



pennsylvania
DEPARTMENT OF HUMAN SERVICES

TITLE 55. HUMAN SERVICES

CHAPTER 5200 PSYCHIATRIC OUTPATIENT CLINICS

COMPLIANCE GUIDE

Office of Mental Health and Substance Abuse Services

(OMHSAS)

INTRODUCTION

On October 12, 2019, 55 Pa. Code Chapter 1153 (relating to outpatient behavioral health services) and 55 Pa. Code Chapter 5200 (relating to psychiatric outpatient clinics) became effective. These regulations govern the payment and operation of psychiatric outpatient clinics in the Commonwealth of Pennsylvania. In most cases, the regulations speak for themselves. There are, however, some regulations that require additional clarification. Even when the meaning of a regulation is very clear, the purpose and intent of the regulation may not be. There are also different ways to measure regulatory compliance, and both operators and OMHSAS Licensing Representatives need to know how compliance will be determined. This guide is meant to help operators and OMHSAS Licensing Representatives better understand the regulations.

This guide is a companion piece to 55 Pa. Code Chapter 5200; it should be used along with the regulations, not instead of them. The explanatory material in this guide is not meant to be “new regulations” or to extend meaning of the regulations beyond their original intent.

In addition, this guide has been developed to provide clear explanations of the regulatory requirements of 55 Pa. Code Chapter 5200 to help psychiatric outpatient clinic operators provide safe environments and effective services to individuals through regulatory compliance, and to help regulators protect individuals by conducting consistent and comprehensive inspections. It provides a detailed explanation of each regulatory requirement, including expectations for compliance, guidelines for measuring compliance, and the primary purpose for the requirement. Finally, this guide includes general regulatory requirements and procedures, a glossary of regulatory terms, and overviews of complex regulatory issues to provide a more global understanding of the chapter and its purpose.

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PART 1:

An Introduction and Overview of the Regulatory Process

How to Use the Regulatory Compliance Guide

This guide has been developed to provide clear explanations of the regulatory requirements of 55 Pa. Code Chapter 5200 to help licensed operators provide safe environments and effective services to individuals in treatment through regulatory compliance, and to help OMHSAS Licensing Representatives protect these individuals by conducting consistent and comprehensive inspections. This guide provides a detailed explanation of each regulatory requirement, includes explanations for compliance, guidelines for measuring compliance, and the primary benefit of the requirement.

Each regulation that can be measured during an inspection is included in the Regulatory Compliance Guide (RCG) and is accompanied by clarifying information. The illustration below shows how regulations are presented and how OMHSAS Licensing Representatives and providers can effectively use the RCG.

This area lists the regulation exactly as it appears in § 5200.



Regulation: § 5200.12. Linkages with mental health system.

(a) A psychiatric outpatient clinic requires a close relationship with an acute psychiatric inpatient service and a provider of emergency examination and treatment. A written statement describing the accessibility and availability of the services to individuals is required and shall be maintained on file at the psychiatric outpatient clinic and updated as needed.

The "Discussion" section provides information about applying the regulation, including referencing other regulations and applicable narratives.



Discussion: It is recommended by OMHSAS to update linkage agreements at least every three years to ensure linkages are current and providers are still operational.

The "Inspection Procedures" section describes how Representatives may measure compliance with the regulation.



Inspection Procedures: OMHSAS Licensing Representatives will review the facility's linkage agreements.

The "Primary Benefit" section explains how the regulation protects individuals in treatment, including: health, safety, and well-being.



Primary Benefit: Establishing close relationships with other agencies helps to ensure that individuals served by the facility receive the appropriate agency services that are needed. Written statements describing the accessibility and availability of the services to individuals helps to make certain that the facility has a plan in place for effective delivery of services.

"Recommended"

Throughout the RCG the word "recommended" is seen repeatedly. This word indicates that what is written is a suggestion based on best practices, not a regulatory requirement. Failure to follow a recommendation will not result in a regulatory violation.

Inspection Procedures

Please note that the "Inspection Procedures" are guidelines, and the specific means of measuring compliance with a regulation may differ depending on circumstances specific to the facility, the reason for the inspection, and the nature of the regulatory violation.

Overview of the Licensing Process

The following section outlines the processes that OMHSAS Licensing Representatives will follow, as the situations allow, for initial, annual and unannounced licensing visits.

Licensing Visit Preparation

Prior to the licensing visit, OMHSAS Licensing Representatives will provide the Psychiatric Outpatient Clinic with the following:

- A letter/e-mail confirming the date and time of the licensing visit, and provides a list of documents that will need to be reviewed when on-site.
- A confirmation of location where the licensing visit will occur and a request for a workspace in the facility where OHMSAS Licensing Representatives may work in private. If the clinic maintains electronic records, a computer to access these records must be available for each representative who will be present.
- Pre-inspection documents including the program information form and CPSL tracking form (if applicable). The agency must complete and return to the OMHSAS Licensing Representative prior to the licensing visit.

Conducting the Entrance Conference

During the entrance conference, OMHSAS Licensing Representatives will:

- Facilitate introductions that include name and title.

OMHSAS Licensing Representatives will wear Commonwealth ID badges in a conspicuous place at all times while on-site for the benefit of facility staff and individuals.

- Briefly state the purpose of the inspection.
- Discuss the agenda for the day.
- Request a point of contact and discuss a way to maintain communication throughout the visit.
- Provide an opportunity for the director or clinical supervisor to give updates on the program to inform of any changes, issues, successes that occurred since the previous licensing visit, and ask any questions.
- Discuss waivers or policy updates as needed.

Source of Inspection

Compliance with regulations can be measured through three methods:

- "On-site" – Direct observation during an on-site inspection. This includes direct observation using all five senses. Site observations include, but are not limited to, the physical inspection of staff offices, conference rooms, waiting room, rooms used to provide therapy, room where medication may be stored and/or dispensed. This is conducted to assure compliance with Federal, State and local requirements for safety, fire, accessibility, health, and medication.
- "Records" – Inspection of written documents. This may include, but is not limited to, inspection of written and electronic materials, photographs, and other paper and electronic materials.
- "Interview" – Asking questions for further insight into how services are provided and how regulatory requirements are met. This may include, but is not limited, to the following: Directors, Supervisors, staff members, and individuals receiving treatment.

Records

The following minimum number of records for staff and individuals in treatment must be reviewed for each facility. Additional records should be reviewed if there is reason to suspect violations, or if the minimum sample is not representative of the population served or of the various staff positions.

For records of individuals in treatment, a variety of records are selected to provide an accounting of the different services and populations served by the facility. Selected records will account for, but are not limited to, the following: main location and satellite locations, therapy and medication management only, site-based and mobile therapy, adult and child/youth/young adult. The OMHSAS Licensing Representatives assigned to work with the facility will request information prior to the inspection to help in their selection of individual records.

- OMHSAS Licensing Representatives will review a minimum of 12 individual records. Of these 12, two must be records of individuals who have been discharged.
- OMHSAS Licensing Representatives will review additional files as necessary for a variety of other factors.

For staff records (HR files), OMHSAS Licensing Representatives review these records to determine whether staff meet position qualification requirements, and have all required clearances and trainings.

- For newly licensed programs, all staff records will be reviewed during the initial site visit.
- For established programs, the staff records of all staff members who have been hired or promoted in the time period following the previous site visit will be reviewed. This includes any staff member who has left the agency during this timeframe. At least 10 percent of all tenured staff files should be reviewed.
- OMHSAS Licensing Representatives will review additional files as necessary for a variety of other factors.

OMHSAS Licensing Representatives will also review additional records; these records will be either requested prior to, or during the on-site inspection. This includes, but is not limited to, the following: current description of services, organizational chart, current waivers, changes in policies and procedures, documentation of trainings and supervision, quality improvement plans and reports, and current linkages agreements.

Conducting the Exit Conference

If the inspection will last more than one day, OMHSAS Licensing Representative will conduct a partial exit conference with the director or clinical supervisor at the end of each day on-site. OMHSAS Licensing Representatives will explain the progress of the inspection, including what has been and what remains to be done and when OMHSAS will return to complete the inspection.

Prior to conducting the final exit conference, OMHSAS Licensing Representatives will:

- Review the program using the outpatient survey tool to ensure that compliance has been measured in all areas.
- Confer with any accompanying OMHSAS Licensing Representatives on preliminary findings (strengths, recommendations, citations)

- Notify the facility of the time and place of the exit conference at least one hour prior to the full exit conference, whenever possible.

During the final exit conference, OMHSAS Licensing Representatives will:

- Allow the facility to include any staff they wish to have present.
- Allow the facility a chance to provide additional information or clarification when needed.
- Remind attendees that the purpose of the conference is to provide preliminary findings.
- Review each citation found, provide the rationale for each regulation cited, provide technical assistance, and discuss the Plan of Correction (POC) process.
- Explain that all citations must be reviewed by an OMHSAS supervisor before being recorded on a written licensing inspection summary (LIS) and sent to the facility.
- Refer to appropriate local or state training sources, as needed.
- Provide forms, technical assistance materials, and other documents to assist with compliance.
- Explain the next steps in the license process (preparation and mailing of the LIS, POC submission by the facility, review of POC, follow-up on the POC as needed, recommendation re: licensure).
- Explain that the OMHSAS Community Program Managers/Regional Director makes all decisions regarding license issuance or enforcement action.

During the final exit conference, OMHSAS Licensing Representatives will NOT:

- Make preliminary recommendations for licensing actions (i.e. issuance of a provisional license).
- Speculate regarding possible licensing outcomes.
- Make statements of value judgments about the facility's appearance, operations, or staff.

Frequency of OMHSAS Inspections of Primary and Satellite Locations

While the regulation uses the term "site" related to a facility, it is common practice that OMHSAS licensing representatives use the term "satellite" or "satellite site" for any clinic locations that are not deemed the primary location on the certificate of compliance.

OMHSAS licensing staff are required to inspect the licensed organization annually. They are additionally expected to ensure all facilities, including the primary location and satellites, are reviewed at least every three years. However, clinic sites that administer medications should be seen annually. OMHSAS licensing staff may rotate the location at which they complete the yearly onsite inspection to ensure all sites are seen within the three-year period.

The Plan of Correction

The Department of Human Services (DHS) has created a consistent approach to licensing throughout DHS which assures that every plan of correction (POC) is implemented timely to protect the ongoing safety and well-being of those served by a program. This process is outlined in DHS Bulletin *14-Bul-107* and below.

The Plan of Correction Process

1. If any licensing violations are found during an on-site inspection or investigation, an LIS with identified deficiencies will be issued. An attempt will be made to issue the LIS within 15 business days of the date of the exit conference.

2. In response to the LIS, the program shall return an acceptable POC to the assigned OMHSAS Licensing Representative no later than 10 calendar days after the LIS was sent to the program. Based upon the violation, OMHSAS may request the POC be submitted earlier than 10 calendar days after the LIS was sent to the program.
3. An acceptable POC must include, at a minimum, concrete and measurable corrective actions to address each specific violation, including any measures or systemic changes to ensure the licensing violation will not reoccur.
4. OMHSAS either accepts or does not accept the POC. OMHSAS will attempt to accept or not accept the POC within 10 business days of receipt of the POC.
5. If OMHSAS does not accept the POC, then the program shall submit a second, revised POC. The program should submit the second, revised POC within five business days (or less if OMHSAS determines it necessary) of the date of the notice that the first POC was unacceptable.
6. Upon receipt of the second, revised POC, OMHSAS either accepts or does not accept the POC. OMHSAS will attempt to accept or not accept the second, revised POC within five business days of the receipt of the second, revised POC.
7. If OMHSAS does not accept the second, revised POC, then OMHSAS may direct the POC, or may take further licensing action, which could include revocation or nonrenewal of the Certificate of Compliance (COC), or issuance of a provisional COC. OMHSAS will attempt to notify the program within 10 business days from the date the second POC was determined not acceptable.
8. Upon acceptance of the POC, OMHSAS will send a written notification to the program that the POC is acceptable. OMHSAS' acceptance of a POC only serves as OMHSAS' acknowledgement of the program's willingness to adequately and timely correct the licensing violations. Acceptance of a POC did not and does not absolve the program of the obligation to achieve and maintain compliance, nor does it confirm that the program is compliant with licensing requirements.
9. OMHSAS verifies compliance by an on-site reinspection or by reviewing documentation that was submitted by the program and that conclusively demonstrates the POC was implemented, compliance was achieved and is being maintained.
10. The timeframe for verification of compliance should be based upon how the regulatory violations may impact the health and safety of individuals. OMHSAS will attempt to re-inspect those violations that pertain to serious health and safety issues within five business days after the implementation date of the POC for that specific violation. For all other compliance issues, OMHSAS will attempt to re-inspect or review documents within 30 calendar days after the last implementation date specified in the POC. By way of further explanation on the 30-day timeframe, if a POC contains multiple items and plans responsive to an LIS, then the latest date should be used when determining the timeframe for completing the re-inspection. Nothing in this guidance precludes an OMHSAS Licensing Representative from conducting on-site monitoring visits before the specific implementation date of the POC or any item within the POC.

