Department of Health and Mental Hygiene

Behavioral Health Integrated Regulations Workgroup

Recommendation

November 9, 2012
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Overview

The Department of Health and Mental Hygiene, Behavioral Health and Disabilities aims to strengthen the foundation for an integrated behavioral health care system by integrating the regulations applicable to community-based mental health and substance use disorder services in Maryland. This document puts forward a proposal for regulatory reform that requires treatment providers be accredited by a State-approved accrediting entity by July 1, 2015. Please submit comments on this proposal by November 28, 2012 to www.regulations_integration@maryland.gov.

Introduction

In July, 2011 the Deputy Secretary for Behavioral Health and Disabilities appointed a Behavioral Health Integrated Regulations Workgroup to develop integrated regulations governing providers of behavioral health, which includes both mental health and substance use disorder services. The Workgroup consists of representatives from the Mental Hygiene and Alcohol and Drug Abuse Administrations, the Office of the Attorney General, the Office of Health Care Quality, the Office of Health Care Financing, as well as providers of behavioral health services.

The Workgroup has been guided by these principles:

- Reflect and encourage both system and service integration
- Promote administrative simplicity
- Facilitate and support the use of evidence-based interventions
- Support a person-centered approach

Further, given the direction of behavioral health care’s role vis-à-vis medical health care, the workgroup used the regulatory structure of somatic health care as a touchstone. This meant we viewed a new regulatory structure through the lens of how medical services are regulated, which are highly reliant upon the scope of a professional’s license. And, although the charge was to develop an integrated regulatory structure, there were inevitable discussions about the financial structure and how this workgroup’s activity both impacted upon, and would be impacted by, the future financial model for behavioral health services. Those issues are not addressed in this document as they will be under consideration during Phase 3 in the development of the financial model for behavioral health services.

The Workgroup Process

To achieve the goal of creating integrated regulations, the Workgroup met to review the current and prospective health-care climates. Several salient points were raised about the current
the current system operates contrary to a whole-person system by providing care by different providers for different behavioral health disorders; authorization for behavioral health services is not consistent and is diagnosis dependent; and, providers access different funding streams based upon the patient’s diagnosis. It is also acknowledged that services for mental health and substance use disorders are similar in that they consist of outpatient treatment (talk and pharmacological therapies), and rehabilitation, residential, and inpatient services. Additionally, health care reform and parity will change the profile of insured/uninsured and expand choice and reimbursement mechanisms.

Given this context, the Workgroup developed a roadmap that would lead to a recommendation of a regulatory structure that is accessible, streamlined, and durable. The activities identified below built upon one another and served to educate the workgroup and the provider community about the strengths and challenges of using an accreditation model.

- Held conference calls with The Joint Commission (TJC), CARF International (CARF), and the Council on Accreditation (COA) to gather information about coverage, costs, other states’ experiences, implementation barriers, etc.;
- Organized webinars and conference calls for providers with The Joint Commission (TJC), Council on Accreditation of Rehabilitation Facilities (CARF), and Council on Accreditation (COA);
- Requested that the Joint Commission, CARF, and COA provide a crosswalk of accreditation standards with current COMAR regulations for substance use and mental health treatment services (10.47 and 10.21);
- Discussed the sub-committee's draft definition of "program," considered provider comments, and evaluated related policy issues to clarify who is to be accredited;
- Prepared a draft outline of basic regulations required to implement proposal;
- Contacted other states requesting information on role of national accreditation as an oversight vehicle;
- Performed analysis of crosswalk of DHMH regulations with CARF and TJC standards for the purpose of determining what provisions, if any, will be included in new behavioral health regulations.

Throughout this process, there have been multiple opportunities for stakeholder input and reaction, including through an email address, a webinar, and presentations at several provider and consumer-based meetings. Feedback was received from providers who are currently accredited as well as those who are not. This input helped shape the proposal and identified advantages and challenges associated with adopting an accreditation model.
As a result of the workgroup’s activities to date, the workgroup is recommending that the Department of Health and Mental Hygiene (DHMH) require that treatment programs currently covered through mental health regulations (COMAR 10.21) or substance use disorder regulations (COMAR 10.47) apply for and become accredited by a State-approved accrediting organization by July 1, 2015. There are some specific exceptions to this requirement that will be described later. The State will require that programs be approved for licensure through DHMH in order to provide behavioral health services. Receiving accreditation is one step in the process to becoming licensed to provide behavioral health services. This approach, then, requires accreditation as part of the application for licensure to operate in Maryland as a behavioral health provider.

