Proposed 10.09.80 Regulations: Overview of Comments Recived and Departmental Responses

Comment	Commenters	Department Response
Urine Toxicology Testing		
Urine Toxicology testing for new illicit substances can be life-saving, but it can also be very expensive. Some toxicology tests could cost as much or more than the proposed weekly bundled reimbursement rates of $63 for Methadone and $56 for Buprenorphine. If providers cannot afford new or special tests, the tests may not be ordered. Stakeholders recommend that an "exception" process be established that provides OTPs the ability to request and receive authorization for reimbursement of "exception tests", on a case by case basis.	Maryland Association for the Treatment of Opioid Dependence, Inc. (MATOD) Center for Addiction Medicine. (CAM) Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC Joe Adams, MD- Hampden Health Solutions; BD Health Services; Eastern Avenue Health Solutions	The current bundled weekly rate for OMT services includes reimbursement for point of care drug tests (code 80305) completed in the OTP's office as well as when the provider sends tests to laboratories (80306, 80307, and G0480-G0483) in accordance with the December 15, 2014 Maryland Medical Assistance Transmittal re: "Medical Billing and Enrollment for Provider Type 32". This directive is in accordance with COMAR 10.09.09.05F, which excludes coverage of laboratory services when the charge is part of a bundled rate. OTPs engage in contracts with laboratories to reimburse for drug screens and tests beyond point of care drug screens that are completed in the office. This process will not change under the rebundling initiative. However, The Department was aware of OTPs' concerns about the cost of presumptive and definitive drug screens and increased the proposed rate for the weekly bundle to account for the costs of laboratory tests. Additionally, the Department does not expect that OTPs would order the high level, expensive tests for 22 or more drug classes every month for every participant. COMAR 10.63.03.19 requires that OTPs conduct random drug tests for at a minimum: benzodiazepines; marijuana; cocaine; opiates; alcohol; methadone or buprenorphine as appropriate; and oxycodone. The Department will release additional guidelines for drug screens in the coming weeks. Under rebundling, providers are able to bill Medicaid for the weekly bundled rate when a patient is receiving take home medication as long as the patient is seen monthly. This additional reimbursement should be budgeted by programs for other costs, including laboratory testing.
This part of the rebundling must be further addressed in a larger work group where all providers are equally represented. We request that in the interim laboratories be allowed to bill directly for qualitative testing outside of the bundled rate for type 32 providers when medically necessary.	Concerted Care Group (CCG)- Barbara Wahl.	
Please clarify the requirements for point of care presumptive drug testing, when this test is conducted and frequency requirements of this type of test.	Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	According to 42 CFR § 8.12(f) (6), OTPs must provide adequate testing or analysis for drugs of abuse. Frequency of point of care presumptive drug testing should be determined based on clinical appropriateness in relation to the patient's stage of treatment. For more information please refer to SAMHSA's Federal Guidelines for Opioid Treatment Programs here: http://store.samhsa.gov/shin/content//PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf.
Please clarify the requirements for when definitive drug testing completed by a laboratory is conducted and the frequency requirements of this type of test.	Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	Federal regulations require that OTPs provide at least eight random drug abuse tests per year, per patient according to 42 CFR § 8.12(f)(6). Additionally, OTPs are required by Federal regulation, 42 CFR § 8.12(f)(6), to perform initial and monthly random tests on each patient receiving long-term detoxification treatment. For more information please refer to SAMHSA's Federal Guidelines for Opioid Treatment Programs here: http://store.samhsa.gov/shin/content//PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf. This SAMHSA publication states that point of care presumptive drug screens are not adequate to meet these requirements.
Please clarify the provider reimbursement for point of care presumptive drug testing and definitive drug testing when completed by a laboratory, is it billed separately under Section 08.D.h. or is it included under one of the required "service" protocols?	Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	The current bundled weekly rate for OMT services includes reimbursement for point of care drug tests (code 80305) completed in the OTP's office as well as when the provider sends tests to laboratories (80306, 80307, and G0480-G0483) in accordance with the December 15, 2014 Maryland Medical Assistance Transmittal re: "Medical Billing and Enrollment for Provider Type 32". This directive is in accordance with COMAR 10.09.09.05F, which excludes coverage of laboratory services when the charge is part of a bundled rate. OTPs engage in contracts with laboratories to reimburse for drug screens and tests beyond point of care drug screens that are completed in the office.
There is no billable amount associated with the test under Section 05.G.(c) "Definitive drug testing when completed by a laboratory;". Can you please clarify what the reimbursement policy is regarding this type of testing? Who orders it and who is reimbursed for the service?	Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	Under the current system, OTPs engage in contracts with labs and this does not change under rebundling. Definitive drug tests are ordered by OTPs and completed by laboratories. OTPs are reimbursed through the weekly bundled rate.