11. If, upon reinspection or document review, OMHSAS finds that the program has achieved and is maintaining compliance, then OMHSAS will notify the program in writing and issue a new annual COC. OMHSAS will also update, accordingly, any documents posted to the web to indicate that the plan of correction has been implemented and the licensee has achieved compliance.
12. If OMHSAS finds that a POC has not been fully implemented or the program has not achieved and maintained compliance with any licensing requirements, then OMHSAS will issue a provisional COC unless there is an extraordinary circumstance.

Please note, nothing in this process limits OMHSAS in any way from taking other licensing action, as OMHSAS finds appropriate, pursuant to applicable law.

Elements of an Acceptable Plan of Correction

Regulations are necessary to ensure the safety and well-being of those that we serve. It is important that this is kept in mind as an agency writes a POC. To help provide all the elements needed in a Plan of Correction, the following sections have been created to assist an agency write an acceptable POC.

Why did it happen? Understanding why the violation happened is critical to keep it from happening again. Sometimes the most easily identifiable cause may not be the real reason the violation occurred. One way an agency can identify the root cause of the problem is by asking “Why” multiple times. This is a very simple approach for identifying each violation’s source.

What do you do now to fix the problem? When writing the immediate solution, it should address who is responsible for fixing the problem and monitoring compliance, what action that person will take, and when that action will happen. The solution needs to be realistic, sustainable, and specific.

How do you prevent this from happening again? The goal of the POC is not only to fix the violation, but make sure there is a sustainable plan in place to keep it from happening again. These long-term solutions should greatly reduce or eliminate the chances of the violation happening again and do it in a manner that is sustainable over time. The POC should detail specific, realistic, actionable steps that keep the violation from happening again.

Provider’s Plan of Corrective Action / Projected Dates of Completion. The provider’s plan of corrective action includes itemized steps that are needed to fix the violation and keep it from happening again. It clearly denotes each specific, realistic, and actionable step, and the person responsible for implementation of each step. The projected dates of completion is the date that each step will be completed.

Provider’s Plan of Corrective Action	Projected Dates of Completion	
	Provider	Approved
Provider’s Plan of Correction is entered here.	Date in which each step of plan will be implemented	Leave blank

Waivers

Occasionally, a psychiatric outpatient clinic is unable to comply with a regulation due to the structure, operation, or population served. It is for this reason that psychiatric clinics are permitted to request waivers of certain regulations. When waivers are issued, additional conditions may apply. Psychiatric clinics must comply with all regulations unless a waiver has been approved. Submitting a request for a waiver does not permit noncompliance, nor is a plan to submit a waiver an acceptable plan of correction for a regulatory violation.

Requesting a Waiver

To request a waiver, a program shall submit a waiver request that outlines the following information:

1. The facility or agency's name and address.
2. The number on the Certificate of Compliance, when applicable.
3. Citation to the Pa. Code or Bulletin section from which the waiver is requested.
4. The citation to the Pa. Code or Bulletin section that permits the requested waiver.
5. The period of time covered by the requested waiver.
6. The reason the facility or agency is requesting the waiver.
7. Detailed justification for granting the waiver request.
8. Explanation with concrete assurances how the health, safety and welfare of individuals will be safeguarded during the proposed period of the waiver.
9. Measures taken to meet the purpose of the regulation throughout the proposed period of the waiver.
10. Measures taken or planned to reestablish compliance with the regulation as written.

Agencies must submit the request for a waiver to the County MH/IDDD Administrator of each county the agency serves or will serve. Agencies must include the written response from the MH/IDDD Administrator(s) with the waiver request and submit them to the regional OMHSAS Field Office.

OMHSAS will make a decision to approve or deny the waiver as soon as operationally possible. Determinations may be delayed or denied if all of the information required is not included in the waiver request.

Facilities and agencies should not consider the submission of a waiver request to mean that it is approved and that they are excused from following the regulation. Instead, facilities or agencies must comply with the regulation as it is written unless and until they receive a written notice that the waiver has been approved, along with any additional conditions of the approval.

The Waiver Decision

If the waiver is granted, the Department will specify the length of time for which the waiver is granted and any conditions that the facility must meet.

If the waiver is denied, facilities have the right to appeal. Instructions for filing an appeal will be included in the denial letter.

Waiver Denials, Renewals, and Revocations

Agencies may also request renewal of an approved waiver. It is recommended that requests for continuation of the waiver be submitted to the assigned OMHSAS Licensing Representative 60 days in advance of the approved waiver's expiration date or 60 days prior to the date of license renewal, whichever is earlier to be consistent with 55 Pa. Code Chapter 20 requirements around reapplication. Requests for renewal must contain all information listed above, including a letter of support from the County MH/IDD Administrator(s).

Agencies may appeal adverse rulings (such as denials) regarding requests for waiver. Appeals are directed to:

OMHSAS Bureau of Policy, Planning & Program Development
ATTN: Waiver Appeals
P.O. Box 2675
Harrisburg, Pennsylvania 17105

Or: RA-PWBPPD@pa.gov

Any appeal must be in writing and must be received within 30 days of the mailing date of the letter being appealed.

The Department may revoke a waiver at any time if the conditions required by the waiver are not met, if conditions have not been met on a continual basis or if there is a risk to the health, safety, or well-being of the individuals served.

Occupancy Permits

Agencies that wish to begin providing services, or wish to provide services at a location that is not on their current certificate of compliance, must submit an occupancy permit for this new location. The address on the occupancy permit address must exactly match the address of the location where the services will be provided. A post office box is not accepted for a program facility address; rather, the street address is required. If the address has been changed, the agency should speak with either the Post Master or Emergency Medical Services (911 change) and request this be explained in written form. The agency could also check with the county organization that issued the permit to verify whether it has a permit with the updated address. Occupancy permits must have at a minimum the address of the structure, the name of the building official, the use code, and the maximum occupancy. One of the following is required for the main site and satellites:

- A copy of the Department of Labor and Industry (L&I) Certificate.
- Pittsburgh, Philadelphia, Scranton or participating Municipality Occupancy Certificate (after April 9, 2004) under the Uniform Construction Code (UCC) for the building in which the program is located. A list of UCC participating municipalities is available online.
- A report from a private inspection service stating the results of its review, along with the credentials of the inspector and the criteria by which the review was conducted.

PART 2:

**Regulations, Discussion,
and Inspection Procedures**

GENERAL PROVISIONS

Regulation: § 5200.3. Definitions.

Advanced practice professional—A person who holds a current Pennsylvania license as a certified registered nurse practitioner or a physician assistant and:

- (1) Holds a mental health certification, or
- (2) Obtains a mental health certification within 2 years of being hired by the psychiatric outpatient clinic or by July 30, 2020, whichever is later.

Discussion: OMHSAS will accept the following certifications at this time and will consider other certifications based upon review of the qualifications and experience on a case by case basis.

Certified Registered Nurse Practitioner Certifications

Pennsylvania Department of State approved certifications:

- Adult Psych Mental Health
- Family Psychiatric Mental Health
- Psychiatric Mental Health

National Certifications in Psychiatric-Mental Health issued by:

- The American Nurses Credentialing Center (ANCC)

Completion of a psychiatric-mental health program accredited by:

- The Commission on Collegiate Nursing Education (CCNE)
- The Accreditation Commission for Education in Nursing (ACEN)
- The National League for Nursing Accrediting Commission (NLNAC)

Pediatric Nursing Certification Board certification:

- Pediatric Primary Care Mental Health Specialist Certification

Physician Assistant Certification

National Commission on Certification of Physician Assistants:

- Certificate of Additional Qualification (CAQ) in Psychiatry

Certifications are renewed on a two-year cycle.

Advanced practice professionals that do not have a mental health certification may not be counted towards the agency overall psychiatric hours required per the regulation.

Inspection Procedures: OMHSAS Licensing Representatives will review the staff record to verify staff member has a required license and certification to be considered an advanced practice professional.

Primary Benefit: Programs are allowed to utilize advanced practice professionals to provide services which historically were provided only by physicians. The expanded pool of professionals who can provide these services will increase access to individuals receiving services in the outpatient setting. The requirement that advanced practice professionals have a mental health certification assures they have the knowledge necessary to perform these services.

Regulation: § 5200.3. Definitions.

Mental health professional—A person who meets one of the following:

- (i) Has a graduate degree from a college or university that is accredited by an agency recognized by the United States Department of Education or the Council for Higher Education Accreditation (CHEA) in a generally recognized clinical discipline in which the degree program includes a clinical practicum.
- (ii) Has an equivalent degree from a foreign college or university that has been evaluated by the Association of International Credential Evaluators, Inc. (AICE) or the National Association of Credential Evaluation Services (NACES). The Department will accept a general equivalency report from the listed evaluator agencies to verify a foreign degree or its equivalency.
- (iii) Is licensed in a generally recognized clinical discipline that includes mental health clinical experience.

Discussion: The October 12, 2019, update to § 5200 added a requirement that mental health professionals who meet qualifications by subsection (i) should have a graduate degree that includes a clinical practicum. OMHSAS has decided to legacy in mental health professionals who have graduate degrees without a clinical practicum hired prior to the publication of the regulation update, however, it is important to note that this legacy is only valid while remaining in the program in which the mental health professional was employed prior to October 12, 2019. After October 12, 2019, all applicants must meet the updated qualification requirements when applying for a mental health professional position regardless of previous legacy status.

It is recommended to verify a person’s education through official college transcripts, as they are sent directly to the hiring agency and not the individual and contain a seal as well as the accrediting agency name. College diplomas can be forged more easily than transcripts. Transcripts also provide course names which assist in verifying the number of hours in a particular curriculum, and denote a clinical practicum.

Accredited colleges can be verified on the federal Department of Education website, <https://www.ed.gov/accreditation>. Even though colleges may sound familiar, diploma mills have been known to use familiar colleges by changing the name slightly so that it appears familiar (e.g. Ohio State University to Ohio State College). There are not only fake colleges but also fake accreditation counsels; therefore, accrediting agencies may be verified through this website. Please note, the Dept. of Education does not keep historical information on this website. In the case of Pennsylvania colleges that have gone from State Colleges to Universities, the State College information is not kept in the database.

Clinical practicum and clinical internship can mean the same thing, depending on the program. Documentation in the form of an official transcript is required to verify.

Inspection Procedures: OMHSAS Licensing Representatives will review the staff record to verify the staff member has a required license, or graduate degree and transcripts that show a clinical practicum, or an equivalent degree from a foreign college.

Primary Benefit: Individuals receiving services in an outpatient program are best served by staff members who have an appropriate education in the mental health field

that includes the training required to maintain a license, or experiences gained in a clinical practicum.

Regulation: § 5200.3. Definitions.

Mental health worker—A person acting under the supervision of a mental health professional to provide services who meets one of the following:

- (i) Has a bachelor's degree from a college or university that is accredited by an agency recognized by the United States Department of Education or the CHEA in a recognized clinical discipline including social work, psychology, nursing, rehabilitation or activity therapies.
- (ii) Has a graduate degree in a clinical discipline with 12 graduate-level credits in mental health or counseling from a program that is accredited by an agency recognized by the United States Department of Education or the CHEA.
- (iii) Has an equivalent degree from a foreign college or university that has been evaluated by the AICE or the NACES. The Department will accept a general equivalency report from the listed evaluator agencies to verify a foreign degree or its equivalency.

Discussion: The October 12, 2019, update to § 5200 added specific standards to be met to achieve recognition as a mental health worker. OMHSAS has decided to legacy in mental health workers who do not meet updated requirements if they were hired prior to the publication of the regulation update, however, it is important to note that this legacy is only valid while remaining in the program in which the mental health worker was employed prior to October 12, 2019. After October 12, 2019, all applicants must meet the updated qualification requirements when applying for a mental health worker position regardless of previous legacy status.

It is recommended to verify a person's education through official college transcripts, as they are sent directly to the hiring agency and not the individual and contain a seal as well as the accrediting agency name. College diplomas can be forged easier than transcripts. Transcripts also provide course names which assist in verifying number of hours in a particular curriculum.

Accredited colleges can be verified on the federal department of education website, <https://www.ed.gov/accreditation>. Even though colleges may sound familiar, diploma mills have been known to use familiar college by changing the name slightly so that it appears familiar. I.e. Ohio State University to Ohio State College. There are not only fake a colleges but also fake accreditation counsels; therefore, accrediting agencies may be verified through this website. Please note, the Dept. of Education does not keep historical information on this website. In the case of Pennsylvania colleges that have gone from State Colleges to Universities, the state college information is not kept in the database.

Inspection Procedures: OMHSAS Licensing Representatives will review the staff record to verify staff member has a degree that meets the qualifications of this section. OMHSAS Licensing Representatives will also review staff supervision records to determine staff is being supervised by a mental health professional.

