Medication Monitoring Program Essentials

AEGIS® Sciences Corporation

Disclosure Statement

The information and resources contained in this document are intended to educate stakeholders on the purpose and rationale for drug testing in various clinical populations and to provide actionable tools to maintain appropriate drug testing practices. This document is for informational purposes and not intended to replace or supersede a clinician's judgment or assessment of individuals in their care. Other aspects of care remain important considerations, such as:

> **Review of the state prescription monitoring database (if available), pill counts, treatment agreements, practitioner evaluation and documentation of aberrant behavior, individualized counseling and education on the risks of chronic opioid therapy, possible drug and substance interactions, prescribing naloxone, and any other treatments, interventions, assessments, or clinical care activities deemed necessary by the practitioner.**

The ultimate decision of who, when, and how to test individuals for appropriate and inappropriate drug use remains at the sole clinical judgment of the clinician.

Introduction to Medication Monitoring

Content Objective:

Helping clinicians make better decisions.
To promote the awareness and value of clinical medication monitoring protocols that can provide valuable insight, leading to improvements in medication adherence and clinical outcomes.

Audience:

- Prescribing clinicians
- Non-prescribing clinicians
- Health administration leadership (managed care, health system leadership, etc.)

Opportunities to Optimize Care:

May provide clinical and analytical insights to customers, resulting in:

- Improved adherence
- Improved outcomes
- Reduced human tragic events (overdose, addiction, death, etc.)

Measurement tools showing:*

- % non-adherence
- % poly-pharmacy or unknown medication/drug use
- % illicit use
- All of these over time

**Accuracy is dependent upon correct completion of laboratory requisition form*

Table of Contents

Overview

Mapping a Protocol

References....25

Appendices

Introduction

Medication monitoring programs can help clinicians with risk assessment and identification of medication non-adherence. Non-prescribed substance use, drug diversion, unintentional ingestion of substances in counterfeit pills, and unrealized drug interactions are just a few examples of how individuals can be at risk of harm during treatment with controlled substances. Whether a clinician is managing chronic pain, treating mental health disorders, or following an addiction recovery journey, the results of drug testing as part of a holistic medication monitoring program can assist clinicians in safely reaching treatment goals.

While overall United States overdose death rates have shown a slight decrease as of 2023,[1] overdose deaths involving counterfeit pills doubled and tripled in some parts of the country in recent years.[2] Unexpected positive findings in toxicology results can help with educating individuals about hidden dangers in the illicit drug supply and the risks of non-prescribed drug use or obtaining medication from elsewhere than a licensed pharmacy.

As of 2023, the Center for Forensic Science Research and Education NPS Discovery group has reported 154 newly discovered NPS (novel psychoactive substances) in the united States. NPS are among the substances contributing to an increasingly adulterated illicit drug supply and leading to unintended exposures and elevated risk for adverse outcomes.[3-4]

Medication Monitoring Can Help Support Safer Prescribing

The prescribing of controlled substances has become increasingly regulated.[5] Although opioid prescribing has decreased from an all-time high in 2012 at an average of 81.3 prescriptions per 100 persons, there are still a significant number of prescription opioids being dispensed in communities across the country.[6] To help with appropriate prescribing decisions, multiple governing agencies require continuing medical education related to opioid prescribing. In many cases, these courses contain information concerning treatment protocols and best practices addressing the prescribing of controlled substances, including drug testing.[7] Check with your state licensing board for specific continuing education requirements related to controlled substance prescribing.

The Importance of a Medication Monitoring Program

As mentioned in the previous section, there are several different types of clinical populations that may benefit from a medication monitoring program. These may include, but are not limited to, pain management, addiction/recovery, behavioral health, primary care, and obstetric populations. Providers may care for individuals across multiple populations and therefore need to be familiar with multiple guidelines and state/federal regulations before implementing a medication monitoring program.

Individuals often do not voluntarily report prescription drug misuse or illicit substance use, and some may falsely describe symptoms to obtain opioids for diversion, which necessitates objective assessments such as drug monitoring.[8] The American Society of Addiction Medicine describes periodic and unannounced drug testing as useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs.[9]

Several professional organizations have developed guidelines, recommendations, and positions addressing the incorporation of drug testing in the clinical management of individuals.[10-19] These guidelines recommend criteria by which a drug testing practice is implemented, and such criteria vary according to assessed risk and other factors.

With the increase in opioid overdoses and the potential for development of opioid use disorder (OUD) and substance use disorder (SUD), it is becoming increasingly important for providers and health systems to better understand risk factors when evaluating individuals. There are no definitive ways for a provider to accurately predict the risk of an individual simply by an instinctive feeling, a person's appearance, or even by socioeconomic status. Multiple guidelines, professional societies, and regulatory bodies provide recommendations regarding practices of assessing risk and documenting responsible care in a systematic way.[10-19]

Recommendations for screening for SUD and OUD include the use of medical records, interviews with patient/client and family, information from state prescription drug monitoring programs (PDMPs), and urine drug testing (UDT).[10-19] There are multiple tools available to use as part of assessing overall risk for SUD and OUD. These tools range in complexity and should not be solely relied upon as the final measure of risk. The results of these tools may be helpful in establishing a starting point for the patient/client relationship. However, this relationship may evolve over time as the clinician has more opportunity to become familiar with the individual and evaluate their response to drug therapy and other treatment interventions.

The American Society of Interventional Pain Physicians (ASIPP) guidelines state that individuals may be stratified into risk categories with proper assessment, with or without the use of formal assessment tools, along with monitoring through PDMP reports, UDT, and simple psychological evaluation.[12]

The Federation of State Medical Boards (FSMB) offers additional information concerning clinical evaluation and risk stratification and they suggest that such assessment be completed and documented concurrent with the decision as to whether to prescribe an opioid.[16] The latest edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM–5) may be especially helpful to clinicians providing care to behavioral health clients, as it highlights enhanced risk factors for individuals with a history of SUD or OUD.[20] Such risk is not exclusive to the behavioral health population, however, as SUD affects individuals across the clinical spectrum.

The integration of an appropriate risk assessment plan can provide additional supporting documentation that the medication monitoring protocol is guiding reasonable and necessary health care services to treat the individual.

