Electronic Reporting Guidance

Electronic reporting and electronic data exchange refer to the format of the data that are being exchanged and the method reporters use for transmission to the central cancer registry (CCR). This exchange of information is defined as the process of transferring data from one computer system to another in a standardized format that eliminates or significantly reduces the need for manual data entry and minimizes the need for human intervention.

Electronic reporting is the transfer of data collected from source documents by hospitals, physician offices, clinics, or laboratories in a standardized, coded format that does not require manual data entry at the CCR level to create an abstracted record.

Electronic data exchange involves data transmission from the reporting source to the CCR. Data must conform to the appropriate nationally adopted standardized formats for data exchange and mapping to the North American Association of Central Cancer Registries (NAACCR) record layout for inclusion in the central cancer registry database. There are several nationally adopted standards for reporting different types of data from non-hospital sources. Linkage with other data sources or databases, including claims data, to add or enhance cancer data is considered electronic data exchange.

Electronic reporting and electronic data exchange do not include faxing, mailing a portable storage device, or any similar methods of transferring data. The CCR will use secure Internet-based software such as the Public Health Information Network Messaging System (PHINMS), Association of Public Health Laboratories Informatics Messaging Services (APHL AIMS), Web Plus, secure File Transfer Protocol (sFTP), or encrypted e-mail such as HyperSend to receive data from all reporting sources. The use of portable storage devices for data transmission is not recommended, but may be used if Internet access is not available.

CCRs are required to use standardized, CDC-recommended data transmission formats for the electronic exchange of cancer data. Registries will promote the use of the CDC-recommended formats by reporting sources that transmit data electronically to the registry. The CDC-recommended data exchange formats are identified in the following sections.

Hospital Reporting

The electronic data system should use the NAACCR record layout version specified in year-appropriate *Standards for Cancer Registries Volume II: Data Standards and Data Dictionary.*

Physician Reporting

Electronic reporting includes not only proactive reporting, but also responses from physicians to CCR inquiries such as death certificate only cases. Electronic reporting can be accomplished using CDC's Web Plus software. Physician offices wanting to report directly from their electronic medical record (EMR) or electronic health record (EHR) software should use the following standard for reporting:

- *HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm* (www.hl7.org/implement/standards/product_brief.cfm?product_id=398) or more recent updates if included in Office of the National Coordinator for Health Information Technology (ONC) Certification Rule or newer standards such as HL7 Fast Healthcare Interoperability Resources (FHIR). This guide uses the HL7 CDA with added cancer-specific sections and constraints to meet the public health needs of reporting to cancer registries. It has updates from the previous version, including tighter requirements on data elements needed by the CCRs and new data elements not included in the last version. CDC's eMaRC Plus software can process reports submitted in this format.

Other (Non-Hospital) Reporting

Reporting sources include radiation and medical oncology centers, ambulatory surgery centers, and any other reporting source that provides health care services to cancer patients outside the hospital setting.

Electronic reporting can be accomplished using CDC's Web Plus software. Non-hospital sources wanting to report directly from their EMR or EHR software should the same standard as physician offices.

- Laboratory Reporting

Laboratories should use the following recommended standards for reporting to central cancer registries:

- **Anatomic pathology laboratory reports:** *NAACCR Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting* (version 5.0) or newer standards such as HL7 FHIR. This exchange format will be used for reporting pathology, biomarker and prognostic factor data for narrative reports and College of American Pathologists (CAP) Cancer Checklist reports.
- **Other laboratories:** NPCR is working with CCRs, HL7, and national standard setters to identify the appropriate format that laboratories should use to report molecular data to CCRs. Several standards could be used, such as the NAACCR Volume V standard, the *HL7 FHIR Genomics Reporting Implementation Guide, 1.1.0 - STU 1 Ballot, HL7 Version 2 Implementation Guide for Clinical Genomics,* and others. More research and evaluation must be completed before a standard can be adopted for broad implementation. CCRs are encouraged to pay close attention to the progress being made in this area so they can help laboratories adopt the new standards for reporting these data.

Notes

Not all facilities can submit data electronically. However, as the technology and resources become available, those facilities are expected to embrace it. The goal is to increase electronic reporting.

Some reporting facilities may not have trained staff for data collection, and the CCR abstracts the data. These data should be abstracted into a secure cancer software program such as Web Plus, which can populate the appropriate fields at the CCR.

All cancer data should be transmitted to the CCR in an electronic format.

Facilities that cannot submit cancer data electronically should use a flat ASCII text file.

