2019 ANNUAL PROVIDER NOTICE

As part of our commitment to our partners and to honor our core value of Commitment to Regulatory Compliance from the "top down," Cordant Health Solutions™ is providing this annual notice to support our mutual goals of compliant business practices and adherence to the guidelines issued by the Office of Inspector General (OIG). This notice serves to educate, update and inform our partners on issues related to compliance with federal laws and regulations, as well as updates to billing and coding practices of Cordant. It is also designed to ensure that providers are aware of regulatory changes, issued treatment guidelines, applicable Medicare/Medicaid reimbursement rates, procedural codes and enforcement actions.

There have been a great number of changes for the industry over the past couple of years. The experiences and stories of abuse and overdose, prescribers being penalized, etc. in the press are numerous. The Centers for Disease Control and Prevention (CDC) has published a new study that confirms an increase in drug overdose deaths in 2017 compared with the previous year. The study reveals that of the 70,237 drug overdose deaths in 2017 (192 per day), 47,600 (67.8 percent) involved opioids, representing an increase of 12.0 percent from 2016. Synthetic opioids (including illicitly manufactured fentanyl) were involved in 59.8 percent of all opioid-involved overdose deaths, an increase of 45.2 percent from 2016 to 2017. More and more providers are being reviewed and cited by state medical boards or worse, have been found personally liable; thus, it is essential to have a medication monitoring and treatment program in your practice that meets or exceeds the industry standards of care.

Cordant partners with providers to supplement and provide solutions for their current programs. Cordant believes information shared and care-coordinated between prescribers, dispensers and labs can significantly reduce diversion and waste and abuse, while simultaneously improving patient outcomes, increasing access to care and ensuring proper medications for legitimate chronic pain patients. Cordant is an industry-leading College of American Pathologists (CAP), Clinical Laboratory Improvement Amendments (CLIA), and Substance Abuse and Mental Health Services Administration (SAMHSA) certified laboratory system offering solutions to various provider practices, hospitals and health systems to fight prescription medication and illicit drug abuse in the United States. Cordant's national laboratory and pharmacy network offers proven tools, with a preventive and integrated approach, to assist providers through risk identification, comprehensive drug testing services and data analysis to address the growing abuse and dependency problem.

Our integrated pharmacy program offers a review of prescription drug monitoring program (PDMP) data in conjunction with review of toxicology test results, providing a more detailed view of patient risk of abuse or diversion. In addition, it dispenses controlled substances in a manner that protects patients and prescribers, sponsors a national takeback program that has compliantly disposed of 211 pounds of medication (approximately 192,000 pills), and facilitates access to naloxone. Cordant's drug takeback and neonatal abstinence prevention programs are geared toward protecting innocent victims of the opioid crisis, while also attempting to mitigate and avoid longer term healthcare cost and improve overall population health. Additionally, Cordant offers Cordant CORE™ (Comprehensive Oral fluid Rx Evaluation), a patented and proprietary oral fluid dose correlation tool which provides insight to providers to help them better understand if a patient is taking his or her medication as prescribed. CORE is the first patient-monitoring screening test to use oral fluid samples to correlate oral fluid prescription pain medication levels to an expected level at steady-state range. This technology is available today through blood testing but is not widely used because of the challenges in collecting blood. CORE offers many of the benefits of blood plasma dose correlation with the convenience and reduced costs of quick, painless and observable oral fluid collection. Additionally, Cordant provides actionable practice analytics which can identify opportunities for improvement and benchmark success against local and national trends, important data as health plan reimbursement shifts toward value-based criteria.

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DRUG TESTING CODING AND REIMBURSEMENT CHANGE

The last couple of years we saw a dramatic change in the coding and reimbursement for testing drugs of abuse. The Centers for Medicare and Medicaid Services (CMS) addressed its concern about the potential for overpayment when billing for individual drug tests, and thus changed its coding to a bundled system. CMS reimburses definitive testing through four Healthcare Common Procedure Coding System (HCPCS) procedure codes for presumptive screening tests and four HCPCS procedure codes for definitive confirmation testing in tiers based on the number of drug classes tested. Cordant's requisition forms were updated a few years back to align with the new coding and classification of testing based on drug classes.