Primary Benefit: Individuals receiving services at an outpatient program are best served by staff members who have an education in a clinical discipline related to the mental health field.

Regulation: § 5200.5. Application and review process.

(b) Facilities will be inspected a minimum of once per year, and are subject to visits by the Department's designee at other times at the Department's discretion. The facility shall provide information concerning program and fiscal operation at the Department's request.

Discussion: According to § 5200.45. Physical facility. (g), "A psychiatric clinic is defined by its staff and organizational structure rather than by a specific building or facility. It may operate at more than one site if the respective sites meet all physical facility standards and the sites operate as a portion of the psychiatric clinic...The Department will issue a single certificate of compliance to the parent organization which will list all operational sites." Additionally, although the term "facility" is used in the regulation, it is common practice that OMHSAS licensing representatives use the term "satellite" or "satellite site" for any clinic locations that are not deemed the primary location on the certificate of compliance.

OMHSAS licensing staff are required to inspect the licensed organization annually. They are additionally required to ensure all facilities, including the primary location and satellites, are reviewed at least every three years. However, clinic sites that administer medications should be seen annually. OMHSAS licensing staff may rotate the location at which they complete the yearly onsite inspection to ensure all sites are seen within the three-year period. In each instance that a provider requests to add a satellite location, whether school or clinic based, a walk-through inspection should be completed prior to adding to the license. Satellites will be inspected as needed when issues arise.

OMHSAS Licensing Representatives do not need to sign confidentiality forms to access provider records. Article X gives the Department the power and duty to license facilities that provide mental health treatment. In the exercise of these powers and duties, each licensing staff is authorized to enter and inspect programs that possess or may require a license and to have full and free access to the program's records. See 62 P.S. § 1016. Additionally, Title 55 PA Code Chapter 20 Licensure and Approval of Facilities and Agencies – 20.34 Access. states: "The facility or agency shall provide to authorized agents of the Department full access to the facility or agency and its records during both announced and unannounced inspections. The facility or agency shall provide the opportunity for authorized agents of the Department to privately interview staff and clients."

Inspection Procedures: OMHSAS Licensing Representatives will review the program annually, and as needed, may request documents at any time, and have access to staff and client interviews.

Primary Benefit: Ensures OMHSAS Licensing Representatives have the means to make full and informed review of the program during announced and unannounced visits and allows request of information as needed.

ORGANIZATION

Regulation: § 5200.11. Organization and structure.

(a) The psychiatric outpatient clinic must be a separate, identifiable organizational unit with its own director, clinical supervisor and staffing pattern. When the psychiatric outpatient clinic is a portion of a larger organizational structure, the director and clinical supervisor of the psychiatric outpatient clinic shall be identified and their responsibilities clearly defined.

Discussion: This section of the regulation is primarily focused on ensuring organizations that have programs in multiple levels of care do not inappropriately share staff between the programs. OMHSAS needs to be assured that the outpatient program has a distinct director, clinical supervisor and staffing pattern that is sufficient to provide services to all members receiving services in the program.

Inspection Procedures: OMHSAS Licensing Representatives will review organization chart of program, and could potentially review time sheets, job descriptions and staffing schedules, and conduct interviews with appropriate program staff.

Primary Benefit: Ensures that each unit has appropriate staff designated for specific roles and responsibilities required by the regulation.

Regulation: § 5200.11. Organization and structure.

(b) The organizational structure of the unit must be described in an organizational chart.

Discussion: The Department interprets the requirement to describe the organizational structure to include an outline of the roles, responsibilities and relationships between organizational staff. The organizational chart may depict the structure of the organization as a whole, or broken down by department or unit.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's organizational chart, and may conduct staff interviews to determine compliance with the regulation.

Primary Benefit: Organizational charts help to clarify responsibility for specific tasks, ensuring that all of the processes required by regulation are completed and that each staff person is aware of what is expected of him or her.

Regulation: § 5200.11. Organization and structure.

(c) A written description of programs provided by the unit shall be available to the Department.

Discussion: A service description must be submitted as part of the application process; it must include the following at a minimum:

- Name, address, and telephone number of the agency contact person for this license application.
- The specific services that are to be provided by the licensed program.
- Age and/or special needs populations to be served by the program.

- Staff roster and supervisory table of organization for the program that will be licensed. The staff roster should include the name (or vacant position), job title, education, mental health experience, and hours per week that work will be performed in the licensed program for each staff person. It should clearly show who will be the Program Director.

Inspection Procedures: OMHSAS Licensing Representatives will review the program's service description at the time of application and as updates are submitted. As needed, OMHSAS Licensing Representatives may also review any relevant documentation and may conduct staff interviews to determine compliance with the regulation.

Primary Benefit: A comprehensive, written description of programs ensures that a facility has a written plan as to what services the facility offers, as well as how the services will be provided.

Regulation: § 5200.11. Organization and structure.

- (d) The psychiatric outpatient clinic shall notify the Department within 10 days of a major change in the organizational structure or service

Discussion: When a facility becomes aware of a major change in the organizational structure or services provided, it shall notify the Department within 10 days. Facilities may contact their regional OMHSAS Licensing Representatives.

A service description should be updated and submitted to the OMHSAS Licensing Representative when changes are made. This is an informal process. The updated description can be submitted and approved via email. The OMHSAS Licensing Representative will review and approve submissions. Any changes in the service description should be submitted to Field Office staff prior to the implementation of any new services.

Inspection Procedures: OMHSAS Licensing Representatives will review pre-inspection documents, organizational charts, current service descriptions, and facility's records and may conduct staff interviews to determine compliance with the regulation.

Primary Benefit: Notifying the Department of major changes helps to ensure that the Department is kept informed of organizational or service modifications.

Regulation: § 5200.12. Linkages with mental health service system.

- (a) A psychiatric outpatient clinic requires a close relationship with an acute psychiatric inpatient service and a provider of emergency examination and treatment. A written statement describing the accessibility and availability of the services to individuals is required and shall be maintained on file at the psychiatric outpatient clinic and updated as needed.

Discussion: It is recommended by OMHSAS to review linkage agreements annually to ensure linkages are current and providers are still operational. They must be updated any time there is a change in process or signatory.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's linkage agreements.

Primary Benefit: Establishing close relationships with other agencies helps to ensure that individuals served by the facility receive the appropriate agency services that are needed. Written statements describing the accessibility and availability of the services to individuals helps to make certain that the facility has a plan in place for effective delivery of services.

Regulation: § 5200.12. Linkages with mental health service system.

(b) A psychiatric outpatient clinic shall maintain linkages with other treatment and rehabilitative services for a full continuum of care, including crisis services, partial hospitalization programs, peer support, psychiatric rehabilitation programs, intensive community services, community residential programs and community psychiatric hospitals. A written statement describing the accessibility and availability of the services to individuals is required and shall be maintained on file at the psychiatric outpatient clinics and updated as needed to accurately state the services currently available.

Discussion: It is recommended by OMHSAS to review linkage agreements annually to ensure linkages are current and providers are still operational. They must be updated any time there is a change in process or signatory.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's linkage agreements.

Primary Benefit: Establishing linkages with other agencies helps to ensure that individuals served by the facility receive the appropriate agency services that are needed. Written statements describing the accessibility and availability of the services to individuals helps to make certain that the facility has a plan in place for effective delivery of services.

Regulation: § 5200.12. Linkages with mental health service system.

(c) When the psychiatric outpatient clinic serves children, linkages with the appropriate educational and social service agencies shall also be maintained. A written statement describing the accessibility and availability of the services to children is required and shall be maintained on file at the psychiatric outpatient clinic and updated as needed to accurately state the services currently available.

Discussion: It is recommended by OMHSAS to review linkage agreements annually to ensure linkages are current and providers are still operational. They must be updated any time there is a change in process or signatory.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's linkage agreements.

Primary Benefit: Establishing linkages with other agencies helps to ensure that individuals served by the facility receive the appropriate agency services that are needed. Written statements describing the accessibility and availability of the services to individuals helps to make certain that the facility has a plan in place for effective delivery of services.

Regulation: § 5200.12. Linkages with mental health service system.

(d) A psychiatric outpatient clinic shall participate in the overall system of care as defined in the County Mental Health/Intellectual Disability (MH/IDD) plan. A psychiatric outpatient clinic shall have an agreement regarding continuity of care and information exchange with the County MH/IDD authority. A copy of an agreement must be included in the application package. Psychiatric outpatient clinics shall document the need for their services in their application for a certificate of compliance.

Discussion: It is recommended by OMHSAS to review linkage agreements annually to ensure linkages are current and providers are still operational. They must be updated any time there is a change in process or signatory.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's linkage agreements.

Primary Benefit: Having agreements and information exchanges with the County MH/IDD authority regarding continuity of care helps to ensure that measures are in place for delivery of services.

Regulation: § 5200.12. Linkages with mental health service system.

(e) New psychiatric outpatient clinics or new sites of existing psychiatric outpatient clinics established after the effective date of this chapter shall document the need in the proposed service area for the expansion of outpatient services. County MH/IDD authorities shall review this documentation and make a recommendation to the Department. The Department may deny approval of the expansion where inadequate justification is provided.

Discussion: In this section of the regulation the linkages with the mental health service system refers to the county letter of support needed for the initial licensure or addition of a new site to the existing license. A letter of support is needed from each county where a site is located.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's linkage agreements when a new application is received or when a new site is added to an existing license.

Primary Benefit: Documenting the need for new psychiatric outpatient clinics or additional sites helps both County MH/IDD authorities and the Department to determine if the request is justified.

STAFFING AND PERSONNEL

Regulation: § 5200.21. Qualifications and duties of the director/clinical supervisor.

(a) Each psychiatric outpatient clinic shall have a director and clinical supervisor, who may be the same individual. A clinical supervisor shall be a mental health professional with at least 2 years of supervisory experience.

Discussion: If a facility chooses to employ the same individual as both Director and Clinical Supervisor, this Director/Clinical Supervisor must be able to cover both administrative and clinical job duties as outlined in § 5200.21(b)&(c). If one individual performs the duties of both Director and Clinical Supervisor, they must meet qualifications to provide clinical supervision.

Inspection Procedures: OMHSAS Licensing Representatives will review the Director and/or Clinical Supervisor's documentation of his/her qualifications, and review the facility's records to determine compliance with the regulation. OMHSAS Licensing Representatives may also conduct staff interviews.

Primary Benefit: Ensures that the Director and/or Clinical Supervisor will have the necessary education and experience to successfully perform the duties and responsibilities required of the position. Ensures that directors and/or clinical supervisors have the knowledge, skills, and abilities required to properly manage and administer a psychiatric outpatient clinic.

Regulation: § 5200.21. Qualifications and duties of the director/clinical supervisor.

(b) The director shall be responsible for the overall operation of the psychiatric outpatient clinic, including daily management, ensuring that clinical supervision is available during all operational hours, developing a quality improvement plan for the psychiatric outpatient clinic and monitoring adherence with this chapter.

Discussion: None.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's records which may include, but are not limited to, supervision schedules and policies and procedures to determine the role of the director in the areas of: supervision hours, quality improvement plan, monitoring for regulatory compliance, and daily management of the program. OMHSAS Licensing Representatives may also conduct staff interviews.

Primary Benefit: Establishes the responsibilities required for the director position in the facility. Ensures the director has the knowledge, skills, and abilities to address any issues of supervision, quality improvement, and regulatory compliance.

Regulation: § 5200.21. Qualifications and duties of the director/clinical supervisor.

(c) The clinical supervisor's responsibilities shall include all of the following:

- (1) Supervision of clinical staff.
- (2) Development or implementation of the policies and procedures for the operation of the psychiatric outpatient clinic.
- (3) Regular meetings of clinical staff to discuss clinical cases, treatment plans, policies and procedures.
- (4) Liaison with other portions of the service system.
- (5) Employment, supervision and discharge of clinical staff according to established personnel policies.
- (6) Supervision and documentation of clinical staff training and development.

Discussion: The Department interprets 5200.21(c)(2) to require that documentation of policies and procedures includes the requirement that the policies and procedures represent current practices and training. Failure to maintain current policy and procedures documentation may result in a citation of a violation of 5200.21(c)(2). It is a common practice of OMHSAS Licensing Representatives to request that policies and procedures updated in the period following the previous inspection be highlighted to assist in their review, though it is at the discretion of the licensed agency to fulfill this request. Updated policies may also be submitted to the licensing representative throughout the year.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's records which may include, but is not limited to, supervision schedule and documentation around training and supervision, policies and procedures, administrative notes, and staff records to determine compliance with the regulation. OMHSAS Licensing Representatives may also conduct staff interviews.

Primary Benefit: Establishes the responsibilities required for the clinical supervisor position in the facility. Ensures that clinical supervisors have the knowledge, skills, and abilities to address any issues in training, supervision and clinical oversight.