Comment	Commenters	Department Response
Recommend that one lab be assigned as the regional preferred laboratory in Maryland. OTP's could send their patient urine specimens for specialized testing to one central location. This lab would have a contract with Medicaid to complete tests at a lower cost to all OTP's.	Center for Addiction Medicine. (CAM)	While the Department appreciates the comment, Medicaid enrolls any appropriately licensed provider and cannot steer, recommend, or restrict to one provider. However, providers are free to coordinate their use of laboratories.
Medication Management		
Please clarify the requirements defining "periodic medication management". This appears to be a new term and there is no definition provided in the definition section of the proposed rule change. Can you provide a definition, or reference the section of COMAR where this can be found?	Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	The Department will add a definition for medication management in the proposed regulations. Periodic medication management includes visits for the management of medications for substance use disorder symptom reduction or withdrawal management and is provided by physicians and nurse practitioners. Ongoing medication management (E&M codes 99211-99215) may be used as clinically necessary, typically six times per year, but not to exceed every 30 days.
(g) Periodic medication management through office based evaluation and management visits, according to COMAR 10.09.02.07D. Please clarify section (g) of this section. What services are billable, what codes are utilized, and at what rates for this type of periodic medication management. It looks to us like COMAR 10.09.02.07 has been repealed.	Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	COMAR 10.09.02.07 has not been repealed. Please find COMAR 10.09.02.07 here: http://www.dsd.state.md.us/comar/comarhtml/10/10.09.02.07.htm. COMAR 10.09.02.07.D refers to the Physicians' Services Fee Schedule, the most recent version of which can be found here: https://mmcp.dhmh.maryland.gov/pages/Provider-Information.aspx. Relevant evaluation and management (E&M) codes may include: 99211-99215.
Induction		
When an OTP patient fails to receive their prescribed medication for 3 consecutive days and returns for treatment, they are re-Inducted, as an important safety precaution. MATOD recommends that the Department modify 10.09.80.06.G to read: In order for an opioid treatment program to bill for medication assisted treatment induction, the provider shall bill this service only in the first week of treatment per participant or in the first week of treatment after a break from treatment of 3 or more consecutive days.	Maryland Association for the Treatment of Opioid Dependence, Inc. (MATOD) Center for Addiction Medicine. (CAM) Concerted Care Group (CCG)- Barbara Wahl. Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	The Department is not precluding OTPs from providing induction services to individuals who were involved with the OTP and subsequently stopped receiving treatment for a time shorter than six months. The limitation is on billing, not on services provided. The Department considers reimbursement for induction when an individual with a break from treatment of less than 6 months to be encompassed under the weekly bundled rate.
Section I 0.09.80.06.G. would prohibit an OTP from billing for medication assisted treatment induction more frequently than twice a year per participant. We are confused by the logic of this rule and note that programs that offer buprenorphine induction will not be subject to the same reimbursement restriction even if a former patient is provided induction within six months of a previous treatment episode. The latter standard is appropriate and should be applied to OTPs. This reimbursement restriction also runs counter to the Parity Act. We are unaware of any reimbursement rule for medical services that imposes a waiting period for the delivery of medical services to a patient who may have discontinued care with a practitioner.	Drug Policy Clinic- Ellen Weber, Esq.	
We would like a clarification on what the requirements for the reauthorization would be. Administratively, trying to submit removals and then reauthorizations for each occurrence could become burdensome and costly. We would recommend that some sort of more streamlined capability be implemented.	Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	The Department expects that participants will be discharged within 30 days of the break in treatment. If the participant returns to the OTP after a break of 30 days, the OTP would need to submit a new authorization.
Treatment Planning		

Comment	Commenters	Department Response
Potential conflicts arise when a Type 32 OTP must conduct a regulatory or clinically required Treatment Plan review session (H0004) during the same time span that the patient in enrolled in an IOP, receiving individual (H0004) and group (H0005) counseling. MATOD recommends that the Department support best practices of treatment planning and collaboration, and allow both Type 32 and Type 50 providers to conduct, bill and be reimbursed for necessary individual sessions for treatment planning in the same week.	Maryland Association for the Treatment of Opioid Dependence, Inc. (MATOD) Center for Addiction Medicine. (CAM)	The Department appreciates your concerns however disagrees and reiterates that codes for IOP and OP are mutually exclusive.