Activities Relating to Electronic Reporting

a. The CCR uses a secure Internet-based FTP, https, or encrypted e-mail mechanism to receive electronic data from reporting sources.

b. The CCR has a plan to implement a mechanism for receiving and processing data from EMRs and EHRs over the 5-year project period.

c. The CCR participates in NAACCR Physician Reporting Workgroup if applicable.

d. The CCR participates in quarterly CDC NPCR Meaningful Use Workgroup calls on the second Wednesday of January, April, July, and October from 3:00 to 4:30 pm Eastern Time.

e. The CCR implements electronic physician reporting to the state or territory cancer registry using Meaningful Use (MU) Stage 3 Clinical Document Architecture (CDA) or newer standards.

f. The CCR communicates with NPCR on issues identified with EHR vendors and providers during MU implementation.

g. The CCR participates in calls with EHR vendors.

h. The CCR helps identify bugs and develop enhancements to software tools used for physician reporting, including eMaRC Plus, CDA Validation Plus, and the Cancer Report Validator.

i. The CCR participates in quarterly NPCR-AERRO ePath Reporting Workgroup calls on the second Thursday of January, April, July, and October at 3:00 pm Eastern Time.

j. The CCR implements use of NAACCR Volume V specification with laboratories to report cancer pathology and biomarker data to the CCR.

k. The CCR helps identify bugs and develop enhancements to eMaRC Plus software for processing electronic pathology reports.

The CCR provides input regarding the natural language processing (NLP) service or application programming interface (API).

Appendix 4-12: Physician Reporting Guidance

NPCR legislation requires awardees to have "a means to assure the complete reporting of cancer cases to the statewide cancer registry by physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients, except for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that state and reported by those facilities." State and territorial laws vary in how the physician reporting requirements are implemented. The NPCR Program Standards for 2022 through 2027 identify the following goals for physician reporting:

- Annually increase the reporting by urologists, dermatologists, and gastroenterologists to the central cancer registry (CCR) as required by state or territorial law to meet the standard of having most of these physicians reporting by the end of the 5-year project period.

- Annually increase the reporting by medical oncologists, radiation oncologists, and hematologists to the CCR as required by state or territorial law to meet the standard of having most of these physicians reporting by the end of the 5-year project period.

For CDC to monitor compliance with these standards, funded NPCR registries should use consistent methods to count and report improvements in physician reporting. This document defines the minimum requirements for physician reporting, describes methods to monitor compliance, and provides additional guidance for improving physician reporting.

Health Care Practitioners Required to Report

By law, all physicians may be required to report. For the purposes of the NPCR Program Standards, the following physician specialties, *at a minimum,* should be prioritized for reporting cancer cases that are not reported by another source:

- Dermatology
- Urology
- Gastroenterology
- Hematology
- Medical oncology
- Radiation oncology
- Independent surgery

Types of Reporting

Physician reporting can be active or passive. The CCR should strongly encourage active reporting.

- **Active Reporting:** The physician takes the initiative to report cancer cases proactively. This may include the use of abstracting software, transmission from electronic medical records, and submission of paper reports, if necessary. Cases are submitted without prior CCR request.

- **Passive Reporting:** The physician reports cancer cases in response to CCR requests, including death certificate inquiries and CCR casefinding audits.

Methods to Monitor and Determine Compliance with NPCR Program Standards

Recognizing the complexity of defining a complete list of all physician specialties in the state or territory (the denominator), the NPCR Program Standards focus on increasing the total number of physician specialties reporting to the CCR (the numerator) annually. CCRs must have a method in place to track the type and number of physician specialties that are reporting at the beginning of the year (baseline) and the total number reporting at the end of the year, including those added during the year, to monitor annual progress. The tracking system also should indicate whether the reporting source is a practice or individual

physician (see definition below). Both active and passive reporting are included in the number of reporting sources.

CCRs can count the number of reporting sources by practice, individual physician, or a combination of the two methods.

- **Practice Method:** Each specialty practice is counted as a single reporting source, regardless of the number of physicians in the practice.

- **Individual Physician Method:** Each physician is counted as a single reporting source, regardless of the number of locations in which he or she works.

CCRs should develop a consistent methodology that is in alignment with this guidance document.

- If the CCR cannot determine if a physician is reporting on behalf of a practice, count the reporting source as an individual physician.

- If the type of physician is unknown or not listed as one of the priority physician specialties, group the physician into an “Other” category.