Regulation: § 5200.22. Staffing pattern.

- (a) There shall be qualified staff and supporting personnel in sufficient numbers to provide the services included in the psychiatric outpatient clinic's program as follows:
- (1) At least 50% of the treatment staff providing psychotherapy services shall be mental health professionals.
 - (2) A psychiatric outpatient clinic is required to have 2 hours of psychiatric time per week for each FTE mental health professional and mental health worker providing clinical services.
 - (3) The psychiatrist must provide 50% of the required psychiatric time at the psychiatric outpatient clinic.
 - (4) The remaining 50% of the psychiatric time may be provided by:
 - (i) An advanced practice professional.
 - (ii) A psychiatrist off-site by the use of tele-behavioral health.
 - (iii) A combination of subparagraphs (i) and (ii).

Discussion: Please refer to the definition of Mental Health Professional as the qualifications have been changed in the October 12, 2019, update to § 5200. The two hours of psychiatric time per week per FTE MHP & MHW is inclusive of the total number of these staff at the main office and any satellite locations connected to the license. Those staff identified as a psychiatrist or physician extender are not included in the calculation to identify total psychiatric time unless they are being utilized to provide psychotherapy.

Per Bulletin OMHSAS-20-02, Tele-behavioral health refers to the delivery of compensable behavioral health services at a distance using real-time, two-way interactive audio-visual transmission.

Please refer to the section of this Regulatory Compliance Guide on advanced practice professionals in § 5200.3 (relating to definitions) for further explanation of the qualification requirements.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's pre-inspection documentation, staff schedules, personnel records, and policies and

procedures on the use of tele-behavioral health in order to determine compliance with the regulation.

Primary Benefit: Ensures that a person qualified to meet individuals' needs is present in the facility. Ensures individuals receive high quality and consistent care by properly trained staff members. Ensures that sufficient staff hours are provided to meet individuals' mental health needs.

Regulation: § 5200.22. Staffing pattern.

(b) All clinical staff shall be supervised by the psychiatrist having the overall responsibility for clinical services provided by the psychiatric outpatient clinic as defined in § 5200.23 (relating to psychiatric supervision).

Discussion: Supervision does not need to be provided by a single psychiatrist, but the clinical staff need to be supervised by psychiatrists and not advanced practice professionals. Supervision includes not only the required supervisory elements located in § 5200.23, but also the supervision of the treatment planning as outlined in § 5200.31(b)(2)(3)(4), § 5200.31(d)(1), and § 5200.31(g).

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's documentation that shows proper supervision is provided. These documents may include: the psychiatrist's job description and/or policies and procedures dictating the psychiatrist's responsibilities, supervision notes, staff meeting attendance forms, consultation notes in the individual's records, or other documentation, and may also include staff interviews, in order to determine compliance with the regulation.

Primary Benefit: Supervision protects individuals receiving services by ensuring that services are clinically appropriate and treatment modalities and interactions align with diagnoses of the individual receiving services.

Regulation: § 5200.22. Staffing pattern.

(c) There shall be sufficient clerical staff to keep correspondence, records and files current and in good order.

Discussion:

None

Inspection Procedures: OMHSAS Licensing Representatives will review policies and procedures, individual records, job descriptions, pre-inspection documents, and may conduct staff interviews in order to determine compliance with the regulation.

Primary Benefit: Maintaining records and files in an organized manner helps to provide necessary information to staff persons who may oversee the services of an individual, as well as helps to protect the security and privacy of an individual's health information.

Regulation: § 5200.22. Staffing pattern.

(d) The psychiatric outpatient clinic shall recruit and hire staff that is appropriate for the population to be served.

Discussion: The demographic and clinical needs of the population served should be considered when recruiting and hiring staff.

Inspection Procedures: OMHSAS Licensing Representatives will review the files in the staff record including credentials, certificates and training records. OMHSAS Licensing Representatives will also review documents filed in the individual records including the intake, assessment and referral documentation in order to determine demographic and clinical needs of individuals served.

Primary Benefit: Ensures that staff persons are qualified to meet individuals' specific needs in the facility. Failure to recruit and select qualified staff to meet the needs of individuals can result in poor delivery of services to individuals.

Regulation: § 5200.22. Staffing pattern.

(e) If the psychiatric outpatient clinic serves children, specialized personnel are required, as appropriate, to deliver services to children.

Discussion: It is also recommended that the program includes the ages of individuals receiving services and their assigned therapist in the list of current and discharged individuals provided to the OMHSAS Licensing Representative to use when selecting files for review.

Staff members should have experience and knowledge of the developmental stages and diagnoses of the children they are treating. If a specialized therapy is recommended, such as art or play therapy, the staff member should be appropriately credentialed.

In addition to any education, training, and credentials necessary to deliver services to children, all staff members who have contact with children must fulfill requirements of the child protective services law.

Inspection Procedures: OMHSAS Licensing Representatives will review staff records for documents that support the staff member's specialization, and documents in the client record to verify the staff members who provided services to children are those who have specialization, to determine compliance with the regulation.

Primary Benefit: Having staff members who are specially trained in the delivery of services to children helps to provide an understanding of the needs and symptoms of children served in the program. Failure to recruit and select qualified staff to meet the specific needs of children can result in poor delivery of services to the children.

Regulation: § 5200.22. Staffing pattern.

(f) Each psychiatric outpatient clinic shall have a written comprehensive personnel policy.

Discussion: Psychiatric outpatient clinics shall have policies and procedures that cover personnel issues. If the program elects to use volunteers as authorized under § 5200.22(j), OMHSAS interprets the requirement to develop a comprehensive personnel policy to include establishment of policies and procedures governing the use of volunteers and limitations on their roles. These policies and procedures may be reviewed by an OMHSAS Licensing Representative and made available to staff by request. Any changes to any policy and procedure should be reported to the OMHSAS Licensing Representative during the annual

site visit at the entrance conference and a copy of the updated document should be provided for review.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's personnel policies and procedures during initial review and when updates are made. OMHSAS Licensing Representatives may also review staff records as needed in order to determine compliance with the regulation.

Primary Benefit: Written personnel policies provide a consistent approach to the management of the facility, as well as establish working guidelines for staff persons working in the facility.

Regulation: § 5200.22. Staffing pattern.

(g) There shall be a written plan for regular, ongoing staff development and training.

Discussion: Psychiatric outpatient clinics must have a training plan that is comprehensive of both the onboarding training of newly hired staff, and the continued training for tenured staff. A staff training plan may include general topic areas, and specific topic areas applicable to the position. It may also include any trainings requested by staff based on their own areas of interest.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's training plan, policies and procedures around training, and staff records to determine compliance with the regulation.

Primary Benefit: Written training plans provide the facility with an organized plan to ensure all staff persons receive the required training and any other training the facility deems necessary. Ensures individuals receive high quality and consistent care by properly trained staff members.

Regulation: § 5200.22. Staffing pattern.

(h) Graduate and undergraduate students in accredited training programs in various mental health disciplines may participate in the treatment of individuals receiving services when under the direct supervision of a mental health professional, but are not to be included for the purpose of defining staffing patterns.

Discussion: Pre-inspection documentation must identify these staff with a notation that they are graduate/undergraduate, but they should not be counted in staffing pattern. Some examples of facility activities that graduate and undergraduate students in accredited training programs may participate in are: observation of new admission intakes; participation in group psychotherapy, clinical assessment and diagnosis, crisis assessment and intervention, initial treatment planning, and case management; attendance in multidisciplinary clinical team meetings; and the provision of assistance to clinicians in a variety of patient care work.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's pre-inspection documentation to assure these students are not included in the staffing pattern. OMHSAS Licensing Representatives will also review staff records and may conduct interviews with staff to determine compliance with the regulation.

Primary Benefit: Provides graduate and undergraduate students with opportunities for informal clinical consultation similar to independent practice and to learn about organizational aspects of a psychiatric outpatient clinic operation.

Regulation: § 5200.22. Staffing pattern.

- (i) Psychiatric residents with an unrestricted license to practice medicine in this Commonwealth who are under the direct supervision of a psychiatrist are defined as mental health professionals for the purpose of defining staffing patterns.

Discussion: This regulation applies to persons with an unrestricted license to practice medicine in the state of Pennsylvania only. The current status of the license can be verified on the Pennsylvania Department of State website.

Inspection Procedures: OMHSAS Licensing Representatives will review an individual's license and documentation around supervision in the staff records and may conduct interviews with staff in order to determine compliance with the regulation.

Primary Benefits: Ensures that staff persons have the knowledge, skills, and abilities required to perform the services offered in a psychiatric outpatient clinic.

Regulation: § 5200.22. Staffing pattern.

- (j) Volunteers may be used in various support and activity functions of the clinic but are not considered for the purposes of defining staffing patterns.

Discussion: Volunteers must adhere to all Child Protective Services Law requirements and maintain confidentiality of the individuals receiving services.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's policies and procedures if the program utilizes volunteers. They will additionally review pre-inspection documentation to ensure volunteers aren't counted in the program's staffing pattern, and review staff records and supervision to ensure services provided by the volunteer conform with the policies and procedures.

Primary Benefits: Provides volunteers with opportunities to participate in the aspects of a psychiatric outpatient clinic operation, and to potentially make a positive difference in the life of an individual receiving services.

Regulation: § 5200.23. Psychiatric supervision.

The supervision of a psychiatric outpatient clinic shall be by a psychiatrist and, at a minimum, include the following:

- (a) Establishment of appropriate standards for treatment and prescribing practices.

Discussion: The facility's standards for treatment and prescribing practices should provide staff members with a greater understanding of their responsibilities. It should provide a comprehensive overview of staff members' responsibilities related to providing treatment and prescribing, as well as address general medical standards and the prevention of medication errors. The facility's standards for treatment and prescribing practices should also provide guidance on the legal standards and boundaries applicable to prescribing in medical practices, as well as summarize the practical and technical requirements related to prescribing.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's policies and procedures, and the psychiatrist's job description or other documentation that verifies the psychiatrist's involvement to determine their role in the development of standards for treatment and prescribing practices. OMHSAS Licensing Representatives will also review the actual documentation that outlines these standards and practices, review documents in the individual records to determine services are provided accordingly and may conduct staff interviews.

Primary Benefits: Establishing appropriate standards for treatment and prescribing practices helps to ensure that individuals receive high quality and consistent care by staff members.

Regulation: § 5200.23. Psychiatric supervision.

The supervision of a psychiatric outpatient clinic shall be by a psychiatrist and, at a minimum, include the following:

- (b) Involvement in the quality management process.

Discussion: Quality management should be focused not only on the quality of services offered, but also on the means to achieve it. Involvement in the quality management process may include attending meetings and developing and implementing plans for improvement. The psychiatrist's involvement in this process may be in person, over the phone, through emails and other electronic communication formats, and documented in the format as chosen by the program. The outpatient regulations do not dictate the specifics of a provider's QM process, only that a psychiatrist must be involved. The extent of the psychiatrist's involvement should be determined by each provider.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's policies and procedures and/or psychiatrist's job description to determine their involvement in the quality management process. OMHSAS Licensing Representatives will also review documentation related to the psychiatrist's involvement in the process which may include quality management meeting attendance forms and may conduct interviews with staff in order to determine compliance with the regulation.

Primary Benefits: The psychiatrist's involvement with the quality management process helps to ensure that the facility has a systemic tool for identifying and addressing problems with care and management of the facility.

Regulation: § 5200.23. Psychiatric supervision.

The supervision of a psychiatric outpatient clinic shall be by a psychiatrist and, at a minimum, include the following:

- (c) Participation in clinical staff meetings 2 times per month. The psychiatric outpatient clinic shall maintain written documentation of clinical staff meetings, including attendance.

Discussion: When documenting participation in staff meetings, it is recommended that the program records information such as the specific date, time, location, names of participants, and topics discussed for each staff meeting. The psychiatrist's involvement in the clinical staff meetings may be in person, over the phone, through emails, and other electronic communication formats, and documented in format as chosen by the program.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's policies and procedures and/or psychiatrist's job description to determine their required attendance in the clinical staff meetings. OMHSAS Licensing Representatives will also review clinical staff meeting documentation to determine who participated in the meetings and may also conduct staff interviews to determine compliance with the regulation.

Primary Benefit: The psychiatrist's participation in clinical staff meetings helps to ensure that clinical staff members have access to the psychiatrist's expertise in the discussion of information provided during clinical meetings, and individuals receive high quality and consistent care by staff members.

Regulation: § 5200.23. Psychiatric supervision.

The supervision of a psychiatric outpatient clinic shall be by a psychiatrist and, at a minimum, include the following:

(d) Consultation to all clinical staff.

Discussion: The psychiatrist's consultation with clinical staff may be in person, over the phone, through emails, and other electronic communication formats, and documented in format as chosen by the program.

Inspection Procedures: OMHSAS Licensing Representatives will review documentation of the psychiatrist's consultation with clinical staff and may conduct staff interviews to determine compliance with the regulation.