The rationale for this approach is based in both the current and anticipated health care climate. It is broadly acknowledged that existing regulations governing mental health and substance use disorder services are overly burdensome, duplicative of each other, and do not promote the principles identified at the start of this process: reflect and encourage both system and service integration, promote administrative simplicity, facilitate and support the use of evidence-based interventions, and support a person-centered approach. In contrast to a regulations-based approach, accrediting organizations are extremely proficient in responding to changes in practice standards and adopting newly-identified best practices. Their business model allows flexible and timely improvements to their standards to ensure quality of care in treatment services. Their standards focus not just on the clinician/patient interaction but also on policies and practices that affect the entire program, including competence of staff, emergency management, infection control, information management, medication management, and performance improvement. Through contemporary standards, accrediting entities focus on a program’s responsiveness to whole health problems.

Accreditation is not a new concept for mental health and substance use disorder providers. There are currently 13 organizations operating accredited mental health programs and 49 organizations operating accredited substance use disorder programs in Maryland. The reasons for becoming accredited vary among these providers, but this number shows that the concept of accreditation has taken hold. For those who spoke to our Workgroup, accreditation reflects both professional pride and business acumen. Providers have been able to diversify their referral base and increase their patient population and services as a result of being accredited. In anticipation of the implementation of health care reform when many currently uninsured individuals will have coverage, these providers are preparing for new referrals. Some of these programs have offered to provide informal technical assistance to interested providers.

Advantages of Accreditation

Accreditation offers advantages over State-adopted regulations.

1. **Accreditation will strengthen and enhance the behavioral health treatment system.**
   Accreditation strengthens the system of care across substance use and mental health disorders providers through accreditation standards that are regularly reviewed and
updated to reflect the field’s best thinking about how we serve patients. This on-going review ensures that evidence-based and best practices are reflected in the standards and, therefore, in practice. Accrediting bodies use professionals who are experts in behavioral health to develop and amend the standards. Before introduction to behavioral health providers, new and revised standards are vetted through a process that is timely, flexible, and responsive.

Additionally, the move to accreditation will result in an increased base of providers that will be eligible to bill third party insurers. Private insurers require providers to be independently licensed or accredited. When the Health Insurance Exchange becomes operational, many currently uninsured individuals will have coverage through private insurance. The number of individuals with third party insurance coverage accessing care will significantly increase, and our provider system must be prepared to serve them.

2. **Accreditation requires adherence to a single set of behavioral health accreditation standards.**

   Providers will no longer have to be concerned with adherence to two different sets of regulations that can contradict each other and where compliance with both is financially and administratively inefficient. Instead, the provider will be expected to respond to one set of standards that are consistent across the treatment system as a whole. Every behavioral health provider will comply with similar standards, as all accrediting entities are similar in the kinds of standards used to ensure quality of care. Accreditation allows providers to concentrate their resources on improvement rather than compliance with redundant regulations. And, accreditation standards address behavioral health issues and do not distinguish between substance use disorders and mental health disorders. Although interventions in treatment will vary depending upon professional licensure, the standards reflect an expectation that the whole person is treated, whether on site or through referral. This means there will be one set of standards regardless of presenting problem. This is in stark contrast to the existing system of having two separate sets of regulations that are diagnosis driven.

3. **Accreditation will support implementation of best practices.**

   Accreditation standards support the provider in offering services that reflect best practices. The accreditation review encompasses administrative and clinical operations. One of the hallmarks of accreditation is the focus on quality, which every provider agrees should be a priority of the treatment system. Programs that are already accredited speak to how accreditation presented new ways of introducing quality to their care as well as sparked enhancement of existing processes. The accreditation review process is characterized as an opportunity to appreciate existing quality practices and identify areas where improvements can be made. Accreditation focuses on performance and implementation; documentation is required only when necessary. Therefore, unlike regulations, there is a level of autonomy and flexibility in determining how a program will implement practices that work towards achieving concordance with the standards.
4. Accreditation reviews will replace regularly scheduled visits by Office of Health Care Quality (OHCQ).