Progress toward the NPCR Program Standards should be reported in the CCR’s progress reports, grant applications, and the NPCR Program Evaluation Instrument (PEI).

Suggestions for Increasing Physician Reporting

I. Develop a Strategic Plan to Increase Physician Reporting.

A. Develop a physician reporting advisory group. Consider a working group in the cancer registry advisory group or cancer coalition. Include key players such as the cancer leadership team, American College of Surgeons state liaison, state or territorial medical society, and respected retired specialty physicians.

B. Ask physicians on the advisory committee for advice on ways to achieve compliance and advocate for physician reporting.

C. Communicate with other CCRs about physician reporting to exchange ideas for success.

D. Focus on physician specialties with the highest number of missed cases identified through linkages with pathology reports, death certificates, or other databases.

E. Compare state or territory and national rates for specific cancer sites to identify specialties where cases may be missing, such as urology (prostate) or dermatology (melanoma).

F. Increase physician reporting gradually to make the process more manageable. Start with one specialty physician or group and then move on to the second. At least one new category of specialty physicians should be completed each year.

G. Work with NPCR to identify electronic medical record (EMR) and electronic health record (EHR) systems capable of transmitting cancer reports, and identify physicians and practices using these systems.

II. Identify Physicians and Practices.

A. Develop a memorandum of agreement with the state or territory physician licensing agency that includes a mechanism to:

1. Receive lists of new licensees regularly.

2. Include CCR information in license applications.

3. Institute a continual process to include renewals and exclude physicians who no longer practice in the state or territory.

4. Develop a process to require compliance with reporting laws for physician licensure. In other words, licensing is contingent on meeting all state or territory reporting rules. The CCR sends a list of noncompliant physicians to the licensing board.

B. Look for other programs, associations, or societies which may have physician directories that can be shared.

C. Obtain lists of hospital staff physicians that may be updated annually.

D. Investigate the use of physician address services.

E. Use follow-back for pathology reports and death clearance certificates to identify new physician sources.

III. Recruit.

A. Make presentations on the importance of physician reporting.

1. Possible venues include meetings of the American Medical Association, urologists, dermatologists, and oncologists.

2. Speakers include physician advisory board members and officers of the specialty associations.

3. Include examples of how data are used and list the reports available.

4. Focus on the effect of physician reporting on cancer surveillance and the importance of population-based cancer data for cancer control efforts.

5. Follow up with a personal contact with the physician or practice manager.

B. Send new physician reporters a package.

1. Include the law that requires physicians to report all cases not reported by other facilities, Health Insurance Portability and Accountability Act of 1996 (HIPAA) information, procedures for how and when to report, a copy of the reportable list, and any documents specific to the state or territory.

2. An introductory letter may be sent from state or territory officials or the CCR administrator

outlining reporting requirements.

3. Address letters to the practice's medical director or office manager. Set up a continual process to include new physicians and exclude physicians who no longer practice in the state or territory.

IV. Determine Software and Develop Operation Procedures and Manuals.

A. Use NPCR's Web Plus software for physician reporting when possible. Web Plus can create custom data collection displays specific to the physician specialty. This program uses the Internet for reporting, and all software and case information are maintained on a CCR server providing data security. Alternatively, if physicians or practices have EHRs and can report in the format specified in the *HL7 CDA® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1—US Realm,* they can transmit these reports using a secure transport mechanism such as Web Plus, Public Health Information Network Messaging System, Direct, Nationwide Health Information Network (NwHIN) Connect, or secure (FTP).

B. Use NPCR's eMaRC Plus software for receiving and processing physician reports transmitted from physician EHRs in one of the HL7 CDA formats.

C. Use NPCR's Abstract Plus software for physician reporting if the physician office does not have Internet access.

D. See NPCR's website www.cdc.gov/cancer/npcr/tools/registryplus/ for information on software products including Web Plus, Abstract Plus, and eMaRC Plus.

E. Develop operations procedure manuals to guide physician reporting.

V. Train.

A. Provide training with focused, clear, and concise educational materials and provide ongoing support.

B. Demonstrate available tools.

C. Provide training for the physician office staff learning how to abstract reportable information.

VI. Establish a Physician or Clinic Database to Monitor Physician Reporting.

A. Determine if the primary database will be of physicians or practices. Decide whether it will be separate or part of a larger database that includes other reporters.

B. Determine if any other division of the health department maintains a physician or practice database that could be used, such as physician licensing or emergency medical service.