Primary Benefit: Psychiatric consultation provides access to a deeper level of expertise and can help to strengthen the successes of the clinical staff, address any weaknesses, and help to ensure that individuals receive high quality and consistent care by staff members.

Regulation: § 5200.24. Criminal history and child abuse certification.

(a) A psychiatric outpatient clinic shall have documentation of the completed criminal history background check for staff, including volunteers that will have direct contact with an individual.

Discussion: Regardless of the age of the individuals served, criminal background checks will be reviewed for all staff members that have contact with individuals served.

When criminal history background checks return a positive result, the program should base its hiring decision by reviewing and considering factors such as the nature of the crime; facts surrounding the conviction; time elapsed since the conviction; and the nature and requirements of the job and the performance of individualized risk assessments.

There are four possible criminal history background check results:

1. No Record – The employee has no criminal record.
2. Record Attached – The employee has a criminal record, and it is attached for the facility to review.
3. "Disposition under Review" or "Disposition Unreported" – The employee has a criminal record, but the charges, the type/grade and/or outcome of the charges are not listed.

- Information about missing charges or types/grades of offenses can be obtained from the municipality in which the person was charged.
4. "Adjudicated Delinquent" – An adjudication of delinquency is not a criminal conviction. If the facility is not sure whether the background check shows a criminal conviction or an adjudication of delinquency, it should instruct the employee to obtain additional documentation about the offense.

Further questions can also be directed to the local OMHSAS regional licensing office or the Department's Criminal Background Record Unit at 717-265-7887.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's policies and procedures relating to criminal history background checks and will review background checks as follows: during an initial site visit for a new license, all staff and volunteers will be reviewed; in subsequent annual license visits, all staff and volunteers hired after the previous year's license visit will be reviewed.

Primary Benefit: Ensures safety and security of individuals served and assists providers in making educated decisions on the staff they hire.

Regulation: § 5200.24. Criminal history and child abuse certification.

(b) A psychiatric outpatient clinic that serves children shall have documentation of the completed criminal history and child abuse certifications, and mandated reporter training in accordance with 23 Pa. C.S. §§ 6301-6386 (relating to the Child Protective Services Law) and § 3490 (relating to protective services) for all staff, including volunteers that have direct contact with children.

Discussion: For psychiatric outpatient clinics who provide services to children, per updates to Child Protective Services Law published in Act 47 of 2019, effective January 1, 2020, all prospective employees or volunteers, including front of office staff, who might come in contact with children through the course of their job duties, must have criminal history background checks, including both Pennsylvania State Police and FBI, and child abuse certification reviewed by program prior to hire, including onboarding. These criminal history background checks and child abuse certification expire 60 months after the date that appears on the documentation. If the prospective employee or volunteer submits a criminal history background check that was attained at a prior employment or volunteer position, it is recommended that the employee sign the disclosure statement found on the Keep Kids Safe website. For prospective employees, the "certification purpose" section of the child abuse certification and the "purpose of request" section of the Pennsylvania State Police background check must state "Employment" for it to be acceptable.

Additionally, all employees stated above must have a mandated reporter training certification from a department contracted provider or from a provider that appears on the list of additional approved courses found on the Keep Kids Safe website. As outlined in 23 Pa. C.S. § 6383 Education and training. (c)(3), mandated reporter training certification must be completed within 90 days of hire and certifications expire 60 months after the date on that appears on the certification.

When criminal history background checks return a positive result, the program should base its decision by reviewing and considering factors such as the nature of the crime; facts surrounding the conviction; time elapsed since the conviction; the evidence of the

individual's rehabilitation; the nature and requirements of the job and the performance of individualized risk assessments.

There are four possible criminal history background check results:

1. No Record – The employee has no criminal record.
2. Record Attached – The employee has a criminal record, and it is attached for the facility to review.
3. "Disposition under Review" or "Disposition Unreported" – The employee has a criminal record, but the charges, the type/grade and/or outcome of the charges are not listed.
 - Information about missing charges or types/grades of offenses can be obtained from the municipality in which the person was charged.
4. "Adjudicated Delinquent" – An adjudication of delinquency is not a criminal conviction. If the facility is not sure whether the background check shows a criminal conviction or an adjudication of delinquency, it should instruct the employee to obtain additional documentation about the offense.

Further questions can also be directed to the local OMHSAS regional licensing office or the Department's Criminal Background Record Unit at 717-265-7887.

Inspection Procedures OMHSAS Licensing Representative will review the facility's policies and procedures relating to criminal history background checks and will review background checks and mandated reporter certifications as follows: during an initial site visit for a new license, all staff and volunteers will be reviewed, in subsequent annual license visits, all staff and volunteers hired after the previous year's license visit will be reviewed.

Primary Benefit: Ensures safety and security of individuals served and assists providers in making educated decisions on the staff they hire.

Regulation: § 5200.24. Criminal history and child abuse certification.

(c) A psychiatric outpatient clinic shall develop and implement written policies and procedures regarding personnel decisions based on the criminal history and child abuse certification, including volunteers.

Discussion: The program's written policies and procedures should address the review of criminal history background checks, and if serving children, additionally address the review of child abuse certifications and mandated reporter training certifications. The policies and procedures should also address the tracking mechanism used to assure that background checks and certifications are current and comply with applicable laws and regulations. The policy should specifically address the review of criminal history background checks with a conviction, and how the facility will come to a determination as to whether an applicant should be hired to work in the facility.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's policies relating to criminal history background checks.

Primary Benefit: Ensures safety and security of individuals served and assists providers in making educated decisions on the staff they hire.

TREATMENT STANDARDS

Regulation: § 5200.31. Treatment planning.

(a) For each individual receiving services, a mental health professional or mental health worker under the supervision of a mental health professional shall complete an assessment of the behavioral health, medical, psychological, social, vocational, educational and other factors important to the individual prior to the development of the initial comprehensive treatment plan.

Discussion: An assessment that contains all of the information required in this section must be performed. Assessments could include psychiatric evaluations, psychological evaluations, or biopsychosocial evaluations. Psychiatric evaluations can only be completed by a psychiatrist per § 1153.52(2).

For an individual who is receiving medication management only and had a psychiatric evaluation completed, it is not necessary to have an additional assessment performed by a Mental Health Professional (provided that the psychiatric evaluation contains all necessary information outlined in this section). The psychiatric evaluation meets the requirements of this section because the psychiatrist who performs the psychiatric evaluation is qualified as a Mental Health Professional per the definition in subsection (iii) of § 5200.3.

Similarly, if an assessment was performed by any staff member whose qualifications and title are above what is required to be considered a Mental Health Professional, an additional assessment by a staff member who is traditionally identified as a Mental Health Professional is not necessary.

Inspection Procedures: OMHSAS Licensing Representatives will review the assessment and the initial comprehensive plan in the individuals' records, and may interview staff to determine compliance with the regulation.

Primary Benefit: Ensures information relevant to multiple facets of the individual's treatment are assessed, which helps to inform the creation of a treatment plan that is inclusive of the individualized needs of the individual receiving services.

Regulation: § 5200.31. Treatment planning.

(b) An initial comprehensive treatment plan shall be developed, reviewed and approved within 30 days of the intake and assessment with every individual who continues to participate in the treatment process in accordance with the following:

- (1) The mental health professional or the mental health worker under the supervision of the mental health professional and the individual receiving services shall develop, sign and date the initial treatment plan.
- (2) If the individual is receiving psychotherapy and other clinical services, the psychiatrist or advanced practice professional shall review, approve, sign and date the initial treatment plan.
- (3) If the individual is receiving medication management services only, the psychiatrist, physician, certified registered nurse practitioner or physician assistant responsible for prescribing and monitoring the use of the medication shall review, approve, sign and date the initial treatment plan.

(4) For individuals under an involuntary outpatient commitment, the mental health professional or advanced practice professional providing services and the individual shall develop, sign and date the initial treatment plan. The treatment plan shall be reviewed and signed by the psychiatrist as part of the oversight of the treatment services provided.

Discussion: An initial comprehensive treatment plan does not mean a generic treatment plan created as a stopgap to allow time to create an individualized updated treatment plan. The initial comprehensive treatment plan should be fully individualized and inclusive of the information received through the assessment. It is important to note that a comprehensive treatment plan for medication management only may look different than a comprehensive treatment plan for psychotherapy or other clinical services.

All plans must be signed by the individual in treatment and a mental health professional or a mental health worker under the supervision of a mental health professional.

If an individual is receiving psychotherapy AND other clinical services voluntarily, the individual receiving services, the mental health professional/mental health worker, and the psychiatrist or advanced practice professional must sign the treatment plan.

If an individual is receiving medication management only, it is sufficient (in addition to the individual in treatment) that only the professional prescribing and monitoring the use of the medication (i.e. the psychiatrist, physician, advanced practice professional, certified registered nurse practitioner or physician assistant) reviews, approves, signs and dates the initial comprehensive treatment plan. This is allowable because this person is qualified to be considered as a Mental Health Professional under the subsection (iii) of § 5200.3, thereby fulfilling the requirements of both subparagraphs (1) and (3) of this section.

If an individual is receiving any outpatient clinical services involuntarily, the individual receiving services, the mental health professional or the advanced practice professional, and a psychiatrist who is responsible to provide the psychiatric supervision of the psychiatric outpatient clinic must sign the treatment plan.

The entire treatment team needs to participate in the development of the treatment plan within the expected time frame for completion. To be considered a completed treatment plan, evidence of participation must be present from each member of the treatment team in the identified time frame for completion and review. If one member of the treatment plan does not sign the treatment plan until a later date and no other documentation supports participation is present, the plan is not considered complete until the date of the last signature.

Evidence of participation is the signature (ink or electronic, or PIN) of the treatment team member(s) on the treatment plan. Providers may have a paper signature page that is signed the day of the treatment planning meeting to verify those treatment team members who participated. Sign in sheets may also document that a member of the team participated by phone in the treatment plan development. Progress notes containing a list of all participants may be utilized to verify participation in a treatment planning meeting as well, particularly in extenuating circumstances when the signature cannot be obtained until a later date.

Inspection Procedures: OMHSAS Licensing Representatives will review the initial treatment plan in the individuals' records, intake documentation, and may interview staff to determine compliance with the regulation.

Primary Benefit: Having an initial comprehensive treatment plan ensures that each individual's needs are met, and that accountability for meeting those needs is firmly established. Having individuals who participate in the development of the treatment plan sign and date the treatment plan provides a record of who participated in the development of the treatment plan, and shows that all parties have agreed with the content of the plan.

Regulation: § 5200.31. Treatment planning.

(c) The treatment plan must be based upon the assessment and shall:

- (1) Specify the goals and objectives of the plan, prescribe an integrated program of therapeutic activities and experiences, specify the modalities to be utilized and the expected duration of services and the person or persons responsible for carrying out the plan.
- (2) Be directed at specific outcomes and connect these outcomes with the treatment modalities and activities proposed.
- (3) Be developed with the active involvement of the individual receiving services and shall include strengths and needs. The treatment plan may also address individual preferences, resilience and functioning.
- (4) For children and adolescents under 14 years of age, be developed and implemented with the consent of parents or guardians and include their participation in treatment as required by statute or regulation.
- (5) Specify an individualized treatment program for each individual, which shall include clinically appropriate services such as psychiatric evaluation and diagnosis, psychological evaluation, individual, group and family psychotherapy, behavior therapy, crisis intervention services, medication evaluation and management, and similar services.

Discussion: The treatment plan should be based on the individual's strengths and include recovery language. Goals and objectives should be measurable, individualized and relevant to the assessment.

Inspection Procedures: OMHSAS Licensing Representatives will review individuals' records, and may interview staff to determine compliance with the regulation.

Primary Benefit: Ensures a comprehensive treatment plan is developed and that each individual's needs are met. Establishes accountability for meeting those needs.

Regulation: § 5200.31. Treatment planning.

(d) The treatment plan shall be reviewed and updated throughout the duration of treatment as follows:

- (1) For individuals under an involuntary outpatient commitment, the treatment plan shall be reviewed and updated every 30 days by the mental health professional or advanced practice professional providing treatment services and the individual receiving services. The treatment plan update shall be reviewed and signed by the psychiatrist as part of the oversight of treatment services provided.
- (2) For individuals voluntarily receiving treatment, the treatment plan shall be reviewed and updated at a minimum of every 180 days by the mental health professional, mental health worker under the supervision of a mental health professional, certified registered nurse practitioner or physician assistant providing treatment services and the individual receiving services.

- (3) The treatment plan update shall be signed and dated by the mental health professional, mental health worker under the supervision of a mental health professional, certified registered nurse practitioner or physician assistant providing treatment services.
- (4) The mental health professional or mental health worker shall request the individual to sign and date the treatment plan update. In the event the individual does not sign the treatment plan update, the mental health professional or mental health worker shall document the request in the record.