Test Panels, Testing Custom Profiles and Standing Orders

The OIG has stated that testing panels and profiles are "problematic because referred tests are supposed to be patient specific and not practice wide" (see BNA Health Law Reporter, Issue 1064-2137, 11-05-15). Additionally, nearly all Medicare Administrative Contractors (MACs) have also set forth language requiring that each test ordered is individualized. Every drug test ordered and submitted to Cordant for laboratory testing services MUST be based on the individual patient treatment plan and the testing and basis thereof must be clearly explained and documented in that patient's medical records for every date of service. In other words, justification for each definitive drug confirmation test ordered must be set forth in the medical records for that date of service. The provider's use of the testing result in the treatment of the patient's medical condition should also be captured in the medical records.

Cordant CORE-

The American Medical Association (AMA) has assigned a discreet Current Procedural Terminology (CPT®) code to facilitate the reimbursement of CORE, Cordant's proprietary quantitative oral fluid test. CORE uses a noninvasive, readily observable collection method, a unique algorithm, and patient-specific criteria to help determine whether patients' oral fluid drug levels are consistent with what has been prescribed. The CORECPT code, 0011U, is defined by the AMA as "prescription drug monitoring, evaluation of drugs present by LC-MS/MS, using oral fluid, reported as a comparison to an estimated steady-state range, per date of service including all drug compounds and metabolites."

MEDICAL NECESSITY

Medicare policy guidelines state that Medicare will only pay for laboratory testing that is reasonable and medically necessary for use in the treatment of the patient's medical condition. The medical necessity determination by providers should be based on the individual patient's history, clinical indications, risk rating and treatment protocols. Drug testing for routine screening or monitoring purposes, undertaken without focusing on the treatment of the individual patient, is not covered by Medicare and Medicaid programs. To help document that medical necessity requirements are being met, Cordant requires a supporting diagnosis code (ICD-10 codes) for all outpatient test requisitions. Please be advised, even if a service is determined to be reasonable and medically necessary, individual patient coverage may be limited if the service is provided more frequently than allowed under Medicare, Medicaid or other private insurance coverage policies. We have a mutual interest in providing only necessary tests as individual ordering providers requesting unnecessary tests may be subject to civil penalties under the False Claims Act and Civil Monetary Penalties authorities, see 42 U.S.C. § 1320a-7a.

Cordant, as an indirect healthcare provider, is expected to have sufficient processes and safeguards in place to ensure that all services are delivered only when ordered by the physician or non-physician provider (NPP). Additionally, Cordant takes steps to audit referral patterns and practices to identify referrals and testing which may not be medically reasonable and necessary. Based on the findings, Cordant may conduct client business

reviews to ensure that our partners understand and review their test ordering. During these business reviews, Cordant runs frequency of testing reports to highlight outliers so that they can be reviewed with the client regarding the appropriateness and use of drug testing. Positivity reports are also included so practices can examine their patient population and testing patterns/outcomes so that they can adjust their ordering as they deem appropriate. Providers interested in receiving these client business reviews may contact our business development team at 855-895-8097.

Medicare Local Coverage Determinations

Numerous Medicare administrative contractors (MACs) have issued local coverage determinations (LCDs) which were created for controlled substance monitoring and drugs of abuse testing. These LCDs set forth appropriate and medical necessity for drug testing within the MAC's region of jurisdiction. These LCDs apply to both presumptive drug screens and definitive confirmation drug tests. These LCDs are available upon request or found on CMS's webpage at https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx.

Payer Coverage Policies

Many payers have over the past couple of years issued payer coverage policies limiting the number of both presumptive screen and definitive confirmation drug testing, but also, more importantly, when they believe definitive confirmation drug testing is appropriate. Direct-to-definitive confirmations are rarely appropriate. As an example, Harvard Pilgrim only covers definitive confirmation testing for a specific drug class when the presumptive screen has had a positive for the specific drug class with an exception for when there is no commercially available presumptive test or if there was an unexpected negative presumptive screen result. If you have questions about payer coverage policies seen within your practice's payer mix, please reach out to your Cordant representative.

DRUG TESTING ORDERS

All authorized providers who order clinical toxicology laboratory services for Medicare payment must fully understand and follow all existing laws, regulations and rules for coverage. A clinical laboratory may only bill Medicare and Medicaid for testing ordered by a licensed physician or other individuals authorized by law to order laboratory tests who have not been excluded or disbarred. Providers who have had their license revoked or suspended must immediately notify Cordant.