C. Determine if CCR software can generate a file that provides information on the CCR's reporting physicians.

D. Develop a new database if necessary.

E. Update the database as responses are returned, or at least annually.

F. Develop database elements to include:

1. Physician or practice identification number.

2. Contact information, including the name and address of the person responsible for responses.

3. Reporting source, which can be an individual physician, clinic, or physician group; one physician can be listed with multiple clinics or practices.

4. Physician specialty.

5. Reporting status (proactive, responsive to inquiries, does not respond).

6. Method for reporting (Web Plus, HL7 CDA, electronic form, or other).

7. Provider participating in Meaningful Use.

8. Date last updated.
9. Initials of the person updating.

10. Sources of the update.

11. Use follow-back for information to complete missing fields.

VII. Communicate.

A. Place easy-to-find links on CCR's web page that include:

1. Laws and rules.

2. Reporting form and manual.

3. Physician reporting procedures, including Meaningful Use registration processes.

4. Software manual for physician office staff.

5. Telephone and e-mail contact information for the CCR coordinator.

Send written reports such as an annual monograph to physicians, so they can view a positive outcome of participating in CCR reporting.

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Appendix 4-13. – Electronic Data Exchange Guidance

Appendix 4-13: Electronic Data Exchange

I. The central cancer registry is required to adopt and use standardized, CDC-recommended data transmission formats for the electronic exchange of cancer data (see CDC NPCR Electronic Reporting and Data Exchange Guidance). Registries will promote the use of the CDC- recommended formats by reporting sources that transmit data electronically to the registry. The CDC-recommended data exchange formats include

   A. Hospital reporting: The NAACCR record layout version specified in the year-appropriate *Standards for Cancer Registries Volume II: Data Standards and Data Dictionary.*

   B. Anatomic pathology laboratory reports: NAACCR *Standards for Cancer Registries Volume V: Pathology Laboratory Electronic Reporting* (version 5.0) or newer standards such as HL7 FHIR. This exchange format will be used for reporting pathology, biomarker and prognostic factor data for narrative reports and College of American Pathologists (CAP) Cancer Checklist reports.

   C. Non-hospital sources using electronic medical records (EMRs) or electronic health records (EHRs): *Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA),* Release 1.1 or newer standards such as HL7 FHIR.

II. Every year, increase the percentage of hospitals reporting electronically to the central cancer registry to meet the standard of having all hospitals reporting electronically by the end of the 5- year project period.

III. Every year, increase the percentage of non-hospital facilities reporting electronically to the central cancer registry to meet the standard of having at least 80% of these facilities reporting electronically by the end of the 5-year project period.

IV. The central cancer registry uses a secure Internet-based, FTP, https, or encrypted e-mail mechanism to receive electronic data from reporting sources.

V. The central cancer registry has a plan to implement a mechanism for receiving and processing data from EMRs and EHRs over the 5-year project period.

Appendix 4-14: NPCR Hospital, Pathology Laboratory, and Physician Progress Report

NPCR-funded registries are encouraged to use this template to track and report progress on the following activities. If useful, please include this form in the Annual Progress Report (continuation application). If space is limited, please include in the appendices or email to your program consultant.

Hospital and Pathology Laboratory Reporting

Please list the number, by type, that are required to report, and the number that were compliant with reporting at the end of the year. Also report the number reporting electronically in a standardized format that minimizes the need for manual data entry.

- A *hospital cancer registry* is defined as one single or joint institution that collects data to be used internally, and that would continue to do so regardless of the central cancer registry requirements to collect and report cancer data.
- For the types of hospitals and pathology laboratories that are not applicable to your state or territory, such as Indian Health Service (IHS) hospitals, record zero (0) in all three columns, according to Program Standards V c–d and IV b–c.

	Number Required to Report[1] (Denominator)	Number Compliant with Reporting[2] at the End of the Year	Number Reporting Electronically[3]
Hospitals			
Hospitals with a cancer registry (nonfederal)			
Hospitals without a cancer registry (nonfederal)			
Veterans Affairs hospitals			
IHS hospitals and clinics			
Tribal hospitals and clinics			
Pathology Laboratories			
Independent laboratories in the state or territory			
Independent laboratories outside the state or territory			
Other			
Total			

Physician Reporting

[1]Although these groups are not required by law to report, please indicate the number of known facilities that diagnose or treat cancer for residents of your state or territory.
[2] Those that report, not only those reporting in a timely manner.
[3] Electronic reporting is the transfer of data collected from source documents by hospitals, physician offices, clinics, or laboratories in a standardized, coded format that does not require manual data entry at the CCR level to create an abstracted record.