The accrediting body selected by the program will review the program at pre-determined intervals. For example, The Joint Commission and the Council on the Accreditation of Health Care Facilities each give a maximum of a three-year accreditation. The Council on Accreditation gives up to a four-year accreditation. All accreditors have a mid-cycle review. These visits will replace the reviews performed by OHCQ. As described below, OHCQ will retain the right to review programs at any time but will not be scheduling regular reviews for compliance with standards or regulations. Instead, OHCQ will focus on strengthening those programs that receive unsatisfactory reviews. There is more information on the role of OHCQ at the end of this document.

Challenges of Accreditation

There are many advantages to pursuing an accreditation model. However, the Workgroup acknowledged that that there are challenges as well. The issues below must be addressed for there to be a successful implementation.

1. Clarify Role of State, Accrediting Organizations, and Treatment Providers

The roles of the State agencies involved with behavioral health care will change with this model. We need to clearly identify the authority and responsibility of all involved. The State will have to discuss lessons learned from other accredited services as we pivot away from specific regulations and move into accreditation standards. The accrediting organizations must play a key role in assisting with corrective action against underperforming or otherwise problematic providers. Their role cannot be limited to that of surveying the program and issuing a report. They must participate in follow up action when needed to address problems discovered during the survey. And, they must be an active partner when there are complaints against the program outside of the time of the survey. The providers will have to adjust to a new manner of viewing how they provide services. Compliance with regulations is different than compliance with accreditation standards. The accreditation process views every aspect of the program to ensure there is coordination between administrative and clinical operations. Providers will be in a unique position of paying for a service that will review and critique their services from the bottom up and press for improvement. All of these changing roles will have to be identified and understood to avoid confusion.

2. Treatment Provider Resources

The Workgroup acknowledged the financial and other resources needed to prepare for, undergo, and implement improvement activities in order to become accredited. The cost of becoming accredited is based on number of provider locations, number of patients served, and complexity of services provided. Costs will have to be determined quickly so plans can be made by the provider to adjust services accordingly. Each accrediting organization that has expressed interest to date (The Joint Commission, The Council on the Accreditation of Health Care Facilities, and the Council on Accreditation) has a web site where providers can compare the costs of accreditation and the kinds of services
covered by their standards. In addition to the finances, there are resources associated with time developing new policies and procedures, forms, and other activities required by the standards. Programs that have already undergone accreditation speak to the upfront costs and time commitments entailed in this decision but quickly refer to the compensation of additional revenue through third party payers and an increase in quality of care. It was also mentioned that if the cost of accreditation is calculated over the 3-4 years of the accreditation cycle, it becomes more manageable.

3. Transition between Regulations and Accreditation
If accreditation is accepted as a recommendation, there will be a transition between existing regulations and new accreditation standards. As with any transition, the State and providers will need to anticipate the problems inherent in this kind of transition and prepare time lines, protocols, etc. as needed.

Role of Office of Health Care Quality (OHCQ)
The OHCQ will remain a significant partner with the behavioral health administration in the implementation of this recommendation. It will have several key functions in a system using accreditation as part of its regulatory oversight. The OHCQ will have three main roles.

1. OHCQ will be responsible for processing the approval for accrediting bodies requesting to do business in Maryland. In order for the Secretary to approve an accrediting organization, the organization must first apply for that approval. Prior to approval, the Secretary will ensure that the accrediting organization standards are equal to or more stringent than existing state requirements, and that the integrity of the accreditation process is sound. The State and the accrediting organization shall be required to enter into a formal written agreement that includes several requirements such as notice of all surveys and inspections, sharing of relevant information, including complaints, participation of the Department in accrediting organization activities, and provisions to ensure the integrity of the process. The accrediting organization standards may be incorporated by reference into the state requirements. Maryland acknowledged the benefits associated with accreditation a number of years ago in its creation of enabling legislation under Health General Article 19-2301, et seq., and currently uses this authority for the approval of the majority of health care facilities including hospitals, clinical laboratories, forensic laboratories, and home health and ambulatory care agencies. In all, there are at least a dozen unique accrediting organizations with which the department has entered into formal agreements for provider oversight. The cooperative arrangements created via law and memorandum have fostered good working relationships among the parties and significantly simplified the compliance agenda for both the State and provider community.

