The Office of Inspector General (OIG) was established in the U.S. Department of Health and Human Services to identify and eliminate fraud, waste, and abuse in the Department's programs and to promote efficiency and economy in Departmental operations. The OIG carries out this mission through a nationwide program of audits, inspections, and investigations. In addition, the OIG has been given the authority to exclude from participation in Medicare, Medicaid and other Federal health care programs individuals and entities who have engaged in fraud or abuse, and to impose civil money penalties (CMPs) for certain misconduct related to Federal health care programs (sections 1128 and 1156 of the Social Security Act, (the Act)).

Recent statutory enactments have strengthened and expanded the OIG's authority to exclude individuals and entities from the Federal health care programs. These laws also expanded the OIG's authority to assess CMPs against individuals and entities that violate the law. With this expanded authority, the OIG believes that it is important to explain the effect of program exclusions under the current statutory and regulatory provisions.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191, authorized the OIG to provide guidance to the health care industry to prevent fraud and abuse, and to promote high levels of ethical and lawful conduct.

Statutory Background
In 1977, in the Medicare-Medicaid Anti-Fraud and Abuse Amendments, Public Law 95-142, Congress first mandated the exclusion of physicians and other practitioners convicted of program-related crimes from participation in Medicare and Medicaid (now codified at section 1128 of the Act). This was followed in 1981 with Congressional enactment of the Civil Monetary Penalties Law (CMPL), Public Law 97-35, to further address health care fraud and abuse (section 1128A of the Act). The CMPL authorizes the Department and the OIG to impose CMPs, assessments and program exclusions against individuals and entities who submit false or fraudulent, or otherwise improper claims for Medicare or Medicaid payment. "Improper claims" include claims submitted by an excluded individual or entity for items or services furnished during a period of program exclusion.

To enhance the OIG's ability to protect the Medicare and Medicaid programs and beneficiaries, the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, expanded and revised the OIG's administrative sanction authorities by, among other things, establishing certain mandatory and discretionary exclusions for various types of misconduct. The enactment of HIPAA in 1996 and the Balanced Budget Act (BBA) of 1997, Public Law 105-33, further expanded the OIG’s sanction authorities. These statutes extended the application and scope of the current CMP and exclusion authorities beyond programs funded by the Department to all "Federal health care programs." BBA also authorized a new CMP authority to be imposed against health care providers or entities that employ or enter into contracts with excluded individuals for the provision of services or items to Federal program beneficiaries.

Exclusion from Federal Health Care Programs
The effect of an OIG exclusion from Federal health care programs is that no Federal health care program payment may be made for any items or services (1) furnished by an excluded individual or entity, or (2) directed or prescribed by an excluded physician (42 CFR 1001.1901). This payment ban applies to all methods of Federal program reimbursement, whether payment results from itemized claims, cost reports, fee schedules or a prospective payment system (PPS). Any items and services furnished by an excluded individual or entity are not reimbursable under Federal health care programs. In addition, any items and services furnished at the medical direction or prescription of an excluded physician are not reimbursable when the individual or entity furnishing the services either knows or should know of the exclusion. This prohibition applies even when the Federal payment itself is made to another...
provider, practitioner or supplier that is not excluded.

The prohibition against Federal program payment for items or services furnished by excluded individuals or entities also extends to payment for administrative and management services not directly related to patient care, but that are a necessary component of providing items and services to Federal program beneficiaries. This prohibition continues to apply to an individual even if he or she changes from one health care profession to another while excluded. In addition, no Federal program payment may be made to cover an excluded individual's salary, expenses or fringe benefits, regardless of whether they provide direct patient care.

**Violation of an OIG Exclusion By an Excluded Individual or Entity**
An excluded party is in violation of its exclusion if it furnishes to Federal program beneficiaries items or services for which Federal health care program payment is sought. An excluded individual or entity that submits a claim for reimbursement to a Federal health care program, or causes such a claim to be submitted, may be subject to a CMP of $10,000 for each item or service furnished during the period that the person or entity was excluded (section 1128A(a)(1)(D) of the Act). The individual or entity may also be subject to treble damages for the amount claimed for each item or service. In addition, since reinstatement into the programs is not automatic, the excluded individual may jeopardize future reinstatement into Federal health care programs (42 CFR 1001.3002).

**Employing an Excluded Individual or Entity**
As indicated above, BBA authorizes the imposition of CMPs against health care providers and entities that employ or enter into contracts with excluded individuals or entities to provide items or services to Federal program beneficiaries (section 1128A(a)(6) of the Act; 42 CFR 1003.102(a)(2)). This authority parallels the CMP for health maintenance organizations that employ or contract with excluded individuals (section 1857(g)(1)(G) of the Act). Under the CMP authority, providers such as hospitals, nursing homes, hospices and group medical practices may face CMP exposure if they submit claims to a Federal health care program for health care items or services provided, directly or indirectly, by excluded individuals or entities.