The NPCR Program Standard for physician reporting focuses on increasing the number of physicians reporting to the CCR annually. The NPCR Physician Reporting document provides guidance on how to count physician reporting. In the table below, please provide the number of physician specialties that were reporting at the end of the reporting year in column b. In column c, record the number of physician specialties from column b that are reporting electronically.

CCRs may use the Practice Method, Physician Method, or a combination of the two. The Practice Method counts each specialty practice as a single reporting source, regardless of the number of physicians in the practice. The Physician Method counts each specialty physician as a single reporting source, regardless of the number of locations in which he or she works. For example, you may use the Practice Method to count hematology (two practices) and use the Physician Method to count dermatologists (10 physicians). Do not count the physicians in the hematology practices again in the Individual Physician section.

CCRs should use a consistent methodology. If the CCR is unable to determine whether a physician is reporting on behalf of a practice, count the reporting source as an individual physician. If the type of physician is unknown or is not listed as one of the target physician specialties, group the physician into an "Other" category.

a. Specialty	b. Number Reporting[4] at the End of the Year	c. Number Reporting Electronically[5]	Meaningful Use Stage 2			Meaningful Use Stage 3		
			d. Number Registered Intent	e. Number in Testing or Validation	f. Number Reporting in Production	g. Number Registered Intent	h. Number in Testing or Validation	i. Number Reporting in Production
Physician Groups (Practice Method)								
Independent surgery centers[6]								
Independent radiation therapy centers								
Hematology								
Medical oncology								
Urology								
Dermatology								
Gastroenterology								
Other								
Individual Physicians (Physician Method)								
Surgeons[f]								

[4] Those that report, not only those reporting in a timely manner.
[5] Electronic reporting is the transfer of data collected from source documents by hospitals, physician offices, clinics, or laboratories in a standardized, coded format that does not require manual data entry at the CCR level to create an abstracted record.
[6] Surgeons who diagnose or treat cancer patients in the office.

Radiation oncologists								
Medical oncologists								
Hematologists								
Urologists								
Dermatologists								
Gastro-enterologists								
Other								
Total								

Meaningful Use/Promoting Interoperability

Meaningful Use (MU) Stage3 facilitates electronic reporting from ambulatory health care providers to the state cancer registry using the *Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries August 2012* [PDF-1.9MB]

(www.cdc.gov/phin/resources/guides/documents/implementation_guide_for_ambulatory_healthcare_provider_reporting_t o_central_cancer_registries_august_2012.pdf) OR the *Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.1 (www.hl7.org/implement/standards/product_brief.cfm?product_id=398)*. Please answer the following questions regarding MU.

1. What is the total number of state or territory staff required to support physician MU activities? _____ Examples of activities include responding to physician registrations, tracking communications with physicians and electronic health record (EHR) vendors, testing sample physician reports, providing formal feedback to physicians, facilitating meetings with physicians and EHR vendors, setting up a secure encrypted transport mechanism to receive physician data, and attending NPCR meetings with vendors.

2. What is the average number of electronic cancer reports received per month through providers participating in MU (either stage)? _____

3. What types of secure encrypted transport are you using for MU reporting for physicians in **testing**? (Check all that apply.)

a. PHINMS
b. _____ Secure
c. _____ FTP Web
d. _____ Plus
e. _____ HTTPS
f. _____ Direct
g. _____ Secure encrypted e-mail

Other (specify): _____

_____

4. What types of secure encrypted transport are you using for MU reporting for physicians in **production**? (Check all that apply.)

a. _____ PHINMS
b. _____ Secure
c. _____ FTP Web
d. _____ Plus
e. _____ HTTPS
f. _____ Direct
g. _____ Secure encrypted e-mail

Other (specify): _____

5. Are health information exchanges (HIEs) involved in any of the MU processes for reporting cancer data? Yes or No
If yes, please indicate which of the following roles they play:

_____ Transport only (cancer reports are sent securely through the HIE as a pass-through; the HIE does not have access to any of the data)

_____ Data validation

_____ Data storage

_____ Data analysis

_____ Other (specify):

Appendix 5. – Maryland Evaluation Plan Performance Measures

Contractor will be responsible for supporting the evaluation of the Maryland Cancer Registry by submitting data for the following performance measures to the Contract Monitor annually:

Activity or Outcome	Performance Measures	Data Source
Improved timeliness, quality, completeness, and confidentiality of MCR data	% of data submitted that passes internal audits	Internal audit reports
	# of hospitals passing external case finding and re-abstracting audits	External audit reports
	# of MVA lookups; # of missing fields resolved	MVA records; MCR database
	# of data exchanges with other central cancer registries; and # of abstracts received from other states	Program records; MCR database
	# of reporters contacted as a result of lower-than-expected cases on current processing reports	Jira and program records
	# and type of possible data issues identified and resolved through QA analyses (e.g., quarterly cross-tabulation analysis)	Jira and program records
	# and type of innovation projects conducted; # of abstracts or cases reported as a result	Program records
Increased electronic reporting; increased adoption of data modernization strategies	# and % of facilities reporting electronically; description of changes from prior year	List of reporters; program records
	# of eMaRC Plus submissions by non-hospital facilities	Program records
	# of labs reporting through AIMS platform	List of reporters; program records
Achievement of data quality standards	Data completeness based on observed-to-expected cases computed by CDC for 12-month and 24-month data	MCR database
	% of Death Certificate Only cases for 12-month and 24-month data	MCR database
	Duplicate rate (per 1000) for 12-month and 24-month data	MCR database
	% missing age for 12-month and 24-month data	MCR database
	% missing sex for 12-month and 24-month data	MCR database

	% missing race for 12-month and 24-month data	MCR database
	% missing county for 12-month and 24-month data	MCR database
	% passing CDC-prescribed edit set for 12-month and 24-month data	MCR database

Appendix 6. – Management Reports

Maryland Cancer Registry--Management Reports

Report Name and Description of Reporting Period. Note that reports are due within 10 calendar Days after the end of the reporting period unless specified elsewhere in this document.

Administrative Reports

1	List of Reporting Facilities: Name of organization; address; contact person; telephone, fax, e-mail, type of facility, date facility first reports to MCR, Facility ID number (RepFacilMD_5,RepFacilMD_10), Hospital ID number (if hospital); Method of reporting (WebPlus upload; Web Plus direct entry; hard copy; abs plus; other)	Quarterly for the Fiscal Year
2	List of each reporting facility and name of contractor CTRs responsible for the facility	Quarterly for the Fiscal Year
3	List of contractor's staff and level of access to Master Databases	Quarterly for the Fiscal Year
4	List of contractor's staff denoting that each person has a signed confidentiality agreement on file	Quarterly for the Fiscal Year
5	List of audits performed and findings by reporting facility, month, and year	Monthly
6	Confirmation of database file system backup and locations (Registry Plus—Web Plus; Prep Plus; CRS Plus)	Quarterly for the Fiscal Year
7	Report on contractor's review of NPCR annual Data Evaluation Reports	Annually within 30 Days of receiving report

8	Fiscal Year Report: Activities; Number of Reporting Facilities submitting reports; Number of non-voided abstracts received by reporting facility type (hospital, laboratory, radiation facility, ambulatory surgical center, and physician office); Number of consolidated records; Number of abstracts submitted by diagnosis year for in State and out of state.	Annually
9	Number of technical consultations provided by facility, date, and topic handled	Monthly
10	Training sessions provided for facilities by date, topic, and presenter	Monthly
11	Training sessions/conferences attended by contractor's staff member, date, and topic (Webinars, TRAM meetings, NAACCR meeting, etc.)	Monthly
12	Meaningful Use Reports including a list of active EPs and where they are in the evaluation process	Monthly
13	Security Logs - See Section 3.7.6	Annually

Reports on Facility Reporting

1	Total number of abstracts received by reporting facility and quarter	Quarterly by Fiscal Year
2	Timeliness of reports Facility, quarter, date received, number received, number of total received within 6 months of diagnosis; % received within 6 months of diagnosis	Annually for calendar year
3	Error/Missing information report: Facility, quarter, total abstracts submitted, number (%) with unknown age, race, gender, Behavior, Spanish origin, type reporting source, diagnostic confirmation, County at diagnosis	Monthly

4	Facility-specific summary of cases reported Facility, incidence year, total cases reported, number of cases of certain PSites, Histology, behavior	Annually for calendar year

Reports on Abstracts

1	Percent of abstracts with certain fields missing: race, sex, county, or stage	Annually for calendar year

Reports on Consolidated Records

(All consolidated in Master consolidated file; reportable includes those tumors that are defined in the Reporting Requirements, e.g., excluding non-melanoma skin cancer, excluding CIN, PIN)

These reports should be generated, reviewed by and retained by the Contractor. The reports should be available for review, if requested by the Contract Monitor.