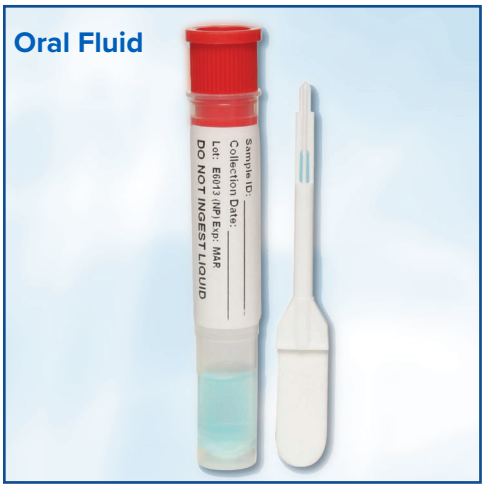
Clinicians should consult their state guidelines for state-specific recommendations regarding assessment or treatment of individuals based on risk.

Specimen Types for Testing in Health Care

Many specimen types are available for drug testing, each with advantages and considerations.[21] Specimen types include urine, oral fluid, blood, breath, hair, nails, and sweat. It is important for a provider to conduct research on each specimen type to determine if its use provides the optimal information to inform appropriate clinical care.

Overview of Selected Specimen Types[21–24]

Common Specimen Types	Advantages	Considerations
 Urine	• Drugs and metabolites are typically present in high concentrations in urine • Drug presence may persist up to five times longer in urine compared to other types • Longer detection period versus other specimen types	• Potential for individual to tamper with sample • Individual may be unable to provide a urine sample
Oral Fluid	• Observed collection • Fewer barriers to collecting sample • Helpful in providing trauma-informed care • May be utilized in a telehealth setting	• Shorter detection period compared to some other specimen types • Drug metabolites typically present in lower concentrations than parent drug
 Blood	• Specimen not subject to adulteration • Observed collection	• Shorter period of detection versus other specimen types • Requires more invasive collection procedures



Each specimen type presents unique insight regarding medication use over time, including the type of information that may be obtained, ease of collection, degree of invasiveness, and analytical and interpretive considerations.[24]

Urine is the most extensively used specimen for drug testing and remains the standard for drug use monitoring.[24] Use of non-urine matrices may help prevent sample adulteration and avoid privacy concerns with observed urine collections; however, urine testing has been widely adopted in clinical practice for monitoring because of adequate drug concentration in the urine, accuracy of developed tests, and clinically relevant detection windows (i.e., three to five days).[8]

Key Advantages of Urine[24]

- Ease of collection
- Less invasive
- Longer detection period
- Ability to detect multiple metabolites
- Minimal preparation required for analysis

Testing Methodologies

Both presumptive and definitive testing methodologies have a role in medication monitoring. It is important to understand the differences between them and how those differences impact result interpretation.

Presumptive

Immunoassay

If a drug is similar in structure to the target analyte, it may bind to the antibody and trigger a presumptive positive result.[23-25] One caveat: some drugs with no clear structural similarity to the target analyte may still bind to the antibody. Cross-reacting compounds may result in false positives, and lack of cross-reactivity across a class may result in false negatives. The extent of cross-reactivity across drugs in a class (or to other cross-reacting compounds) may vary depending on the immunoassay used. For instance, a false negative rate of 50% was found for individuals prescribed clonazepam and lorazepam in a study of 995 pain management patients.[26] Other studies have echoed the concerns of false negatives with benzodiazepines.[27-29] A 2014 study illustrated benzodiazepine false negative rates ranging between 22% and 53%.[29] Definitive methods may alleviate concerns associated with false negatives and may be preferred for this reason.

Definitive

Chromatography / Mass Spectrometry

Chromatography separates compounds in the specimen, which is important for accurate mass spectrometric analysis.[24] The chromatography phase (gas or liquid) is selected based on the target analyte and its chemical properties. Once the compounds in the specimen have been separated, mass spectrometry identifies whether the specific analyte is present based on the unique molecular mass and ion fragmentation pattern of each substance. Incorporation of appropriate internal standards and calibrators within the analytical method permits accurate measurement of drug concentrations in the specimen. These methods are far more complex than immunoassay, requiring more time, specialized equipment, and highly trained personnel to perform.

Presumptive vs. Definitive Testing

Testing Methods Defined	Technology	Advantages	Considerations
Presumptive/ Immunoassay *Defined:* Immunoassay is based on the principle of competitive binding of an antibody to a target analyte or drug	• Point-of-care cups • Chemical analyzer • Drug test cards	• Inexpensive • Rapid results • May be utilized in the office setting • Less training requirements to analyze compared to definitive methods	• Nonspecific binding is possible (false positives) • Potential for false negative results • May be unable to differentiate parent drug from metabolite • Unexpected results may be confirmed via definitive methods[3,21] • Unable to detect certain substances
Definitive *Defined:* Definitive methods include techniques such as GC/MS and LC/MS/MS, which identify the unique molecular properties of the analyte or drug	• Liquid Chromatography/ Tandem Mass Spectrometry (LC/MS/MS) • Gas Chromatography/ Mass Spectrometry (GC/MS)	• Highly sensitive and specific to target drug • Able to detect parent drug and, in many cases, additional metabolites • Provides clinical confidence in results	• Unexpected positives may occur from individual's exposure to unintended sources of target drug • Requires more time, expense, and highly skilled/trained lab personnel

The drug testing methodology chosen may directly impact individuals, as they may be falsely accused of abusing drugs or being non-adherent to their prescribed medications.[30] While point-of-care testing (POCT) can provide timely presumptive results, there are times when a definitive analysis is needed to provide the most appropriate care. Therefore, it is important for clinicians to understand the results of each methodology and their place in the clinical decision-making process.

False positive and false negative results may occur with POCT methods because the test result is dependent upon the selectivity of the reaction between the test antibody and the target drug or drug metabolite.[24] If cross-reactivity occurs with a similar compound (e.g., pseudoephedrine vs. amphetamine), the test result can be a false positive. Alternatively, if desired cross-reactivity fails to occur (e.g., norfentanyl vs. fentanyl), a false negative result can be produced when the parent drug is extensively metabolized.