Provider Signature

Medicare does not require that the ordering provider sign the submitted laboratory requisition forms. However, providers not signing laboratory requisitions are required by CMS to maintain medical record documentation for the patient, which clearly demonstrates the provider's intent to order the performed testing. There are a number of payer policies which do require the authorized ordering provider's signature on each laboratory requisition form so it should be viewed as best practices. Given there is an increase in payer audits for the whole industry, we strongly recommend that ordering providers sign each laboratory requisition form to avoid the potential additional burden of having to provide signed supplemental progress notes or medical records.

Verbal Test Orders

CLIA regulation 42 CFR § 493.1241 provides that the laboratory must have a written or electronic request for patient testing from an authorized person. Cordant may accept oral requests to change a laboratory order if the clinician promptly follows it up with a written or electronic authorization. Please note, there may be a delay in receiving the results until such time as the written authorization is received.

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Ambiguous or Unclear Test Orders

Cordant only submits claims for reimbursement for tests that have been both ordered and performed. If the laboratory receives a requisition without a clear test order, we will be required to put the test on hold and the provider will be contacted to clarify what testing is to be performed before any tests are conducted or billed. Cordant appreciates cooperation in submitting complete, accurate and valid orders so that we can provide the best possible service to providers and their patients.

Reflex Definitive Testing

Reflex definitive testing occurs when initial test results are positive or outside normal parameters. This situation indicates that a second, related test is medically appropriate for confirmation of specific drugs within a class. They should be ordered in accordance with medical necessity guidelines and coverage limitations. Cordant offers the option to choose a reflex definitive confirmation for positive results by quantitative analysis through LC-MS/MS. This allows the specific drug causing the result to be identified (e.g., able to distinguish between heroin and morphine which have similar molecular structures) and the amount precisely quantified. Cordant will bill reflex quantitative tests as well as the initial screen test when reflex definitive tests are ordered.

CORDANT AVAILABLE RESOURCES

There were a significant number of changes issued by CMS and others in regard to the ordering of and payment for drug testing based on and supported by appropriate medical necessity. Cordant provides you with a number of resources if you have any additional questions about these changes. They include toxicology experts, pharmacists, a former Drug Enforcement Administration agent and state Medicaid fraud investigator who are available to speak with physicians and other providers as part of Cordant's medication monitoring program to ensure proper test ordering, documentation, use of results, and to answer questions regarding drug testing results and prescribing. To access this expertise, please call 855-895-8090.

PATIENT-RESPONSIBLE AMOUNTS AND FINANCIAL HARDSHIP WAIVERS

Cordant makes a good faith effort to collect deductibles, copayments, co-insurance and patient-responsible amounts from individuals. Attached hereto is a list of Cordant's testing codes along with the Medicare reimbursement rate.

Patient Financial Hardship

Cordant will provide an adjusted self-pay rate if a patient is experiencing a financial hardship and falls at or greater than 400 percent of the current federal poverty level based on income and family size. Please select hardship on the patient's test requisition form or direct applicable patients to call Cordant's customer service at 855-895-8090. Cordant monitors the selection of this financial hardship and may request additional documentation from the provider making the selection.

Self-Pay Patients

Self-pay patients will receive a bill directly from Cordant. The pricing of the lab services provided will be based on the then current Medicare allowable rates.

Patient Billing

The amount billed by Cordant is wholly based on the patient's insurance plan; as set forth in the explanations of benefits (EOBs) or similar statements furnished by the health insurance plan, not by

Cordant. Cordant makes reasonable attempts to collect patient balances for each date of service. In addition to sending patient bills, Cordant's efforts may include phone calls and other correspondence. Patients who receive payment from their insurance company but fail to remit payment to Cordant may be subject to further collection efforts. Cordant does not blanket or provide routine waivers for patient responsible amounts.

Advance Beneficiary Notice

An advance beneficiary notice (ABN) should be completed for all ordered tests likely to not be paid by Medicare (e.g., Over the Medical Unlikely Edit, Medicare does not pay for the tests related to this diagnosis/ICD-10 code, etc.) and provide the estimated cost of the tests. This notice allows us to bill the patient. The ABN is provided on the back of the first page of the laboratory requisition form and the patient's signature is required at the time of specimen collection.