We propose that IOP, OP, and OTPs be combined into one level of care with one menu of treatment options. Groups that run in excess of two hours may bill at the IOP rate. Groups that run shorter than that may run at the proposed OTP rate. All client care should result in the weekly reimbursement rate because of the similar bundled care that goes into each level – assessments, treatment planning, facility and security coverage, etc.	Concerted Care Group (CCG)- Barbara Wahl.	Under rebundling, OTPs are no longer responsible for providing IOP level of care. OTPs are reimbursed for the administration of the drug and clinically appropriate level 1 outpatient services. If an individual requires IOP, the OTP should refer out to a PT 50. The OTP would only bill for the weekly bundle while the consumer is in IOP.
We also have concerns regarding medication management only patients presenting in crisis or in need of some counseling service while on location at the dispensing facility. What are the obligations and authority to provide counseling services for a patient you are not "treating" behaviorally, what are the requirements for providing that service, and how would such services be reimbursed? We would recommend that this not only address treatment planning but clinical interventions as in cases where patients participating in the medication management treatment only present in crises and require some form of counselor intervention or assistance. We also want clarification if there will be documentation required regarding an agreement of the services being provided by and between multiple service providers.	Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	The OTP bundle should incorporate unique needs of individuals in that the provider is reimbursed an ongoing weekly rate for management even if the patient is not seen during that week with that provider. Appropriate clinical management of patients would always be required regardless of payment. Best clinical practice would encourage any referral made from an OTP to a provider delivering IOP level of care to include a release of information to share the clinical progress of an individual. Each provider is responsible for their own documentation of services. Once an IOP level of authorization is opened, any services billed by the OTP for counseling would be denied, just as they would be under the current system.
Treatment Authorization		
The proposed regulations and the Department's September 2016 Re-Bundling proposal do not address the authorization process for the range of clinical and billable services. MATOD has and continues to recommend that only one (1) authorization be required for approval of 26 weeks of all treatment codes that are consistent with the providers' licensure type, including assessment, medical, medication and counseling services.	Maryland Association for the Treatment of Opioid Dependence, Inc. (MATOD) Center for Addiction Medicine. (CAM) Concerted Care Group (CCG)- Barbara Wahl. Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	The Department has announced in response to previous stakeholder comments that authorizations will be designed to have minimal impact on providers and will include the weekly bundle as well as clinical services. It is our plan that authorization will include 26 weeks worth of the bundle and clinical services. The Department and Beacon Health Options are working closely together in order to prepare for the transition to a re-bundled reimbursement methodology and will provide additional details on the authorization process to providers within the coming weeks.
Implementation Timeline		
The proposed regulatory changes will require extensive re-programming and training related to Electronic Medical Records and Billing Systems, clinical and administrative record keeping, claims processes, quality assurance oversight activities and multiple policies and procedures. MATOD recommends that the Department provides no less than 6 months advance notice of the actual implementation date. We recommend that BHA, Medicaid and the ASO provide on-line and on-site trainings to assist OTPs with the multiple changes contained in the proposed regulations.	Maryland Association for the Treatment of Opioid Dependence, Inc. (MATOD) Center for Addiction Medicine. (CAM) Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	After full consideration of the concerns expressed by MATOD and other stakeholders, the Department has finalized an implementation date for rebundling of May 15, 2017. The Department and Beacon Health Options are committed to providing adequate training to OTPs prior to the implementation date and assistance throughout implementation.
Other		
We would like clarification if the J codes associated with the dispensing of Zubsolv/ Buprenorphine products will still be applicable.	Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	There are no changes proposed to Zubsolv/ Buprenorphine J code reimbursement. As it exists, when providers obtain buprenorphine through contracts with the drug manufacturer, maintain and store buprenorphine themselves, and dispense to patient, they may bill the J code. They may not bill the J code when the point of sale occurs at the pharmacy, whether it is the patient picking up the prescription or the provider arranging for delivery.

Comment	Commenters	Department Response
We want clarification as to the 50:1 patient counselor ratio as it would apply to patients receiving only the medication management services and not the counseling services. Will that requirement only apply to the patient census receiving counseling services and not be applicable to patients receiving medication management services only?	Mary Shashaty, Outlook Recovery LLC and Bayside Recovery LLC	The patient to alcohol and drug counselor ratio may not exceed 50:1; however, patients who have had over 2 years' time in treatment and receives 14-31 days of take-homes shall not be included in the program's total patient count when determining the 50:1 ratio. Please see the Provider Alert from the Behavioral Health Administration for more information: http://maryland.beaconhealthoptions.com/provider/alerts/2016/Clarification-of-OTP-Regulation-06-10-16.pdf.