Studies evaluating multiple types of immunoassay testing reported a range of false positive and false negative rates for the devices they assessed.[31-34]

Reported False Positive Rates for Immunoassay/POCT

Immunoassay	False Positive Rates
Amphetamines	14 – 53%
Benzodiazepines	0.4 – 11%
Cocaine	0 – 12%
Marijuana	0.9 – 39%
MDMA / Methamphetamine	86 – 100%
Methadone	0 – 45%
Opiates	4 – 34%
Oxycodone	2 – 41%
PCP	100%

Reported False Negative Rates for Immunoassay/POCT

Immunoassay	False Negative Rates
Amphetamines	9 – 57%
Benzodiazepines	22 – 37%
Cocaine	40 – 75%
Marijuana	9 – 38%
Methadone	4 – 60%
Opiates	2 – 39%
Oxycodone	3 – 31%

According to multiple guidelines, all unexpected presumptive-based tests are recommended to undergo definitive testing.[10,11,17,35] Definitive drug testing empowers the provider with the clinical information needed to make clinical care decisions. Before making a clinical decision, consider drug testing results within the context of the individual's clinical history, current presentation, and any other relevant clinical information.[16-17] Discussing the results with a clinical toxicologist may also aid with interpreting definitive drug testing results.[18]

Introduction to Protocol Development

The previous sections introduced the basic concepts of assessment as it applies to drug testing, the risk of SUD and OUD, and risk stratification of individuals. In this section, more detail will be provided on translating this information into everyday practice. As stated at the beginning of the document, this information in no way supersedes clinical judgment, as clinical guidelines and available risk tools cannot possibly address every clinical scenario. Excerpts provided from guidelines in this reference tool are intended to provoke further reading and study to fully determine the appropriate application of the guidelines to individual clinical situations.

Impact on Health Care Providers

Medication management protocols provide guidance for making consistent care decisions, but they are not intended to be inflexible plans. While clinical protocols specify a general standard of care, there may be extenuating circumstances that require more or fewer services — either as increased numbers of services at a given time, increased frequency of services over time, or both.

Managing individuals requiring treatment with controlled substances may be more safely accomplished by following a consistent care model, which in turn may be enhanced by the implementation of a medication monitoring protocol.[10-14,16,17] The following sections may be utilized for building a medication monitoring protocol, with portions to be implemented at the discretion of the treating clinician to achieve defined clinical goals and management objectives.

Drug testing can be considered as a part of an overall medication monitoring protocol, with various additional elements, as appropriate for the clinical population.[9-13,17,19,36]

The approach to clinical care will differ substantially based on certain conditions and individual factors, which may warrant referral and/or reference to entirely different guidelines and standards of care.[e]

Such individuals may require more intensive or immediate care, and providers should be vigilant when assessing for signs and symptoms of conditions that may warrant this level of care. Children, adolescents, women who are pregnant or planning to become pregnant, or individuals who have psychiatric diagnoses (such as SUD and OUD) may require additional considerations to successfully develop an appropriately customized medication monitoring protocol beyond those described in this section.

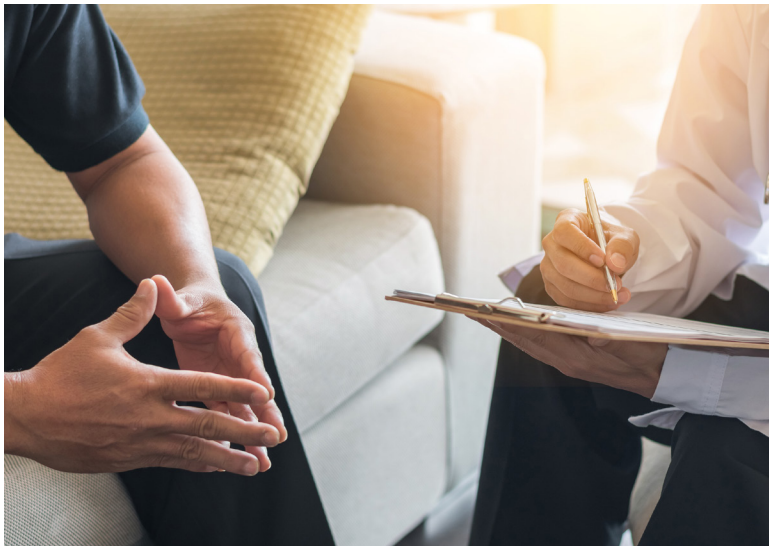
The following information and tables provide a brief extraction from multiple guidelines and organizational statements. This information is not to be utilized as a replacement for guidelines, nor as the sole determinant for the clinical management of individualized assessment, risk evaluation, pharmacotherapy, and overall clinical care. The order of presentation of the information does not reflect any recommended order of implementation or priority of one element over another. Clinicians are highly encouraged to reference and review multiple guidelines prior to providing care and ensure they are reviewing the latest editions of any guidelines. When constructing a medication monitoring protocol, clinicians may find it useful to evaluate the following considerations.

Clinical Assessment and Risk Evaluation

Individualized assessment lays the framework by which care options are identified and delivered. This framework can also provide initial and continuous guidance in the care plan decision-making process. Keeping in mind individual self-reports are potentially unreliable for determining amount of opioid use or aberrant drug-related behaviors, multiple strategies may be implemented to assess the individual.[10,16]

Examples of items that may be utilized include history, physical examination, risk assessment tools, pill counts, urine drug testing, family member and caregiver interviews, psychological history, PDMP data, comprehensive benefit-to-harm analysis, appropriate diagnostic tests, and other tools clinicians deem necessary.[8-12,14-19,36] The risk assessment process is multifactorial, with the weight of each factor determined according to the clinical judgment of the treating provider.

Various risk assessment tools may be utilized by clinicians during the initial screening and monitoring processes.[18] According to the Centers for Disease Control and Prevention (CDC), "clinical evidence reviews found that available risk-stratification tools demonstrate limited and variable accuracy for classification of patients as at low or high risk for opioid use disorder or misuse."[11]



Multiple guidelines do not recommend a specific risk assessment tool, but they do encourage clinicians to use one or more of these tools in the overall assessment process.[10-13,15,19,37] Clinicians should not overestimate the sensitivity and specificity of available risk assessment tools to determine the long-term risk associated with opioid therapy. Assigning a level of risk to an individual is somewhat subjective and encompasses a broader view of the individual than the output of a formal risk assessment tool. Once an individual has been assigned to a risk category based on the clinical judgment of the provider, and all pertinent factors have been considered, the clinician may determine if medication therapy is appropriate.