1	Number of consolidated tumors by behavior, by site, by year.	Annually
2	Number of observed and expected cases (based on prior year), quarterly, during the year. (NAACR Standards for Cancer Registries, Volume III)	Quarterly
3	Number of reportable tumors [cancer, in situ, and benign nervous system tumors] by year by jurisdiction.	Annually
4	Number and percent of reported cases for the 24 and 12 month years, by race, by year, by behavior, by primary site; Number of reported cases by Diagnosis Year and race; behavior; and primary site	Annually

5	Percent of reportable cases with missing race and missing stage by Type of Reporting source	Quarterly
6	Stage of cancer (behavior=2 and 3) by all cancer overall, lung and bronchus, breast, colorectal, prostate, cervical, and melanoma by year.	Annually
7	Certain histologies (8000, 8010, 8140, 8720, 8050, 8500) by type of cancer, including all cancer, lung and bronchus, breast, colorectal, prostate, cervical and melanoma by year.	Annually
8	Number and percent of cancer cases (behavior=3) identified by Death Certificate Only: all cancer and by Cancer Site.	Annually
9	Number of consolidated cases with Psite, behavior, histology, and stage that are "consistent"; e.g., behavior by stage; Psite by Histology	Annually

Reports on Data Processing (from NAACCR online training):

1	Identify steps in processing and develop reporting of length of time between steps for number and percent of abstracts; These are dates that are captured in the MCR Master database: DxDate, Date Created, Date Edited, Date Exported, Date Fac Updated, Date Last Changed, Date OffLoaded, Date PtUpdated, Date Tum Updated, Date Updated.	Monthly
	Time between submission and Prep Plus editing Time between Prep Plus editing and import into CRS Plus Time between CRS import and consolidation if manual consolidation needed Time between hard copy receipt and Web Plus data entry	Monthly
2	A table presenting the number of reports by process completed (e.g. number received and inspected or visually reviewed, number in suspense, number consolidated, etc. by date received in the central registry to monitor workflow. (NAACR Standards for Cancer Registries, Volume III)	Monthly

3	A table showing timeliness of abstracting and reporting by facility	Annually
4	Table showing the number of abstracts received by month by version: Hard copy abstracts Web Plus data entry Web Plus file upload HL7 Other Document Server upload	Annually
5	Table showing the number of abstracts in various stages of processing by month Number of abstracts pending hard copy data entry Number of abstracts pending PrepPlus editing Number of abstracts pending import into CRS Plus Number of abstracts pending consolidation in CRS Plus	Monthly
6	Table showing the number of abstracts processed per month Number of abstracts hard copy entered by CTRs Number of abstracts taken through PrepPlus Number of abstracts manually consolidated	Monthly

Appendix 7. – Labor Resume Form

See link at http://procurement.maryland.gov/wp-content/uploads/sites/12/2018/05/Appendix-xx-Labor-Resume-Form.dotx)

Appendix 8. – Corporate Diversity Addendum - Affidavit I & II

CORPORATE DIVERSITY ADDENDUM
Effective August 18, 2022

Instructions: Pursuant to § 11-101 of the Tax-Property Article, certain entities must provide a Corporate Diversity Addendum, which contains certain diversity data specified by Code of Maryland Regulation ("COMAR") 24.01.07. To determine whether you must provide the Corporate Diversity Addendum, please complete Worksheet A.

Failure to complete the Addendum or failure to meet the criteria therein, may prohibit you from receiving certain State benefits. For more information, refer to COMAR 24.01.07.

Please be aware, the information you include in the Corporate Diversity Addendum may be shared with other Maryland State agencies.

Worksheet A

1. Are you an entity that is required to be in good standing with the State Department of Assessments and Taxation ("SDAT"), and meets the following definition:

   (1) A commercial enterprise or business that is formed in the State or registered with SDAT to do business in the State; or (2) a corporation, foundation, school, hospital, or other legal entity for which none of the net earnings inure to the benefit of any private shareholder or individual holding an interest in the entity?

   ☐ Yes – Proceed to Question 2
   ☐ No – STOP. You are not required to complete the Corporate Diversity Addendum. Complete Affidavit (I) on Page 2 and submit with the application for a State benefit.