Discussion: Treatment plans should be considered a living document and should be updated as individual needs change and new information is received.

If an individual is receiving medication management only, it is sufficient (in addition to the individual in treatment) that only the professional prescribing and monitoring the use of the medication (i.e. the psychiatrist, physician, advanced practice professional, certified registered nurse practitioner or physician assistant) reviews, updates, signs and dates the updated treatment plan (note: for involuntary treatment a psychiatrist, physician, or advanced practice professional must sign off on a treatment plan update). This is allowable because psychiatrists and physicians are qualified to be considered a Mental Health Professional under the subparagraph (iii) of the § 5200.3, thereby fulfilling the requirements of both subparagraphs (1) (2) and (3) of this section. However, when the individual is receiving psychotherapy and other clinical services, the mental health professional or mental health worker under the supervision of the mental health professional must also sign.

The entire treatment team needs to participate in the development of the treatment plan within the expected time frame for completion. To be considered a completed treatment plan, evidence of participation must be present from each member of the treatment team in the identified time frame for completion and review. If one member of the treatment team does not sign the treatment plan until a later date and no other documentation supporting their participation is presented, the plan is not considered complete until the date of the last signature.

Evidence of participation is the signature (ink or electronic, or PIN) of the treatment team member(s) on the treatment plan. Providers may have a paper signature page that is signed the day of the treatment planning meeting to verify those treatment team members who participated. Sign in sheets may also document that a member of the team participated by phone in the treatment plan development. Progress notes containing a list of all participants may be utilized to verify participation in a treatment planning meeting as well, particularly in extenuating circumstances when the signature cannot be obtained until a later date.

Inspection Procedures: OMHSAS Licensing Representatives will review individuals' records, and may interview staff to determine compliance with the regulation.

Primary Benefit: Ensures treatment plans are reviewed and updated at regular intervals and in a timely fashion.

Regulation: § 5200.31. Treatment planning.

- (e) All treatment services shall be provided in accordance with the identified goals in the treatment plan and updates.

Discussion: None.

Inspection Procedures: OMHSAS Licensing Representatives will review individual's treatment plans and compare with progress notes and other documentation that outlines the services provided to determine compliance with the regulation.

Primary Benefit: Ensures that the services provided to the individual are focused on the goals identified by the individual and treatment team, assuring the individual's input in the choice of services provided.

Regulation: § 5200.31. Treatment planning.

(f) The treatment plan and updates shall be kept in the individual record.

Discussion: None.

Inspection Procedures: OMHSAS Licensing Representatives will review individuals' records to determine compliance with the regulation.

Primary Benefit: Ensures the treatment plan is filed within the individual's record, assuring ability to access the plan.

Regulation: § 5200.31. Treatment planning.

(g) The treatment plan shall be reviewed on an annual basis by the psychiatrist or advanced practice professional throughout the course of treatment from the psychiatric outpatient clinic and documented in the individual record.

Discussion: For treatment plans to be considered reviewed "on an annual basis" they should be reviewed and signed by the psychiatrist or advanced practice professional at least every 365 days.

Inspection Procedures: OMHSAS Licensing Representatives will review individuals' treatment plans and may conduct staff interviews to determine compliance with the regulation.

Primary Benefit: Ensures that a psychiatrist or advanced practice professional reviews and provides oversight of the treatment plan of each individual served by the program.

Regulation: § 5200.32. Treatment policies and procedures.

Each psychiatric outpatient clinic shall have on file a written plan specifying the clinical policy and procedures of the facility and shall provide services in accordance with them. This plan must provide for the following:

- (1) Intake and assessment and policy and procedures.
- (2) Admission policies including time frames for the following:
 - (i) Referrals from crisis intervention or emergency services.
 - (ii) Referrals from inpatient units.

- (iii) Referrals for medication management services.
- (iv) Other referrals.
- (3) The services to be provided and the scope of these services.
- (4) Discharge policies providing for continuity of care for individuals discharged from the program.
- (5) Complaint policies and procedures.
- (6) Statement of rights in accordance with §§ 5100.51 – 5100.56 (relating to patient rights).

Discussion: None.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's internal policies relating to treatment to ensure that the policies exist and are properly implemented. OMHSAS Licensing Representatives may also review any charts concerning complaints received by the facility or by OMHSAS. OMHSAS Licensing Representatives may also conduct staff interviews to verify compliance with the regulation.

Primary Benefit: Ensures that the clinical services provided by the program are done in a manner that is standardized for all individuals served. These procedures designate responsibility for specific tasks and specify exactly what those tasks require, ensuring that all of the processes required by regulation are completed and that each staff person is aware of what is expected of him or her. Complaint policies and procedures help to ensure that the facility has a systemic tool for identifying and addressing problems with care and management of the facility. Patient rights help to ensure that individuals are protected from abuse and neglect, as well as have rights in place which establish treatment in a respected and dignified manner.

Regulation: § 5200.33. Discharge.

- (a) A psychiatric outpatient clinic shall complete a discharge summary for each individual at least 45 days before discharge from services that includes the following:
 - (1) Summary of services provided and outcomes.
 - (2) Reason for discharge.
 - (3) Referral or recommendation for other services if needed.

Discussion: Discharge planning is an ongoing process, and that process should be reviewed and updated as needed to ensure continuity of care.

Inspection Procedures: OMHSAS Licensing Representatives will review individual records, including, but not limited to, the treatment plan and progress notes, to determine that discharge planning is an ongoing process for the individual receiving services. Discharge planning should begin at least 45 days prior to discharge. OMHSAS Licensing Representatives may interview staff as needed.

Primary Benefit: Effective discharge planning can help to decrease the chances that an individual is readmitted to the facility, and can also help in recovery, ensure medications are prescribed and given correctly, and adequately prepare another facility to take over care of the individual in need of services.

Regulation: § 5200.33. Discharge.

(b) The psychiatric outpatient clinic shall provide the following information to individuals at discharge:

- (1) Contact information for the local crisis intervention service.
- (2) Contact information for any referrals.

Discussion: None.

Inspection Procedures: OMHSAS Licensing Representatives will review discharge summaries and verify that the required information is present.

Primary Benefits: Ensures that individuals have the appropriate contact information for their aftercare or in the case of a crisis.

MISCELLANEOUS PROVISIONS

Regulation: § 5200.41. Records.

(a) Under section 602 of the Mental Health and Intellectual Disability Act of 1966 (50 P.S. § 4602), and in accordance with recognized and acceptable principles of recordkeeping, the facility shall maintain a record for each individual receiving services from a psychiatric outpatient clinic. The record must include the following:

- (1) Identifying information.
- (2) Referral source.
- (3) Assessment including presenting problems.
- (4) Appropriately signed consent forms.
- (5) Medical, social and developmental history.
- (6) Diagnosis and evaluation.
- (7) Treatment plan and updates.
- (8) Treatment progress notes for each contact.
- (9) Medication orders.
- (10) Discharge summary.
- (11) Referrals to other agencies, when indicated.
- (12) A written recommendation from a LPHA acting within the practitioner's scope of practice for any MMHT services provided.

Discussion: Appropriate documentation is part of the service provided to individuals in treatment. Such requirements are not considered an undue burden on the provider. Providers should not minimize documentation for the sake of efficiency. When templated forms are used, information contained on these forms should be individualized. It is expected that paper records including required signatures be original and not copied.

Assessments could include psychiatric evaluations, psychological evaluations, or biopsychosocial evaluations. Psychiatric evaluations can only be completed by a psychiatrist per § 1153.52(2).

Consent forms include: consent to treatment and consent to release information. Forms for the consent to release information must comply with requirements found in 55 Pa Code Chapter § 5100.34. Consensual release to third parties.

Inspection Procedures: OMHSAS Licensing Representatives will review the individuals' records to determine if the required documentation is present to ensure regulatory compliance.

Primary Benefit: Ensures a complete record for each individual receiving services, containing the information necessary for the proper care of the individual. This regulation also ensures consistency of records across the agency, which informs the staff members providing the services to the individual.

Regulation: § 5200.41. Records.

(b) Records shall also be maintained as follows:

- (1) Legible and permanent.
- (2) Reviewed twice a year as to quality by the director, clinical supervisor or psychiatrist.
- (3) Maintained in a uniform manner so that information can be provided in a prompt, efficient, accurate manner and so that data is accessible for administrative and professional purposes.
- (4) Signed and dated by the staff member writing in the record.

Discussion: The records referred to in this section include all of the items under § 5200.41(a), and any other written documentation relating to an individual receiving services. "Legible" means that entries are capable of being read or deciphered. "Permanent" means that entries cannot be erased. The material needs to be readily available, in a uniform and non-fragmented manner.

The information needs to be provided in a prompt, efficient, accurate manner so that data is accessible for administrative and clinical purposes. If using electronic records, a process for electronic signatures needs to be in place. Electronic signatures and electronic pad signatures are both acceptable, and the use of a PIN is not prohibited.

The bi-annual review does not need to include all records but should include a sample representative and comparable to the size of the agency. Each agency should have an audit plan in place including how and when audits will be completed.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's individuals' records to determine if all entries made are permanent, legible, dated and signed by the staff person making the entry. OMHSAS Licensing Representatives will also review documentation that shows records are reviewed twice a year by the director, clinical supervisor or psychiatrist.

Primary Benefit: Ensures that records are useable and unaltered, and maintained in a manner that allows efficient access. A bi-annual review provides further assurance that records are kept properly. Records which are signed and dated by the staff member writing the entry act as evidence that proper services and actions were carried out within required timeframes.

Regulation: § 5200.41. Records.

(c) All protected individual records, written and electronic, shall be secured in accordance with all applicable Federal and State privacy and confidentiality statutes and regulations.

Discussion: Records should be locked and protected with only authorized personnel permitted access. The records need to be confidential; therefore, information should only be available to staff who are authorized via proper passwords, PINs, etc.

Federal and State privacy and confidentiality statutes and regulations include, but are not limited to, Health Insurance Portability and Accountability Act and 55 Pa Code § 5100.31-39 (relating to confidentiality of mental health records).

For providers enrolled in the MA program, 55 Pa. Code 1101.51.(e) requires they retain, for at least four years, unless otherwise specified in the provider regulations, medical and fiscal records that fully disclose the nature and extent of the services rendered to MA recipients and that meet the criteria established in this section and additional requirements established in the provider regulations. Providers not enrolled in the MA program are similarly recommended to retain medical and fiscal records as outlined above for a period of at least four years. However, such providers are not bound by this section of the regulation to do so unless there is a violation of a State or Federal statute or regulation developed to outline the record retention of Non-MA providers. Providers shall make those records readily available for review and copying by State and Federal officials or their authorized agents. Readily available means that the records shall be made available at the provider's place of business or, upon written request, shall be forwarded, without charge, to the Department.

Providers should follow HIPAA requirements which require the retention of all medical records for six years or two years after the death of the patient.

Paper documents should be secured in the file. Removeable items such as sticky notes should not be used. A line should be drawn through errors or changes such that the original entry is still legible and staff initials are permitted if there is a key that includes the full name, title, and signature of the staff person. Correction fluid/tape should not be used.

Inspection Procedures: OMHSAS Licensing Representatives will review the physical facility as well as the location where the individual records are kept to determine if the records are being maintained in a confidential manner and prevent unauthorized access.

Primary Benefit: Maintaining individual records in a confidential manner while also preventing unauthorized access helps to protect the security and privacy of an individual's personal health information.

Regulation: § 5200.42. Medications.

(a) If medication is prescribed or dispensed by the psychiatric outpatient clinic, the requirements of all applicable Federal and State drug statutes and regulations shall be met. In addition, all of the following apply:

- (1) Prescriptions shall be written only by a licensed psychiatrist, physician, certified registered nurse practitioner or physician assistant within the practitioner's scope of practice.
- (2) The term "written" includes prescriptions that are handwritten or recorded and transmitted by electronic means.
- (3) Written prescriptions transmitted by electronic means must be electronically encrypted or transmitted by other technological means designed to protect and prevent access, alteration, manipulation or use by an unauthorized person.
- (4) A record of any medication prescribed shall be documented in the individual record.

Discussion: Per Act 96 of 2018, prescriptions of controlled substances in Schedule II, III, IV & V shall be transmitted electronically in a manner that meets requirements outlined in 21 CFR 1311.120. The Act outlines several circumstances in which the requirement would not apply, which includes, but is not limited to, a practitioner or health care facility that either does not have internet access or an electronic health record system. Those who do not meet any of the listed exceptions and are unable to timely comply with the electronic prescribing requirements may petition the Department of Health for an exemption from the requirements based on economic hardships, technical limitations or exceptional circumstances. An online hardship exemption form is available here: <https://expressforms.pa.gov/apps/pa/health/Act96-of-2018-Temporary-Exemption>.