Examples of Formal Assessment Tools

Please review the table below for examples of available assessment tools and consult the referenced materials (most updated versions) for further information regarding their utility in clinical practice. Clinicians are encouraged to review the listed materials for further information concerning the implementation of these tools in the assessment process.

Note: *Selected guidelines below may mention additional tools beyond those listed in this table.*

Assessment Tool	APS/ AAPM[10]	AACC[18]	CDC[11]	ASIPP[12]	VA/DoD[19]	NIDA[15]	ACOG[14]	AAFP[17]
Pain Assessment and Documentation Tool (PADT)	✓				✓			
Current Opioid Misuse Measure (COMM)	✓	✓			✓			
SOAPP	✓	✓	✓	✓	✓			
SOAPP-R	✓	✓	✓					
ORT	✓	✓	✓		✓			
DIRE	✓	✓		✓	✓			
Pain, Enjoyment of Life, and General Activity Scale (PEG)			✓					✓
Brief Risk Interview (BRI)			✓					
Drug Abuse Screening Test (DAST)			✓					
Alcohol Use Disorders Identification Test (AUDIT-C)			✓					
Addiction Behaviors Checklist (ABC)				✓				
Atluri and Sudarshan Screening Tool				✓				
Prescription Drug Use Questionnaire (PDUQ)				✓	✓			
Pain Medication Questionnaire (PMQ)				✓	✓			
Ask, Advise, Assess, Assist, Arrange (Five A's of Intervention)						✓		
National Institute on Drug Abuse (NIDA) Quick Screen		✓				✓	✓	
NIDA Modified Assist						✓		
Brief Pain Inventory (BPI)								✓
Work Questionnaire								✓
Generalized Anxiety Disorder (GAD)-7			✓					
Patient Health Questionnaire (PHQ-9 or PHQ-4)			✓		✓			✓
Opioid Therapy Risk Report (OTRR)				✓				
Stratification Tool for Opioid Risk Mitigation (STORM)				✓	✓			
Screening, Brief Intervention, and Referral to Treatment (SBIRT)							✓	
Past Suicide Attempts, Suicide Plan, Probability of Completing Suicide, and Preventive Factors (4Ps)							✓	
CRAFFT Screening Tool for Substance Abuse		✓					✓	
CAGE Substance Abuse Screening Tool		✓			✓			

APS/AAPM – American Pain Society/American Academy of Pain Medicine • **AACC** – American Association for Clinical Chemistry • **CDC** – Centers for Disease Control and Prevention • **ASIPP** – American Society of Interventional Pain Physicians • **VA/DoD** – U.S. Department of Veterans Affairs/Department of Defense • **NIDA** – National Institute on Drug Abuse • **ACOG** – American College of Obstetricians and Gynecologists • **AAFP** – American Academy of Family Physicians

Documentation

While basic protocols and care plans require medical record documentation, especially as services rendered increase, it is of critical importance when a service is denied by a payer. Documentation must include reasoning as to why a service is ordered or requested and should include anticipated management decisions based on test results.

The same documentation thought process is important to consider when utilizing drug testing services. When considering the clinical value of drug testing and determining which testing methodology and frequency is appropriate to provide care for an individual, sufficient medical record documentation must occur.

Numerous guidelines, professional organizations, and regulatory bodies suggest the assessment of risk and documentation processes be conducted in a systematic fashion.[10,12,16,18,19] The FSMB provides a general practice reminder that all assessment, monitoring activities, and referrals should be thoroughly documented in the medical record or electronic health record on an ongoing basis.[16] Listed below are some additional documentation recommendations from FSMB, keeping in mind that state guidelines may have additional requirements. Other guidelines may be pertinent to the care of special populations and may provide further guidance on appropriate documentation standards. Records should remain current and be maintained in a readily accessible manner for review.[16]

- Medical history
- Records of past hospitalizations or treatments by other providers
- Results of overall risk assessment and outputs of any formal assessment tools
- Results of physical examination
- Queries to state PDMP
- Signed informed consent
- Signed treatment agreement
- Description of all treatments provided
- Medical indication(s) and absence of psychosocial contraindications for prescribing an opioid analgesic (an evaluation should be completed and documented concurrent with the decision of whether to prescribe an opioid analgesic)
- Evaluations/consultations from specialists
- Laboratory test orders and results
- Instructions to individual, including risk vs. benefits conversation with individual and/or family
- Medications prescribed/administered (date, type, dose, quantity)
- All prescription orders (e-prescribed, written, telephonic)
- Pharmacy contact information
- Rationale for use of higher medication doses than currently recommended in guidelines
- Ongoing monitoring of clinical progress (or lack thereof)
- Steps taken in response to aberrant medication use behaviors
- Information supporting initiation, continuation, revision, or termination of treatment
- Authorization for release of information to other treatment providers

Documenting Medical Necessity

Medical necessity is defined as accepted health care services by accepted health care professionals that are appropriate for the evaluation and treatment of illness, disease or injury that is consistent with applicable standard of care.[38,39] Centers for Medicare and Medicaid Services (CMS) provides a specific definition under the Social Security Act which states, "... no Medicare payment shall be made for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[39] The "Reasonable and Necessary" standard is founded on evidence-based scientific data, frequently available as clinical practice guidelines published by professional societies or organizations, that may be adjusted, when clinically appropriate, to provide individualized care. Read further on the topic of evaluating and documenting medical necessity in Appendix B: Spotlight on Medical Necessity.