2. Check the appropriate box if you are any of the following types of entities:

   ☐ Sole Proprietor
   ☐ Limited liability company (LLC) owned by a single member
   ☐ Privately held company if at least 75% of the company's shareholders are family members
   ☐ Entity that (1) has an annual operating budget or annual sales less than $5,000,000; and (2) has not qualified for or applied for, and does not intend to apply for, a State benefit, as defined below

   Did you check at least one box?

   ☐ Yes – STOP. You are not required to complete the Corporate Diversity Addendum. Complete Affidavit (I) on Page 2 and submit with the application for a State benefit.

☐ No – Proceed to the Corporate Diversity Addendum on Page 3.

"State benefit" means (1) a State capital grant funding totaling $1.0 million or more in a single fiscal year (July 1 – June 30); (2) State tax credits totaling $1.0 million or more in a single fiscal year (July 1 – June 30); or (3) the receipt of a State contract with a total value of $1.0 million or more. "State contract" means a contract that (a) resulted from a competitive procurement process and (b) is not federally funded in any way.

AFFIDAVIT (I)

UNDER PENALTIES OF PERJURY, I hereby swear that the entity submitting this report is not required to submit the Corporate Diversity Addendum.

Entity/Business Name:

_____

Federal Employer Identification Number (FEIN):

_____

SDAT Identification Number:

_____

Name of Entity's representative completing this Affidavit (print clearly):

_____

Title:

_____

Signature: _____

Date:_____

CORPORATE DIVERSITY ADDENDUM

Instructions: If you are required to provide the Corporate Diversity Addendum, completing Affidavit (II) on Page 4 is mandatory. A response to both items is required. Failure to provide a complete response to either of the two items may render the entity ineligible for certain state benefits. For more information, refer to COMAR 24.01.07.

I. A response to Item I is required. However, the content of your response has no bearing on eligibility for State benefits. Select below the underrepresented communities which are represented on this entity's board or in executive leadership. Select all that apply.

☐ Alaska Native
☐ Asian-Pacific Islander
☐ Black or African-American
☐ Hispanic or Latino
☐ Native American
☐ Native Hawaiian
☐ One or more of the racial or ethnic groups listed above
☐ None of the above

II. Check the box next to the following Corporate Diversity indicators that pertain to this entity. *Note that references to underrepresented communities refers to communities listed in Item I above. The examples provided are intended to be representative, not exclusive.* Select all that apply.

1. ☐ Entity maintains written workforce diversity, equity, and inclusion ("DEI") policies.
2. ☐ Entity offers DEI training to its workforce.
3. ☐ Entity assigns a senior-level employee as responsible for oversight and direction of the entity's DEI efforts.
4. ☐ Entity reports performance of its workforce DEI programs on its website.
5. ☐ Entity includes DEI objectives in performance plans of its managers.
6. ☐ Entity publishes information on its website about its DEI commitments and efforts.
7. ☐ Entity provides career advancement training/opportunities for employees, including members of underrepresented communities.
8. ☐ Entity collaborates with educational institutions, or is an educational institution, serving significant or predominant student populations or affinity groups from underrepresented communities (e.g., career fairs, scholarships, internships, apprenticeships).
9. ☐ Entity has a supplier diversity policy that provides business opportunities to diverse suppliers, including businesses owned by members of underrepresented communities, such as State-certified Minority Business Enterprises ("MBEs").
10. ☐ Entity publicizes its procurement opportunities to encourage participation from businesses owned by members of underrepresented communities.

11. ☐ Entity measures percentage of contract dollars awarded to businesses owned by members of underrepresented communities, including MBEs.
12. ☐ Entity provides support and outreach to underrepresented communities and/or organizations that represent underrepresented communities.

Only entities that meet at least 33% (4) of the Corporate Diversity Indicators above, by checking all the applicable boxes, qualify to receive a State benefit.

AFFIDAVIT (II)

UNDER PENALTIES OF PERJURY, I declare that I have examined this Corporate Diversity Addendum, and to the best of my knowledge and belief, it is true, correct, and complete.

Entity/Business Name:

_____

Federal Employer Identification Number (FEIN):

_____

SDAT Identification Number:

_____

Name of Entity's representative completing this Affidavit (print clearly):

_____

Title:

_____

Signature _____
Date_____

Penalties for Submitting False Information. If information provided by the entity in this form or by other means is materially false, the entity and the individual providing the false information may be subject to criminal prosecution for perjury, procurement fraud, and other crimes and may be subject to debarment, and all State benefits or contracts to the entity made in reliance upon the inaccurate form or other information may be void or subject to termination for default. See COMAR 24.01.07.