**CMP Liability for Employing or Contracting with an Excluded Individual or Entity**
If a health care provider arranges or contracts (by employment or otherwise) with an individual or entity who is excluded by the OIG from program participation for the provision of items or services reimbursable under such a Federal program, the provider may be subject to CMP liability if they render services reimbursed, directly or indirectly, by such a program. CMPs of up to $10,000 for each item or service furnished by the excluded individual or entity and listed on a claim submitted for Federal program reimbursement, as well as an assessment of up to three times the amount claimed and program exclusion may be imposed. For liability to be imposed, the statute requires that the provider submitting the claims for health care items or services furnished by an excluded individual or entity "knows or should know" that the person was excluded from participation in the Federal health care programs (section 1128A(a)(6) of the Act; 42 CFR 1003.102(a)(2)). Providers and contracting entities have an affirmative duty to check the program exclusion status of individuals and entities prior to entering into employment or contractual relationships, or run the risk of CMP liability if they fail to do so.

**Conclusion**
In accordance with the expanded sanction authority provided in HIPAA and BBA, and with limited exceptions, an exclusion from Federal health care programs effectively precludes an excluded individual or entity from being employed by, or under contract with, any practitioner, provider or supplier to provide any items and services reimbursed by a Federal health care program. This broad prohibition applies whether the Federal reimbursement is based on itemized claims, cost reports, fee schedules or PPS. Furthermore, it should be recognized that an exclusion remains in effect until the individual or entity has been reinstated to participate in Federal health care programs in accordance with the procedures set forth at 42 CFR 1001.3001 through 1001.3005. Reinstatement does not occur automatically at the end of a term of exclusion, but rather, an excluded party must apply for reinstatement.
HOW TO ACCESS THE SUD DESK REFERENCE MANUAL?

Written by: Elaine Young, DPH OCPA Compliance Data Analyst.

The SUD Reference Guide is here! Here are three ways you can access the Desk Reference Guide online:

2. Shortcut Link: tiny.cc/SUDref

TIP: You can bookmark this link or save it on your computer for easy future access.

You can visit this link for BOTH the SUD Desk Reference Guide and the SUD Documentation Manual.
“Medical Necessity” and “Medically Necessary Services” are SUD treatment services that are reasonable and necessary to protect life, prevent significant illness or significant disability, or alleviate pain through the diagnosis or treatment of a disease, illness, or injury. For an individual to receive SUD treatment services, there must be documentation in the client record in the form of a narrative statement showing that s/he meets DMC-ODS Medical Necessity Criteria. There are two sets of medical necessity criteria: one for adults, aged 21 and over, and the other for adolescents under 21 years old. Source: Intergovernmental Agreement, Exhibit A, Attachment 1 A2, IV.57

Medical Necessity Determination
The initial medical necessity determination for an individual to receive SUD treatment services must be performed by a Medical Director or a Licensed Practitioner of the Healing Arts (LPHA), acting within the scope of his or her profession. The Medical Director or LPHA must evaluate each client’s assessment and intake information. When a counselor has conducted a client’s intake assessment, the Medical Director or LPHA must meet face-to-face or via telehealth with the counselor to establish a client meets medical necessity criteria. Source: Intergovernmental Agreement, Exhibit A, Attachment 1 A2, III.PP.10.i

I. Medical Necessity Elements for SUD Treatment Admission of Adults, Aged 21 and over

**Element #1**
- Must have one included ICD-10 diagnosis from the Diagnostic and Statistical Manual of Mental Disorders (DSM) Fifth Edition for Substance-Related and Addictive Disorders, with the exception of Tobacco-Related Disorders and non-Substance-Related Disorders

**Element #2**
- Must meet the ASAM Criteria definition of medical necessity for services based on the ASAM Criteria.

**Element #3**
- Must meet the ASAM Adult Dimensional Admission Criteria.

II. Medical Necessity Elements for SUD Treatment Admission of Adolescents under 21 Years Old

Adolescents under age 21 years old are eligible to receive Medicaid services pursuant to the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) mandate that provides clients under age 21 all appropriate and medically necessary services needed to correct and ameliorate health conditions. In offering SUD treatment services to adolescents, EPSDT requirements must be met.

**Element #1**
- An adolescent has one covered ICD-10 diagnosis from the DSM for Substance-Related and Addictive Disorders with the exception of Tobacco-Related Disorders and Non-Substance-Related Disorders, or is assessed to be at risk for developing a substance use disorder

**Element #2**
- An adolescent meets the ASAM Criteria definition of medical necessity for services based on the ASAM Criteria.
A Sample Process to Developing a Good TPOC

GOALS
Identify the hoped-for results achieved through the services provided. Goals are generally related to important areas of life functioning affected by the client’s mental health such as living situation, daily activities, school/work, social support, physical health, substance use, legal situation, and psychiatric symptoms.