Consent, Treatment Agreements, and Individualized Education

The inclusion of the following records will support individualized education and guide clinical management based on collaboratively-developed treatment goals.[12]

- Consent forms
- Treatment agreements
- Risk documentation tools
- Documented regular monitoring of:
  - Pain control
  - Success in performing activities of daily living
  - Presence of adverse effects
  - Observed aberrant drug-related behaviors

Consent is essential for a proper care relationship between the clinician and the individual.[9,13] Consent for drug testing may be included as part of the overall consent for treatment; however, it is important for the provider to evaluate appropriateness and examine payer and regulatory requirements. Several resources address the role of informed consent and treatment agreements.[10,12,15-16,19] The APS/AAPM guidelines recommend obtaining informed consent at the start of therapy and an ongoing conversation with the individual regarding treatment goals, potential risks, and alternative therapies.[10] The VA/DoD guidelines further recommend that this process be patient-centered.[19] Individuals may not be ready for initiation of medication therapy at the first visit, so this may be a good time to assess their level of commitment to treatment and request a review of (and signature on) a treatment agreement. According to the FSMB, informed consent may address[16]:

- Risks and benefits of opioid therapy
- Adverse effects
- Potential impaired motor skills
- Development of tolerance and physical dependence
- Drug and substance interaction risks
- Risk of SUD, overdose, and death
- Limitations of therapy in the management of chronic pain
- Counseling the individual on proper expectation of treatment, including reduction of pain rather than total relief
- Prescribing policies and expectations regarding refills or lost medications
- Changes or discontinuations in therapy

Treatment agreements address the responsibilities of the clinician and person receiving care, including the individual's agreement to random drug testing, which is ordered based upon the clinical judgment of the provider.[16] Such agreements also cover how PDMP data will be queried and used. Multiple guidelines discuss the use of treatment agreements as an ongoing monitoring tool to assess the individual's compliance with treatment and potential change in risk status.[10-12,16-19]

The FSMB strongly recommends that treatment agreements include:[16]

Treatment goals

- Pain management
- Restoration of function
- Safety
- Quality of life (treatment may not result in the elimination of pain)

Individual's responsibility for safe medication use

- Taking no more than prescribed
- Dangers of combined use with alcohol, cannabis, or other substances (like benzodiazepines) unless closely monitored by the prescriber
- Overdose prevention and naloxone use

Secure storage and safe disposal of medications

Individual's responsibility to:

- Obtain prescribed opioids from only one clinician or practice, if possible
- Fill prescriptions at only one pharmacy, if possible

Individual's agreement to periodic drug testing

Clinician's responsibility to be available or to have a covering clinician available to care for unforeseen problems and to prescribe scheduled refills

Thoroughly reviewing the informed consent and treatment agreement process with individuals helps facilitate understanding of their new treatment plan.[15] For some individuals, the medications being prescribed may be entirely new, and such strict expectations regarding behavior and monitoring may seem punitive and invasive apart from thorough individualized education. It is important to discuss each element of the informed consent and treatment agreement documents and assess the individual's understanding through common communication tools such as the teach-back method.[37] Providers may ask the individual to repeat and summarize the instruction given to them. If they are unable to do so, the provider may help fill in gaps in their understanding until they can restate the information appropriately.[15] Materials provided to individuals should be in an appropriate language and reading level to facilitate their understanding, including communications that are accessible to individuals with disabilities.[16]

Monitoring

Once an individual has been placed on chronic medication therapy, thorough monitoring practices should be in place based on risk of substance abuse, misuse, or addiction, as previously determined through the use of multiple assessment techniques.[10-14,16-19] Although there is insufficient evidence for specific recommendations about how to monitor individuals on chronic medication therapy, there is general agreement to include assessment and documentation of pain severity and functional ability, progress toward achieving therapeutic goals, presence of adverse effects, and clinical assessment for presence of aberrant drug-related behaviors, substance use, and psychological issues.[10]

Examples of Monitoring Tools & Methodologies

The following table provides examples of monitoring methodologies and the guidelines/references in which they are mentioned. The absence of mention of any of these monitoring considerations from the guidelines does not necessarily reflect disagreement among the organizations. Please review the referenced materials (most updated versions) for further information regarding their utility in clinical practice, along with other resources, as this is not a complete list of all available recommendations. Clinicians are encouraged to review the listed resources for further information concerning the implementation of these tools in the monitoring process, as this is merely an excerpt.

Monitoring	APS/ AAPM[10]	AACC[18]	CDC[11]	ASIPP[12]	VA\DoD[19]	ACOG[14]	AAFP[17]	ACP[13]	FSMB[16]
Pain severity assessment and documentation	✓	✓	✓	✓	✓	✓	✓	✓	✓
Functional ability assessment and documentation	✓	✓	✓	✓	✓	✓	✓	✓	✓
Progress toward achieving therapeutic goals	✓	✓	✓	✓	✓	✓	✓	✓	✓
Adverse effects	✓	✓	✓	✓	✓	✓	✓	✓	✓
Clinical assessment for aberrant drug-related behaviors	✓	✓	✓	✓	✓	✓	✓	✓	✓
Clinical assessment for substance use	✓	✓	✓	✓	✓	✓	✓	✓	✓
Clinical assessment for psychological issues	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pill counts	✓	✓	✓	✓	✓	✓	✓	✓	✓
Drug testing	✓	✓	✓	✓	✓	✓*	✓	✓	✓
Family member/caregiver interviews	✓	✓	✓	✓	✓	✓	✓	✓	✓
PDMP	✓	✓	✓	✓	✓	✓	✓	✓	✓
Formal screening instruments/tools to assess for aberrant drug-related behaviors	✓	✓	✓	✓	✓	✓	✓	✓	✓
Risk stratification	✓	✓	✓	✓	✓	✓	✓	✓	✓
Risk/harm/benefit evaluation	✓	✓	✓	✓	✓	✓	✓	✓	✓
Discuss patient/client and clinician responsibilities for managing therapy	✓	✓	✓	✓	✓		✓	✓	✓
Consider including discussion of naloxone use for overdose reversal			✓		✓	✓	✓**	✓	✓
Adherence checklist					✓		✓		
Treatment agreement	✓	✓	✓	✓	✓		✓		✓

*ACOG: only with patient consent and in compliance with state laws • **AAFP: Clinicians recommended to offer naloxone to individuals at high increased risk of overdose.
ACP – American College of Physicians • **FSMB** – Federation of State Medical Boards

Drug Testing as a Monitoring Tool

Each monitoring tool has the potential to provide insight in the clinical decision-making process. Drug testing is addressed by the guidelines and organizational statements above as a component of continuous monitoring.[10-14,16-19] Since this activity is a separate billable service with potential financial and treatment impact, clinicians may consider the potential value of information learned from drug testing and its role in safe prescribing.

Information learned from drug testing may not only indicate adherence and substance use, but also provide insight into reasons for intolerance to prescribed therapy, reduced response, or dose escalation requirements.[24] For example, metabolism patterns observed in drug testing may help reveal potential pharmacokinetic variability, which can be further investigated.