A listing of controlled substances and their schedule is available here: <https://www.dea.gov/drug-scheduling>

Medication records should include all information provided on the prescription. This includes the following information, per 49 Pa. Code § 27.18(d):

- (1) The name, address, telephone number and DEA number of the pharmacy.
- (2) The name of the patient.
- (3) Full directions for the use of its contents.
- (4) The name of the prescriber.
- (5) The serial number of the prescription and the date originally filled.
- (6) The trade or brand name of the drug, strength, dosage form and quantity dispensed. If a generic drug is dispensed, the manufacturer's name or suitable abbreviation of the manufacturer's name shall also be shown.
- (7) On controlled substances, the statement: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

Inspection Procedures: OMHSAS Licensing Representatives will review the orders for the prescription medications to determine that they are current and were prescribed by an authorized prescriber, and if they were e-prescribed when required.

Primary Benefit: Ensures that medications are prescribed by a person authorized to do so, and that the prescribed medicine is recorded properly, which will facilitate the accuracy and ease in medication dispensing and administration.

Regulation: § 5200.42. Medications.

(b) Written policies and procedures providing for the safe dispensing and administration of medication by the medical and nursing staff shall be in writing and on file. The policy must include all of the following:

- (1) Medications shall be dispensed only on an order of a licensed psychiatrist, physician, certified registered nurse practitioner or physician assistant within the practitioner's scope of practice.
- (2) All medication shall be kept in a secure place.
- (3) Each dose of medication administered by the psychiatric outpatient clinic shall be properly recorded in the individual's record.

Discussion: Medication should be stored in a location that is locked, with controlled substances behind a system of double locks. Keys or passcodes should not be available to those who are not involved in the prescription or administration of the medication and should be provided to the minimum number of staff to operate efficiently.

Medication administration records should include the information found on the prescription as well as the date and time of medication administration, and the name and initials of the staff person administering the medication. The medication record may include the staff person's initials (in lieu of the staff person's full name) if there is a master key showing each staff person's initials, his or her full printed name, and his or her signature/signature stamp, so the individual staff person can be linked to the specific medication record entry. An electronic signature is permissible, as long as the computer system allows only the appropriate person to sign that a medication was administered to an individual.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's policies and procedures to determine if all the requirements of this regulation are included. OMHSAS Licensing Representatives will review the medication administration record in the individual's files and cross reference administered medication to determine if a valid order is on file. OMHSAS Licensing Representatives review the location where the medications are kept to determine if they are kept in a secure manner, and prevent unauthorized access.

Primary Benefit: Ensures medications that are dispensed to an individual receiving services have been prescribed by a qualified individual, and that medications are securely kept and accurately logged when administered.

Regulation: § 5200.43. Fee Schedule.

Each psychiatric outpatient clinic shall maintain a schedule of uniform basic charges for services which are available to all individuals receiving services.

Discussion: Providers enrolled in the MA program are required, per § 1153.41.(4), to post a current written fee schedule for billing third party and private payors. The Department interprets the posting requirements of § 1153.41.(4) to mean that the fee schedule should be posted in a conspicuously visible area in the clinic waiting room. Providers who are not enrolled in the Medical Assistance program are recommended to post their fee schedule as outlined above as a best practice, but are not bound by regulation to do so.

Inspection Procedures: OMHSAS Licensing Representatives will review the fee schedule during the physical facility walk through to determine compliance with the regulation.

Primary Benefit: Ensures that individuals understand the facility's charges for specific services.

Regulation: § 5200.44. Quality assurance program.

All psychiatric outpatient clinics shall have a utilization review and clinical audit process designed to ensure that the most appropriate treatment is delivered to the individual receiving services and that treatment is indicated. Psychiatric outpatient clinics that provide MMHT services shall include MMHT services in the Quality Assurance plan. The Quality Assurance plan shall include the following:

- (1) Process for the annual review of the quality, timeliness and appropriateness of the services provided, including feedback on satisfaction with services from individuals receiving services.
- (2) Identification of the type of review and the methodology for the review.
- (3) Documentation of the findings of the annual review.
- (4) Utilization of the annual review findings to improve psychiatric outpatient clinic services.

Discussion: Per 55 Pa. Code § 5200.21(b), the director shall be responsible for developing a quality improvement plan for the psychiatric outpatient clinic. The clinic can have a separate staff member in a QA supervisory role, but the director has to have involvement in the process. Additionally, per 55 Pa Code § 5200.23.(b), a psychiatrist must be involved in the quality management process.

Inspection Procedures: OMHSAS Licensing Representatives will review the quality assurance plan to determine that all of the required elements are included and review the documentation of the annual review to determine compliance with this regulation.

Primary Benefit: Utilization reviews help to confirm that the health plan provides coverage for medical services, as well as helps the facility minimize costs and determine if the recommended treatment is appropriate. Clinical audits help to ensure the quality of the services delivered to individuals in the facility.

Regulation: § 5200.45. Physical facility.

- (a) Adequate space, equipment and supplies shall be provided in order that the outpatient services can be provided effectively and efficiently. Functional surroundings shall be readily accessible to the individual and community served.

Discussion: The facility's physical site must be designed, arranged, or furnished to meet individuals' needs. The term "functional surroundings" refers to all interior and exterior physical site spaces and structures, which shall be accessible to individuals in the community and also comply with the American Disability Act (ADA).

Inspection Procedures: OMHSAS Licensing Representatives will examine the facility's physical site.

Primary Benefit: Ensures equipment, supplies, and adequate space that meet the needs of the individuals receiving services.

Regulation: § 5200.45. Physical facility.

(b) All space and equipment shall be well maintained and must meet applicable Federal, State and local requirements for safety, fire, accessibility and health.

Discussion: This requirement applies to all space and equipment accessible to individuals. Occupancy permits are obtained as part of the application process. All of the satellite locations listed under the license that are located in a clinic should be inspected within a three-year period. Clinic sites that administer medications should be inspected annually. Each instance that a provider requests to add a satellite location, whether school or clinic based, a walk-through inspection should be completed prior to adding it to the license. Satellites should also be inspected as needed when issues arise.

Inspection Procedures: OMHSAS Licensing Representatives will examine all areas of the facility to determine if fire extinguishers are maintained as required, evacuation routes/signage are posted, handicap accessibility is afforded, and evaluate general cleanliness of facility to ensure it meets applicable safety laws. OMHSAS Licensing Representatives may also review fire safety reports or other documentation to ensure compliance with the regulation.

Primary Benefit: Space and equipment that is well maintained helps to allow for easy evacuation during an emergency, and prevent health and safety issues/concerns.

Regulation: § 5200.45. Physical facility.

(c) A waiting room which is clean, comfortable and sensitive to the culture of the population served shall be provided.

Discussion: A waiting room should be comfortable, clean and inviting as it is the first room that is seen when an individual enters the facility. Everything from the arrangement of seating, artwork, and intensity of lighting has an impact on an individual's mood and well-being. The culture of the individuals receiving services (including linguistics) should be considered when furnishing the waiting room.

Inspection Procedures: OMHSAS Licensing Representatives will examine the facility's waiting room to determine compliance with the regulation.

Primary Benefit: Ensures a facility's waiting room is a calm and comfortable environment appropriate to the culture of the individuals served.

Regulation: § 5200.45. Physical facility.

(d) There shall be office space for the clinical staff suitably equipped with chairs, desks, tables and other necessary equipment.

Discussion: The demographics, such as age, should be considered when choosing chairs, desks, or tables to be utilized by individuals receiving services.

Inspection Procedures: OMHSAS Licensing Representatives will examine the office space for the clinical staff to determine compliance with the regulation.

Primary Benefit: Ensures that clinical staff have the proper office equipment needed to provide therapy and that the individuals receiving services have equipment that promotes comfort.

Regulation: § 5200.45. Physical facility.

(e) There shall be an adequate number of suitably equipped conference rooms to provide for staff conferences and therapy.

Discussion: "Adequate number" means that there are enough conference rooms accessible such that staff do not have to wait for rooms to become available.

Conference rooms that are "suitably equipped" should have enough chairs for the number of staff that would be in a staff meeting or training or the number of individuals that would be in a group at any given time. Conference rooms should also be equipped with the technological means to allow staff or other individuals to participate remotely if needed.

Inspection Procedures: OMHSAS Licensing Representatives will examine the facility's conference rooms.

Primary Benefit: Ensures that clinical staff have the proper office equipment needed to conduct staff meetings, training, and provide therapy and that the individuals receiving services have equipment that promotes comfort.

Regulation: § 5200.45. Physical facility.

(f) There shall be adequate provisions for privacy within the psychiatric outpatient clinic.

Discussion: Private information regarding individuals receiving services may be discussed only where such information cannot be overheard by others. It is recommended that sound machines are provided for each office or conference room in which services are rendered to ensure confidentiality.

Outpatient satellite sites that are in a school or other community setting should ensure confidentiality as well by utilizing sound machines and utilizing office space with blinds or other coverings on any doors or windows. Provisions should be made to ensure when individuals "check-in" and enter the therapy room that their confidentiality is protected.

Inspection Procedures: OMHSAS Licensing Representatives will examine the physical site premises and may interview staff and individuals to verify that privacy is being protected.

Primary Benefit: Ensures that an individual's right to privacy will be protected.

Regulation: § 5200.45. Physical facility.

(g) A psychiatric outpatient clinic is defined by its staff and organizational structure rather than by a specific building or facility. It may operate at more than one site if the respective sites meet all physical facility standards and the sites operate as a portion of the psychiatric outpatient clinic. The staffing pattern at each site shall be based on the ratio of total individuals served at that site to the total individuals served in the psychiatric outpatient clinic as a whole. The Department will issue a single certificate of compliance to the parent organization which will list all operational sites.

Discussion: The Department should be notified when a site listed on the certificate of compliance is deleted. Additional satellites must be visited by an OMHSAS Licensing Representative before a site is operational. The agency shall ensure that the certificate of compliance listing the specific address is posted at each satellite.

Inspection Procedures: OMHSAS Licensing Representatives will examine the physical site premises, and may interview staff to verify compliance with the regulation.

Primary Benefit: Ensures that there will be a sufficient amount of staff to handle the needs of individuals receiving services and that all sites meet all physical facility standards and the sites operate as a portion of the psychiatric outpatient clinic.

Regulation: § 5200.46. Notice of nondiscrimination.

Programs may not discriminate against staff or individuals receiving services on the basis of race, color, creed, disability, religious affiliation, ancestry, gender, gender identity or expression, sexual orientation, national origin or age, and shall comply with all applicable State and Federal statutes and regulations.

Discussion: All licensed providers are required to maintain non-discrimination in services and ensure employment in a nondiscriminatory manner. To ensure agencies and facilities licensed by the Department operate in compliance with state and federal civil rights laws and regulations, all licensed providers must complete an annual Civil Rights Compliance Questionnaire as part of the licensing and renewal process. All licensed providers must have current Equal Employment Opportunity and Nondiscrimination in Services policies in place.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's policies and procedures around nondiscrimination and ensure the Civil Rights Compliance Questionnaire is completed annually.

Primary Benefit: Ensures that individuals receiving services are not discriminated against, as well as ensures that individuals receiving services are treated in a respectful and dignified manner.

Regulation: § 5200.47. Other applicable regulations.

This chapter does not supplant other applicable regulations which apply to mental health facilities in the Commonwealth such as 34 Pa. Code Chapter 49—59 (relating to administration; general requirement; A-1 assembly group; division A-2 assembly; division A-3 assembly; group B educational; division C-2 hotels, motels, apartment buildings, etc.; division C-3 small group habitation; divisions C-4 single exit apartments; division D-O ordinary commercial, industrial, office; and D-H hazardous commercial, industrial,

office), § § 5100.31—5100.39 (relating to confidentiality of mental health records), and § 5100.51—5100.56 (relating to patient rights).

Discussion: In addition to all sections of § 5200, agencies should comply with other applicable regulations that apply to mental health facilities in the Commonwealth. Agencies should especially familiarize themselves with the regulations cited in this section. The following sections of chapter 5100 are referenced and would be applied to those individuals receiving outpatient regardless of their legal status:

5100.51—5100.56 (relating to patient rights).

5100.31—5100.39 (relating to confidentiality of mental health records),

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's policies and procedures around confidentiality and nondiscrimination. OMHSAS Licensing Representatives will review forms used to record consent to release information to ensure they meet requirements of 55 Pa Code Chapter § 5100.34. Consensual release to third parties.

Primary Benefit: Ensures that agencies providing psychiatric outpatient services are in compliance with additional regulations that apply to mental health facilities in the Commonwealth.

Regulation: § 5200.48. Waiver of standards.

In instances where the development of specialty psychiatric outpatient clinic services is severely limited by these standards, such as rural clinics or specialty clinics, a waiver may be granted. Waivers may be applied only in areas where the need for these services and the attempts to meet the standards are adequately documented. Waivers are to be considered only in exceptional circumstances and are subject to approval by the Department.

Discussion: Federal and state laws may not be waived.