2. OHCQ will issue licenses for treatment and rehabilitation programs that are accredited. An application process will be developed and will result in a license to operate. For existing programs, the application process will require proof of accreditation. For new programs, OHCQ will mirror the accreditation organization’s process; that is, OHCQ will
issue a provisional license when the accreditation organization has issued its provisional accreditation.

3. The Office of Health Care Quality becomes much more complaint- and consumer-focused in its survey activities yet maintains the ability to perform a wider review of provider compliance, if necessary. Under its authority granted through Health General Article 19-2301, it retains its authority to survey, review, investigate, and sanction programs. It also has the authority to perform validation reviews following an accreditation visit to confirm findings by the accrediting body. Importantly, OHCQ, which has a history of using accreditation for other services such as hospitals, labs, etc., will use the remaining regulations and the standards for the purpose of validating the accrediting agency’s findings. It is essential that the State have confidence in the quality of the accreditation survey. Validations are conducted on about 5% of accredited programs to ensure the accrediting body is appropriately evaluating compliance against the standards.

Exemptions to the Requirement of Accreditation

In aligning the behavioral health treatment regulatory structure with medical care settings, the Workgroup recommends that the following exemptions to the requirement of accreditation exist:

1. Licensed professionals in solo or group practice who, because their Board-defined scopes of practice authorize them to provide services independent of additional regulations, will not be required to be accredited. This recommendation mirrors the practice of physicians, nurses, and other health care professionals in a medical office setting.

2. Services that will continue to be overseen by a set of State-mandated regulations because there are no accreditation standards for them. An example of this is DWI education.

Future Regulatory Structure

It has been the intent of the Workgroup to minimize the number of regulations that will remain active if the accreditation model is accepted. However, there are several regulations regarding the licensing of programs and sanctions against programs that the Workgroup recommends remain in place. There are several regulations that will continue to apply regarding data submission and delivery of Opioid Maintenance Treatment. Also, regulations describing a type of service (i.e., Intensive Outpatient), will continue to exist but may be moved to regulations governing reimbursement through Medical Assistance. For those regulations that remain, the accrediting agencies have agreed to incorporate them in their review process. This eliminates the need for OHCQ to schedule visits for the purpose of ensuring compliance with these regulations. The Workgroup has created a list identifying what it recommends be retained from each administration’s regulations. These are sorted by chapter so the reader can quickly reference those amended regulations in each chapter. Please see Appendix I for specific recommendations. If approved, these changes would become effective July 1, 2015.
Appendix I

Behavioral Health Integrated Regulations Workgroup
COMAR Regulations Recommendations

Listed below are all COMAR 10.47 and COMAR 10.21 regulations chapters. The regulations will no longer apply unless specifically listed under each chapter. Each bulleted item will continue to apply. If no regulations appear under a chapter, then that entire chapter will no longer apply. When COMAR 10.47 and COMAR 10.21 have similar regulations about the same topic that will be retained (e.g., licensing requirements), the Workgroup will create one regulation.

**COMAR 10.47 Alcohol and Drug Abuse Administration Regulations**

**10.47.01 – Requirements**
- Data reporting requirements

**10.47.02 – Specific Program Requirements**
- Detoxification schedules by OMTs
- Transportation of medication between levels of care except Level III.1
- Descriptions of levels of service exist in Medicaid regulations

**10.47.03 – Correctional Levels of Care**

**10.47.04 – Certification Requirements**
- Waiver and variances
- Investigations/inspections by OHCQ
- Sanctions

**10.47.05 – Education Programs**
- All regulations remain (may amend in future)

**10.47.06 – S.T.O.P. Fund**
- All regulations remain (may amend in future)

**COMAR 10.21 Mental Hygiene Administration Regulations**

**Program Chapters**
- Descriptions of each program/service type
- Approved for funding vs. mandatory licensure issue
- Eligibility for service, authorization, billing requirements – incorporate into billing chapter
10.21.02 – Psychiatric Day Treatment Services
- Service is also known as Partial Hospitalization Program/Service – incorporate into program description
- Hours required for full-day and half-day billing – incorporate into billing chapter