Drug interactions and genetic polymorphisms may also affect the normal disposition of drug in the body, leading to altered therapeutic response and/or potential adverse effects. Laboratory testing to identify drug-drug and drug-food interactions may be considered in various clinical situations according to a clinician's assessment of medical necessity. Testing for pharmacogenetic variants may also aid in the clinical assessment of some individuals. Comorbid conditions, such as hepatic, renal, gastrointestinal, endocrine, and other diseases may also affect drug metabolism.

The frequency with which drug testing may be deemed appropriate is associated with greater variation within the guidelines and is heavily dependent on a provider's clinical judgment, as well as relevant payer considerations.[10-13,15,19]

Payer Considerations

During the evaluation of an existing – or development of a new – medication monitoring protocol, it is important to evaluate payer mix and expectations regarding laboratory services. This could include commercial and government payers. This type of payer analysis can provide insight from the payer perspective on the perceived value of a specific medication monitoring protocol, as well as the impact on an individual's financial responsibility. Both aspects can assist with providing individualized care.

The payer requirements for coverage among a practice's most frequent insurance payers for a given service(s) can be compared to show:

- CPT code(s) for the service(s) rendered
- Level of service (presumptive testing vs. definitive testing)
- Number of services allowed per designated time (weekly, monthly, annually)
- Documentation and signature requirements (if different from CMS)
- Special requirements for a given payer

Tests ordered and frequency of testing for individuals with OUD/SUD are based on an individual's history and physical examination, previous laboratory test results, suspected substance abuse, stage of treatment or recovery, and presence of a substance that may present high risk for additive or synergistic interactions with prescribed medication. Similarly, tests ordered and frequency of testing for those receiving chronic opioid therapy is based on an individual's history and physical examination, previous laboratory findings, prescribed medication(s), risk assessment plan, and current treatment.

Evaluating Drug Testing Practices

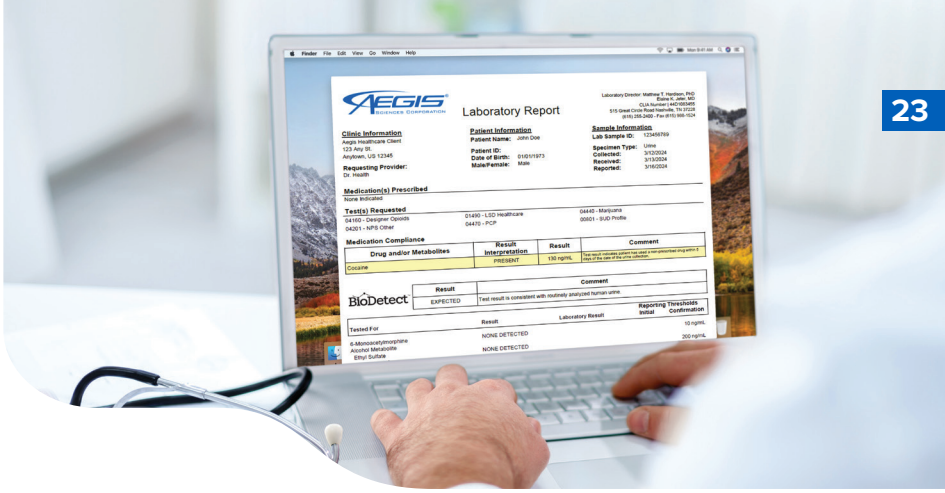
Please see the summary tables below for further information, and consult the referenced materials in full prior to implementing drug testing in clinical practice. There may be additional resources worthy of reference prior to determining a particular testing frequency or drugs for which to test when assessing or monitoring a given individual. As mentioned previously, risk evaluation is ongoing and evolving, and drug testing practices may change with periodic updates to risk stratification. As an individual is monitored over time, consider modifications to the testing based on the many factors discussed throughout this document.

Considerations for Testing Frequencies

Guidelines/Organizational Statements	Testing Frequency
American Pain Society/American Academy of Pain Medicine (APS & AAPM)[10]	• Periodically
Centers for Disease Control and Prevention (CDC)[11]	• Initiation • At least annually (follow-up should be left to the discretion of the clinician)
American Society of Interventional Pain Physicians (ASIPP)[12]	• Baseline • Subsequent use as adherence monitoring
American College of Physicians (ACP)[13]	• Initiation • At least annually
American College of Obstetricians and Gynecologists (ACOG)[14]	• Should be performed only with the patient's consent and in compliance with state laws
National Institute on Drug Abuse (NIDA)[15]	• Clinical judgment
Federation of State Medical Boards (FSMB)[16]	• Periodic; when clinically appropriate
American Association for Clinical Chemistry/American Academy of Pain Medicine (AACC & AAPM)[18]	• Baseline • Low risk (random drug testing a minimum of 1 – 2 times per year) • High risk (more frequent testing)
U.S. Department of Veterans Affairs/Department of Defense (VA/DoD)[19]	• Potential risk mitigation strategy upon initiation (frequency of ongoing, random urine drug testing should align with risk factors)

Considerations for Drugs & Substances to be Tested

Guidelines/Organizational Statements	Drugs
American Pain Society/American Academy of Pain Medicine (APS & AAPM)[10]	• Prescribed opioids • Non-prescribed opioids • Illicit drugs
Centers for Disease Control and Prevention (CDC)[11]	• Prescribed opioids • Other prescription and non-prescription controlled substances that increase risk for overdose when combined with opioids, including non-prescribed and illicit opioids and benzodiazepines
American Society of Interventional Pain Physicians (ASIPP)[12]	• Opioids • Medications not prescribed
American College of Physicians (ACP)[13]	• Prescribed medications • Controlled prescription drugs • Illicit drugs
National Institute on Drug Abuse (NIDA)[15]	• Alcohol • Tobacco • Non-medical prescription drugs • Illicit drugs
Federation of State Medical Boards (FSMB)[16]	• Prescribed medications • Other prescribed and non-prescribed controlled substances
American Association for Clinical Chemistry/American Academy of Pain Medicine (AACC & AAPM)[18]	• Relevant over-the-counter medications • Prescribed drugs • Non-prescribed drugs • Illicit substances
U.S. Department of Veterans Affairs/Department of Defense (VA/DoD)[19]	• Prescribed drugs



Applying the Results

As a reminder, drug testing should not be relied upon as the sole determinant of an individual's substance use.[9] Drug testing should be supplemented by a conversation with the individual concerning their medication and substance use. The individual's self-report, along with other assessment and monitoring methods, provides additional clinically relevant information. If an individual's self-reported medication use differs from the results of a presumptive drug test, the clinician may consider definitive testing.[16-18] The AAFP also recommends clinicians request definitive testing when presumptive testing is negative for prescribed opioids, positive for any medications not prescribed, or positive for substances such as alcohol, amphetamines, or cocaine.[17] According to the FSMB, drug test results that suggest opioid misuse should be discussed with the individual with a positive, supportive approach, to build a stronger treatment relationship and encourage healthy behaviors and any necessary behavioral changes.[11,16] The organization also recommends that these interactions, as well as the test results, are documented in the individual's medical record.