A facility may request a waiver of regulations or program standards, or portion of regulations or program standards. The Department will make a decision to approve or deny the waiver as soon as operationally possible. In reviewing any such waiver request, the Department will consider whether the facility has demonstrated that substitute measures assure the health, safety and welfare of all individuals who reside in the facility or who receive services from the agency.

The Department will review each waiver annually as part of the annual licensing inspection to determine if the waiver is still warranted and if there is continued compliance with the conditions required by the waiver. The Department may revoke the waiver at any time if the conditions required by the waiver are not met, if conditions have not been met on a continual basis or if there is a risk to the health, safety, or well-being of the individuals receiving services.

Inspection Procedures: Prior to the inspection, OMHSAS Licensing Representatives will review the facility's records to determine whether waivers have been granted. During

the inspection, OMHSAS Licensing Representative will verify that the conditions of the waiver are being met.

Primary Benefit: Waivers allow psychiatric outpatient clinics to operate in an exceptional manner, while providing quality services that ensure the health and safety of the individuals served by the program.

MOBILE MENTAL HEALTH TREATMENT

Regulation: § 5200.51. Provider service description.

(a) Prior to the delivery of MMHT services, a psychiatric outpatient clinic shall submit to the Department for approval a MMHT service description that includes the information required under subsection (b). A psychiatric outpatient clinic shall submit a revised service description to the Department if there are changes to the information required under subsection (b).

Discussion: None.

Inspection Procedures: OMHSAS Licensing Representatives will review and approve submitted service descriptions to ensure compliance with the regulation.

Primary Benefit: Reviewing MMHT service descriptions prior to the delivery of services ensures that facilities are providing services which meet regulatory standards.

Regulation: § 5200.51. Provider service description.

- (b) A service description must include all of the following:
- (1) The population to be served, including all of the following:
 - (i) Expected number of individuals to be served.
 - (ii) The age ranges of the individuals to be served.
 - (iii) The presenting problems and other characteristics supporting the need for MMHT.
 - (iv) The location of the provision of the services, whether in the home or community or both.
 - (v) The goals, objectives and expected outcomes of the MMHT services.
 - (2) Staffing pattern, including all of the following:
 - (i) Number of mental health professionals, licensed clinical psychologists, and psychiatrists providing MMHT services.
 - (ii) The qualifications of a staff person providing a MMHT service.
 - (iii) The specific clinical services to be provided by each staff.
 - (3) The policies and procedures for all of the following:
 - (i) The supervision of MMHT services.
 - (ii) Staff support in the provision of MMHT.
 - (iii) Coordination of care with physical health services.

Discussion: If a submitted service description does not include all required elements as required in the regulation, the OMHSAS Licensing Representative will provide technical assistance around necessary revisions.

The delivery of technical assistance on any aspect of compliance with 5200.51(b) does not preclude the Department from citing a violation of this regulation.

Inspection Procedures: OMHSAS Licensing Representatives will review the facility's MMHT service description to determine compliance with the regulation.

Primary Benefit: A comprehensive, specific service description establishes exactly what population the facility serves and clarifies services the facility will provide and will not provide. The policies and procedures designate responsibility for specific tasks and clarify exactly what those tasks require, ensuring that all of the processes required by regulation are completed and that each staff person is aware of what is expected of him or her.

Regulation: § 5200.51. Provider service description.

(c) A psychiatric outpatient clinic shall provide MMHT only as set forth in its approved service description.

Discussion: None.

Inspection Procedures: OMHSAS Licensing Representatives will review approved service description as well individual records.

Primary Benefit: Ensures that services are being provided exactly as approved in the facility's service description.

Regulation: § 5200.52. Treatment planning.

(a) Treatment planning shall be completed in accordance with § 5200.31 (relating to treatment planning) and shall include all of the following:

- (1) Services to be provided.
- (2) Treatment goals.
- (3) Duration of service.
- (4) Supports and interventions necessary to alleviate barriers to receiving services at a psychiatric outpatient clinic. Identification of the professional providing each service.
- (5) Location of service provision.

Discussion: None.

Inspection Procedures: OMHSAS Licensing Representatives will review individuals' records, and may interview the staff of the facility to determine compliance with the regulation.

Primary Benefit: Ensures that each individual's needs are met as those needs change, and focuses the supports and intervention towards the individual's recovery to allow services to be provided in a traditional psychiatric outpatient clinic setting.

Regulation: § 5200.52. Treatment planning.

(b) A MMHT service provider shall complete an assessment as required by § 5200.31(a) prior to developing the treatment plan. In addition, the following shall apply:

- (1) The assessment shall include documentation of the disabling effects of a mental or physical illness that impedes or precludes the individual's ability to participate in services at the psychiatric outpatient clinic.
- (2) The assessment shall be completed by a psychiatrist, mental health professional, or an advanced practice professional trained and qualified to provide services at a psychiatric outpatient clinic.

Discussion: Documentation in the individual record should clearly indicate why services are unable to be provided in a clinic setting as well as supports and interventions necessary to alleviate any barriers.

Inspection Procedures: OMHSAS Licensing Representatives will review individuals' records, and may interview the staff of the facility to determine compliance with the regulation.

Primary Benefit: Ensures that each individual's needs are met as those needs change, and that accountability for meeting those needs is firmly established. Having staff with the necessary education and experience needed to participate in the development of the assessment helps to create a comprehensive profile of an individual's needs and helps to serve as the basis for the plan to meet those needs.

Regulation: § 5200.52. Treatment planning.

(c) Treatment plans shall be updated at a minimum every 180 days.

Discussion: The treatment plan should be seen as a living document. "At a minimum every 180 days" means that the treatment plan should also be updated as needed so individuals receive the appropriate services as their needs change, and staff are aware of the services needing to be provided.

Inspection Procedures: OMHSAS Licensing Representatives will review individuals' records and may interview the staff of the facility to determine compliance with the regulation.

Primary Benefit: Ensures that each individual's needs are met as those needs change, and that accountability for meeting those needs is firmly established.

PART 3:

Additional Resources

Bureau of Equal Opportunity Civil Rights Compliance Contact Information

Please submit your civil rights compliance questionnaire to the Bureau of Equal Opportunity (BEO) regional office which serves the county in which your facility is located. Due to continuing telework by BEO staff, all providers are encouraged to submit completed Civil Rights Compliance Questionnaires (CRCQ) and required attachments electronically.

Central and Northern Region sites may submit CRCQs and attachments electronically to RA-PWBEOCRCQCENTRAL@pa.gov or FAX to 717-772-4366. The following counties are in the Central and Northern Regions: Adams, Bedford, Blair, Bradford, Cambria, Centre, Clinton, Columbia, Cumberland, Dauphin, Franklin, Fulton, Huntingdon, Juniata, Lackawanna, Lancaster, Lebanon, Lehigh, Luzerne, Lycoming, Mifflin, Monroe, Montour, Northampton, Northumberland, Perry, Pike, Snyder, Somerset, Sullivan, Susquehanna, Tioga, Union, Wayne, Wyoming, and York.

Southeastern Region sites may submit CRCQs and attachments electronically to RA-PWBEOCRCQSOUTHEAS@pa.gov or FAX to 717-772-4366. The following counties are in the Southeastern Region: Berks, Bucks, Carbon, Chester, Delaware, Montgomery, Philadelphia, and Schuylkill.

Western Region sites may submit CRCQs and attachments electronically to RA-PWBEOCRCQWESTERN@pa.gov or FAX to 412-880-0207. The following counties are in the Western Region: Allegheny, Armstrong, Beaver, Butler, Cameron, Clarion, Clearfield, Crawford, Elk, Erie, Fayette, Forest, Greene, Indiana, Jefferson, Lawrence, McKean, Mercer, Potter, Venango, Warren, Washington, and Westmoreland.

Contact information for each BEO regional office can be found below.

Central, Northern and Southeastern Regions:

Bureau of Equal Opportunity
DHS – BEO Central Regional Office
Room 223, Health & Welfare Building
625 Forster Street
Harrisburg, PA. 17120
(717) 787-1127

Western Region:

Bureau of Equal Opportunity
DHS – BEO Western Regional Office
301 Fifth Avenue
Suite 410, Piatt Place
Pittsburgh, PA. 15222-1210
(412) 565-7607

Electronic Record Keeping

Many human services facilities and agencies licensed by the Department of Human Services maintain electronic records for the operation and management of their settings.

Procedures for Electronic Recordkeeping

Electronic recordkeeping is permissible if all of the following conditions are met:

- 1) The electronic record is immediately accessible to, and the medium used to produce the electronic records is able to produce paper copies of records for, OMHSAS or any other oversight agency.
- 2) The electronic format conforms to the requirements of applicable federal and state laws.
- 3) The medium used maintains a record of any deletion, change and that shows the original and altered versions, dates of creation and the creator.
- 4) If an agency provides multiple levels of care, the records for each level of care should be maintained separately in the electronic file.

Use of Electronic Signatures

Electronic signatures and electronic pad signatures may be used in lieu of pen-and-ink signatures on any document required by regulation to be signed by the facility, the individual receiving services from the setting, or any other individual who may or must sign the document. The use of a PIN is not prohibited.

As a reminder, a process for electronic signatures needs to be in place. Records should be locked and protected with only authorized personnel permitted access. The record needs to be confidential, therefore, security measures must be in place so that information is only available to staff who are authorized via proper passwords, PINs; etc.

Shared Space/Co-Location Attestation

Currently, when a provider submits an application to enroll in the MA Program, and the provider is attempting to enroll with the same distinct address as another currently-enrolled provider, the Department's Provider Enrollment system identifies the address match and the providers are asked to submit additional information and documentation related to the arrangement between the providers, which has delayed the processing of the provider's enrollment application(s).

In an effort to facilitate the enrollment of providers that are co-located with other providers, the Department has developed the Co-Location Attestation form, that will allow providers to attest to their compliance with State and Federal anti-kickback laws and the MA regulations at §1101.51 (applicable only to providers enrolled in the MA program), including the freedom of choice provision.

When a provider submits an enrollment or revalidation application and is using the same distinct street address as a different currently-enrolled provider, the Department will identify the address match and will forward the attestation form to both the applicant and the currently enrolled provider(s) along with a request for proposed language for signage. This signage advises beneficiaries that they may receive services from any enrolled provider and must be displayed in a prominent place in the provider's office, such as a waiting room or at the point of check-in.

In addition, a provider that seeks to enroll at a location that is located within another provider's offices may also request a copy of the attestation form and submit it and proposed language for signage to the Department prior to the Department identifying the co-location arrangement.

The completed attestation form and proposed language for signage must be submitted to the following by both providers that are at the service location:

Email: RA-ProvApp@pa.gov

Postal mail: DHS Enrollment Unit
PO Box 8045
Harrisburg, PA 17105-8045

Fax: (717) 265-8284

The Department will review the information and proceed with the processing of the application. The Department may, if needed, request additional information or clarification.

Applicable Regulation(s): § 5200.11(a) (relating to organization and structure).

Shared Space/Co-Location Attestation Form

This attestation is to be completed by a provider that seeks to enroll a location that is co-located with another provider enrolled in the Medical Assistance Program. A separate attestation must be completed by both of the providers that are providing services at the service location.

On behalf of _____ ("Provider") which will be co-locating with _____ which is a _____, located at the following address: _____,

I attest to the following:

Any agreements for the use of space or equipment or for personnel or management services by the providers must meet the requirements in 42 CFR § 1001.952(b),(c), and (d);

The provider shall comply with all other Federal and State laws and regulations prohibiting illegal kickbacks and referrals;

The space used by the providers shall be separated by walls, partitions, or other means sufficient to guarantee privacy to patients;

The provider will take whatever other measures are necessary to ensure and maintain patient confidentiality in accordance with applicable laws and regulations, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 (HIPAA);

The provider shall advise patients that they have freedom of choice in selecting providers and that the patients may choose any Medical Assistance enrolled provider;

The provider shall also display signage, approved by the Department of Human Services, displayed in a prominent place, such as a waiting room or at the point of check-in, stating that patients may choose any enrolled provider to provide services;

The provider will not make any direct or indirect referral arrangements between practitioners and other providers of medical services or supplies but may recommend the services of another provider or practitioner;

The provider will not make automatic referrals.

This attestation does not amend, reduce or eliminate any requirements imposed by State and Federal law and regulation relating to, or governing, the individual provider's participation in the Medical Assistance Program.

I possess all necessary powers and authority to execute this Written Attestation on behalf of the provider set forth below and in doing so bind the provider.

I understand that any false statements made therein are subject to the penalties contained in 18 Pa. C.S. § 4904, relating to any unsworn falsifications to authorities.

Printed or Typed Name: _____

Signature: _____ Date: _____

Provider Entity: _____

Provider Type: _____

NPI #: _____

Forward to:

Email: RA-ProvApp@pa.gov

-or-

Postal mail: DHS Enrollment Unit
PO Box 8045
Harrisburg, PA 17105-8045

-or-

Fax: (717)265-8284