10.21.04 – Group Homes for Adults with Mental Illness
- GH statute currently requires licensure and specific admission requirements/exclusions – possibly amend statute
- May need to keep an amended, abbreviated regulations chapter to describe licensure process; or possibly incorporate into the BH regulations chapter, if not too much

10.21.07 – Therapeutic Group Homes
- Keep current OHCQ licensing process in place – rationale is that there are complexities that involve GOC regulations; also, licensure is not dependent on COMAR 10.21.16 or 10.21.17

10.21.16
- Application process description, including application form and required attachments
- Ability for DHMH investigation of life/safety issues, fraud/abuse concerns, and complaints
- Procedures/processes for disciplinary action, sanctions, hearings, appeals, etc. (may be able to incorporate this into the list of applicable laws)
- Process for program discontinuation of services

10.21.17
- Reference to applicable laws (e.g., criminal background checks, death reports, advance directives, client rights, medical records, governing body, CSRRC salary summaries, etc. – will need a complete list; may decide to provide this as an educational list rather than referencing in regulations)
- Prohibition of seclusion and restraint in community programs

10.21.18 – Therapeutic Nursery Programs

10.21.19 – Mobile Treatment Programs
- Incorporate ACT EBP into billing chapter

10.21.20 – Outpatient Mental Health Center
- All clinical services must be rendered by licensed, certified, or otherwise authorized staff – incorporate into either the program description or billing chapter
- Medical Director and multi-disciplinary staff – incorporate into either the program description or billing chapter
- Incorporate IOP (e.g., services and hours needed to bill) into billing chapter, if it remains a reimbursable service constellation

10.21.21 – Psychiatric Rehabilitation Programs for Adults
- Rehabilitation specialist requirement – simplify and incorporate into either the program description or billing chapter
10.21.22 – Residential Rehabilitation Programs
• Description of general vs. intensive level of support – incorporate into billing chapter

10.21.26 Residential Crisis Services
• Treatment foster care model – needs further discussion as to if/how best to preserve this service model

10.21.27 Respite Care Services
• Keep requirement that programs must be either MTS, OMHC, or PRP (possibly add RTC and inpatient to this list) – incorporate into either the program description or billing chapter

10.21.28 – Mental Health Vocational Programs
• 2 face-to-face contacts per month required – incorporate into billing chapter
• Incorporate SEP EBP into billing chapter

10.21.29 – Psychiatric Rehabilitation Programs for Minors
• Rehabilitation specialist requirement – simplify and incorporate into either the program description or billing chapter

NOTE: The following chapters in COMAR 10.21 are NOT affected by this recommendation and will continue to be applied in full:

10.21.01 Involuntary Admission to Mental Health Facilities

10.21.03 Requirement for Individual Treatment Plans

10.21.04 CMHP – Group Homes for Adults with Mental Illness
(May need to amend; further discussion needed.)

10.21.05 Aftercare Plans

10.21.06 Admission to Regional Institutes for Children and Adolescents

10.21.07 Therapeutic Group Homes

10.21.08 Services for Mentally Ill Hearing Impaired Patients in Facilities

10.21.09 Patients’ Rights to Visitors

10.21.10 Psychiatric Residential Treatment Facility Demonstration Waiver Providers

10.21.11 Purchase of Residential Therapeutic Care for Children

10.21.12 Use of Quiet Room and Use of Restraint
10.21.13 Use of Quiet Room and Use of Seclusion

10.21.14 Resident Grievance System

10.21.15 Petition for Emergency Evaluation – Payment for Services

10.21.23 Community-Based Fund

10.21.24 Interagency Discharge Planning for Hospitalized Children and Adolescents

10.21.25 Fee Schedule – Mental Health Services – Community-Based Programs & Individual Practitioners
   (May be amended to incorporate some of the bullets listed above.)

10.21.30 Telemental Health Services