Furthermore, changes to prescribed medications and clinical decisions should not be based on one abnormal result, but rather based on a review of all available monitoring results.[11,13,16-17] Due to the complexities involved in the interpretation of drug testing results and the potential impact to the individual, clinicians should review significant or unexpected results with a laboratory toxicologist or clinical pathologist.[11,16] Facilitating treatment for substance use disorder (or appropriate referral) may be a safer decision if an individual is assessed as unsafe for continued prescribing as dismissal could result in the individual seeking opioids or other drugs from alternative sources.[11]

Providers should consider the above elements and the results of such evaluations as a part of the overall decision-making process in determining an appropriate testing frequency and the necessary drugs to include in testing.[16] It is important to make sure that sufficient documentation is recorded to support such testing and treatment decisions. Proper documentation helps prepare a practice for any legal, regulatory, or payer inquiries.

Putting It All Together

The steps toward initiating a medication management protocol may involve the entire care team, ensuring that the practice is engaged in both its development and implementation.[17] The information previously discussed is intended to be used in conjunction with the clinical judgment of the clinician to support organized, consistent, and well-documented clinical care decisions. The key parts of a medication management protocol can be summarized in the following groups of activities. These may be used as building blocks upon which to base further research toward developing a medication monitoring protocol and incorporating drug testing into clinical practice.

Meet & Assess

Perform initial evaluations and assess risk, including any baseline drug testing if deemed clinically appropriate and medically necessary

Mitigate Risk

Take individuals through an informed consent process, including signing a treatment agreement, educating them on all aspects of their treatment, and reassessing risk throughout the treatment relationship

Monitor Response & **Measure** Results

Observe for changes in clinical status, emerging aberrant behaviors, changes in risk, activity on the PDMP, and any need for repeated drug testing

Evaluate results of any formal assessments, document response to treatment, track dose changes and escalations of therapy, and maintain historical results from all laboratory monitoring and drug testing

Modify Treatment

(according to clinician's professional judgment)

Make changes as needed to achieve clinical goals, minimize risk, and maintain or improve quality of life whenever possible

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Appendix A – Opioid Patient Prescriber Agreement (PPA)[40]

Opioid Patient Prescriber Agreement (PPA)

This Opioid Patient Prescriber Agreement (PPA) is designed to:

- Create an open conversation between the patient and the prescriber about the benefits, risks, and limitations of opioid medicines
- Be used as a decision making tool before an opioid medicine is used for acute or persistent pain, and
- Ensure the appropriate and safe use of opioid medicines

Part 1: For the Patient: Deciding whether to use opioid medicines for pain I will check off each item as I discuss it with my prescriber:

1.___ Pain and pain treatment are different for each person. Opioid medicines are a type of analgesic (pain reliever) medicine used to reduce moderate to severe pain. Opioid medicines can reduce some (but not all) types of pain. It is not known how much improvement in pain, activity and quality of life I may have by using these medicines. My prescriber will routinely check how I am doing to determine whether the benefits of opioid medicines outweigh the side effects of continuing to use them.

2.___ I hope opioid medicines may reduce pain, making it easier to:

___Go back to work
___Climb stairs
___Walk short distances
___Sleep through the night without pain
___Do daily household chores
___Start a light exercise program

3.___ My prescriber and I may also try alternative or additional treatment options for my condition, including:

___Non-opioid medicines (for example, over-the-counter medicines such as Tylenol®, Motrin®, Aleve®, prescription medicine such as antidepressants, or anticonvulsants, as appropriate)
___Physical therapy, appropriate exercises
___Acupuncture
___Self-management techniques and coping strategies such as meditation, stress reduction, counseling and coaching, massage therapy, social support group, and attention to proper sleep
___Surgical or other medical procedures

4. ___ I need to be aware of the following side effects of using opioid medicines.

___a) Physical dependence - If I suddenly stop taking an opioid medicine, I can experience withdrawal symptoms such as a runny nose, chills, body aches, diarrhea, sweating, nervousness, nausea, vomiting and trouble sleeping. This is called physical dependence. If this happens, it can be difficult for me to stop taking an opioid medicine, even if it's not working well. So, when I stop taking an opioid medicine, I understand I will need medical supervision. My prescriber can help me gradually lower the dose and stop the opioid medicine or refer me to a specialist in a way that meets my needs.

___**b) Tolerance -** Over time, I might need more opioid medicine to get the same pain relief. This is called tolerance. It means that the opioid medicine may begin to feel like it's not working anymore. My prescriber can help me by making changes to the opioid medicine or refer me to a specialist in a way that meets my needs.

___**c) Addiction** - I may develop an intense craving for the opioid medicine, even if I take it as prescribed. When a person is not able to control their opioid medicine use and may continue using the medicine despite the side effects it causes, this is called addiction. If addiction occurs, it can be difficult to stop taking the opioid medicine, and I will need medical supervision. My prescriber can help me gradually lower the dose and stop the opioid medicine or refer me to a specialist in a way that meets my needs.

5. ___ **Table 1 - Opioid Side Effects**: The table below lists common and potential opioid side effects in alphabetical order and the percentage of patients that experience them.

Opioid Side Effects	Percentage of Patients
addiction	5 - 30%
breathing problems during sleep, disruption of sleep	25%
confusion	*
constipation	30 - 40%
depression	30 - 40%
drowsiness	15%
dry mouth that can cause tooth decay	25%
intestinal blockage	< 1% per year
itching	*
lowered testosterone levels, infertility and impotence	25 - 75%
nausea or vomiting	*
overdose – can lead to death	< 1% per year
physical dependence	*
tolerance	*
unexpected increased pain	*

*Percentage of patients experiencing side effect unknown

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Opioid Patient Prescriber Agreement (PPA)

6. ___ Opioid medicine can impair my judgment and responses. I understand that I must be cautious if I drive or operate machinery or do any activity that requires me to be alert until I am sure I can perform such activities safely.