• I want a car
• I want a girlfriend/boyfriend
• I want to go back to school/work
• I want to get off SSI and be self-sufficient

OBJECTIVES
Objectives are the smaller accomplishments or the steps in order to achieve a goal. Objectives are concrete skills, behaviors, and attainments. Objectives should be specific, observable, measurable/quantifiable and related to the client’s mental health needs and functional impairments. An objective should answer: Who, What, When, and How to measure.

Source: CCR, Title 9, §1830.205(b)(3)(B)(1-4)(c)

INTERVENTIONS
Interventions are the services practitioners will provide in order to assist client in achieving objectives, and should include a detailed description with frequency, duration, and modality (therapy, targeted case management, collateral, rehabilitation services, medication management services). Each intervention should describe specific strategies and how these strategies address the client’s functional impairments.

(Mental Health Plan Contract, Exhibit A, Attachment I)

INTERVENTION EXAMPLES

POOR EXAMPLES
Individual Rehab as needed

Meet Psychiatrist as needed

CM will check in once a week regarding her symptoms

ACCEPTABLE EXAMPLES

Practitioner will provide individual rehabilitation services twice monthly for the next year to build/teach independent skills—such as budgeting, cleaning, grocery shopping, meal preparation to support client in maintaining current housing.

Psychiatrist will provide medication support services monthly for the next year to evaluate, monitor and ensure medications are managing depressive symptoms of low mood, decreased energy and poor sleep.

Therapist will provide 50 minutes of weekly individual cognitive behavioral therapy for the next 12 months to decrease client’s cognitive distortions about himself and others that contribute to his depressed mood.
**Client Plan/ TPOC FAQs**

*Content from Outpatient Documentation Manual*

**What if my client hasn’t achieved the goals/objectives by the end of the treatment year? Can I just use the same goals/objectives/interventions again next year?**

If goals/objectives have not been met or were only partially met, the clinician should re-assess whether the goals/objectives were realistic and make changes as clinically indicated. Similarly, the efficacy of interventions should be evaluated and new strategies should be implemented.

**What if I meant to include a service modality but didn’t specify it on my treatment plan? Can I still get paid for it since it was a service that was provided to the client?**

If a service (e.g., MSS - Medication Support Services) is provided but was not included on the treatment plan, it will be disallowed. All planned services must be covered by a current and valid TPOC. All planned services must be included on the TPOC in order to receive reimbursement. All services should be directed toward the client’s functional impairments (and those impairments should be reflected in the TPOC objectives). The TPOC Objectives should vary from year to year—unless there is clear documentation of the medical necessity rationale for continuing Objectives that have not been met.

**What is the timeline for completing a TPOC?**

<table>
<thead>
<tr>
<th></th>
<th>Initial Client Plan/ TPOC</th>
<th>Subsequent Client Plan/TPOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Hospital Outpatient Service</td>
<td>Within 60 days of Episode Opening (or prior to first planned service—whichever comes first)</td>
<td>Annually, within 30 days of Anniversary of Episode Opening Or when there are significant changes in client’s condition</td>
</tr>
</tbody>
</table>

**Are there services that can be delivered before the Client Plan/ TPOC is finalized?**

<table>
<thead>
<tr>
<th>Unplanned Services/ Activities</th>
<th>Planned Services/Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Allowable Services Prior to TPOC being finalized</strong></td>
<td><strong>Services ONLY Allowed with a finalized TPOC</strong></td>
</tr>
<tr>
<td>Assessment</td>
<td>Collateral</td>
</tr>
<tr>
<td>Plan Development</td>
<td>Rehabilitation</td>
</tr>
<tr>
<td>Crisis Intervention</td>
<td>Therapy</td>
</tr>
<tr>
<td>Crisis Stabilization</td>
<td>Therapeutic Behavioral Services (TBS)</td>
</tr>
<tr>
<td>Urgent Meds</td>
<td>Intensive Home Based Services (IHBS)</td>
</tr>
<tr>
<td>Specified activities within TCM/ICC like monitoring and follow-up activities</td>
<td>Treatment Foster Care (TFC)</td>
</tr>
<tr>
<td>Specified activities within Medication Support Services like Direct Treatment and Monitoring</td>
<td>Adult Residential Services</td>
</tr>
<tr>
<td>Adult Residential Services</td>
<td>Crisis Residential Services</td>
</tr>
<tr>
<td>Specified activities within Medication Support Services like Direct Treatment and Monitoring</td>
<td>Day Treatment Rehabilitation and Intensive</td>
</tr>
</tbody>
</table>

Shortcut Link to Mental Health Outpatient Documentation Manual: tiny.cc/MHref