7.___ Taking even small amounts of alcohol or taking medicines such as sleeping pills, antihistamines, and anti-anxiety medicines while taking an opioid medicine will increase the chance of opioid medicine side effects. These side effects can include drowsiness, dangerously slowed breathing, and decreased alertness.

8. ___ It may be necessary that I routinely provide a urine, saliva, or blood sample before or while I am taking opioid medicine.

9.___ I agree to discuss with my prescriber my and my family's past and present use of any habit-forming substances before we decide to try to treat my condition with an opioid medicine. These habit-forming substances can include tobacco and alcohol, as well as other opioid medicines or street drugs.

10. ___My prescriber and I have discussed all the information above and have made a decision about using opioid medicines.

___Yes, my prescriber and I have agreed to try an opioid medicine for my condition. If I check "Yes", we will continue to discuss the rest of this checklist.

___No, my prescriber and I have **not** agreed at this time to try an opioid medicine for my condition. If I check "No", we don't need to continue to Part 2 of this checklist.

Part 2: For the Patient: My promise to using opioid medicines safely

Now that my prescriber and I have agreed that I will try an opioid medicine, I understand that I need to take an active role in my own health care to get the most benefit and reduce the chance of side effects from using an opioid medicine. My prescriber wants me to have the following information so that I may have the best possible pain reduction while also protecting my health and reducing the chances of possible harm to myself and others while I am taking an opioid medicine.

11. ___ I told my prescriber about all the medicines I am taking, including any prescription, over-the-counter and herbal medicines. I will also discuss with my prescriber any new medicine that I take in the future. Some medicines and other substances such as alcohol, sleeping medicines, antihistamines and anti-anxiety medicines can increase the chance of opioid medicine side effects. If I use these medicines along with an opioid medicine, they can slow my breathing. This can lead to serious problems, including an increased chance of stopping breathing and death.

Opioid Patient Prescriber Agreement (PPA)

12. ___If I start to have more pain or other unusual or severe side effects, I will contact my prescriber right away. We may need to change the dose or try a different opioid medicine. I will not make any changes to the opioid medicine without first talking to my prescriber.

13. ___I will tell my prescriber if I am pregnant or planning to become pregnant. Taking opioid medicine during pregnancy can harm my unborn baby.

14.___I will not share this opioid medicine with other people. My prescriber and I have selected this opioid medicine for me, and it is only for me. It is against the law to share an opioid medicine with other people. Sharing an opioid medicine with another person can cause serious harm to them, including death.

15. ___I will keep my opioid medicine in a secure place where other people cannot reach it. If someone accidently takes some of my opioid medicine or I accidentally take too many doses, I will contact my prescriber or call the **Poison Control Center** at **1-800-222-1222.**

16.___ I will remove expired, unwanted, or unused opioid medicine from my home to avoid accidentally harming children, other adults, or myself.

- I may be able to drop off unused opioid medicine through a "medicine take-back program." A "medicine take-back program" is an official place and time for dropping off unused opioid and other medicines.
- If I cannot find a "medicine take-back program" or if I want to remove the medicine from my home right away, I can flush my opioid medicine down the toilet.
- My opioid medicine can also be mixed with cat litter or coffee grounds and thrown out with the household trash.
- I can get more information about disposing of my opioid medicine by calling 1-888-**INFO-FDA (1-888-463-6332**) or at the following website http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186187.htm

Part 3: For the patient and the prescriber.

___My prescriber and I have discussed all the items on this checklist.
___We both agree that an opioid pain medicine is the best choice for my condition at this time.
___My prescriber and I agree that we will go over this checklist again in the future.

Patient name_____ Date___/___/_____

Provider name_____ Patient signature_____

Provider signature_____

Appendix B

Spotlight on Medical Necessity – From a DEA Perspective
Q&A with Richard A. Tucker

Assistant Special Agent in Charge, Drug Enforcement Administration (Retired)

Q: How can prescribers demonstrate that they are evaluating the medical necessity of their treatments?

> The case of United States v. Moore (423 U.S. 122 1975) referenced that a prescription must be issued "in accordance with a standard of medical practice generally recognized and accepted in the United States."
>
> The DEA refers to this as Legitimate Medical Purpose. The DEA states that its role is to ensure that controlled substances are prescribed, administered, and dispensed only for legitimate medical purposes by DEA-registered practitioners acting in the usual course of professional practice and otherwise in accordance with the Controlled Substances Act (CSA) and DEA regulations. Each state also has its own laws (administered by state agencies) requiring that a prescription for a controlled substance be issued only for a legitimate medical purpose by state-licensed practitioners acting in the usual course of professional practice."[1]
>
> Detailed notes as to diagnoses, therapeutic plan, and the prescription regimen should be noted in the patient chart. Subsequent notes should be made as to how the plan is working as to the patient's recovery/improvement. Notes should be made as to the logical uses of prescribed medications and adherence by the patient leading to improvements in the diagnosed condition.

Q: What are some examples of information prescribers should document to show progress with prescribed therapy?

> Following the above-mentioned guidelines, a prescriber should document in detail how a diagnosis was obtained, prescribe applicable medication(s), and continue to show therapeutic value in future prescription(s). This should include "quality of life" improvements and linking the therapeutic value to the continued use of the medication, ensuring the improvement in the patient's condition is a result of the prescribed medication.

Q: How can clinicians stay informed about drug trends in their area that might increase risk of substance misuse among their treatment population and potentially warrant changes to their medication monitoring protocol?

> Through continuing conversations with the patient, a prescriber should assess the possibility that a patient is using medication properly and not using other substances that act counter to the prescription therapy regimen. Prescribers should stratify the risk of each patient to determine the possibility of substance abuse (illicit or other controlled substances). These factors should be evaluated on an ongoing basis to ensure patient compliance with a treatment plan. Prescribers should be aware of illicit drug use in their community. The DEA publishes a National Threat assessment each year to show trends of abused drugs.[2] The DEA also publishes a Drugs of Abuse Resource Guide.[3] Both are available for download and are excellent resources for a practice.

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Please Note: *Richard A. Tucker was contracted with Aegis to provide educational content and sessions at the time this was written.*

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