MEDICAL RECORD DOCUMENTATION FOR DRUG TESTING

Many laboratories are going through prepayment audits and post payment reviews. Pursuant to federal law 42 CFR 410.32(d), "The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or non-physician practitioner to document that the services it bills are reasonable and necessary." As an indirect healthcare service provider, Cordant does not obtain all the documentation to support each order and, as such, is required to reach out to the treating provider to obtain documentation that supports the medical necessity of the test when necessary for a payer claim review.

The patient's record should include all required documentation to support the test order and the medical necessity and specific diagnostic information of each drug class tested. It is recommended that each patient's medical records contain the drug testing results and documentation on use of the results in the treatment of the patient's medical condition. The MACs have historically provided the following recommendations around proper documentation:

- Written or electronic documentation of the order for the date of service billed
- Signed and dated physician order for each ordered drug test
- Current treatment plan
- List of patient's prescribed medications
- List of illicit medications
- Risk assessment plan
- Sufficient information to identify the ordering physician or non-physician practitioner
- Diagnostic or other medical information by the ordering physician or non-physician practitioner, including any ICD-10 code or narrative description supplied
- Medical record documentation (e.g., history and physical, progress notes) indicating the medical necessity for performing each drug test
- Test requisition order forms and testing result reports

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 administrative simplification rules require a covered entity, such as a physician, to retain required documentation for six (6) years from the date of its creation or the date, many states have even longer retention requirements.

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CORDANT'S COMMITMENT TO COMPLIANCE

Cordant is committed to compliance with all aspects of applicable state and federal laws and regulations, including but not limited to the physician self-referral law (Stark Law), Anti-Kickback Statute, False Claims Act, Civil Monetary Penalties Law and HIPAA.

Anti-Kickback Statute

Cordant aims to maintain the highest ethical standards in our dealings with all healthcare professionals. It is our belief that patient care should be based on medical need as wholly determined by healthcare professionals without undue influence. Cordant provides only items which are necessary, essential and exclusively used for its lab testing services and provides only such services which provide clinical value and are part of its medication monitoring program. No item or service will be offered, given, solicited or received by a potential or actual referral source (e.g., a physician or practice) in exchange for, or as inducement for, business or referrals, or other business.

Stark Law

Remuneration outside proper arrangements for legitimate items or services of any type or value are never appropriate. Cordant tracks its non-compensation benefits to actual and potential referral sources and strictly adheres to its Business Courtesy to Healthcare Professionals policy. Cordant does not accept referrals from a physician where the referral would violate the Stark Law.

False Claims

Violating the False Claims Act is a very serious matter, and because the fines and exclusion risks are present for both Cordant and providers, it's in our mutual interest to partner with provider ensuring testing is for legitimate treatment purposes and properly documented.

HIPAA – Patient Privacy

Cordant is a HIPAA-covered entity and respects and protects the confidential nature of protected health information (PHI) and other confidential information we receive, whether in verbal, written or electronic form. Cordant's personnel must comply with laws and regulations governing the privacy and security of PHI, including HIPAA and the Health Information Technology for Economic and Clinical Health Act (HITECH). Through our service partnership, we share PHI for treatment purposes. Because Cordant is a HIPAA-covered entity providing treatment services, a Business Associate Agreement is not required pursuant to the Rule and clarifying HHS guidance. In addition, Cordant enters into written Business Associate Agreements with all vendors and contractors that receive, use or access PHI on Cordant's behalf.

Any reports of potential or actual misconduct can be reported 24/7 through the Cordant Hotline 855-RPT-RISK/855-778-7475. Questions about this annual provider notice, Cordant's commitment to regulatory compliance and/or laboratory billing may be directed to:

Betsy C. Donat

Betsy C. Donat, Esq.
Chief Compliance Officer

Cordant Health Solutions™

Urine, Oral Fluid, Hair and Blood Drug Testing				
CMS HCPCS Code	**Code Description**	**2017 Medicare Rate**	**2018 Medicare Rate**	**2019 Medicare Rate**
G0479 (2017) – 80307 (2018)	**Presumptive drug test** – Any number of drug classes, any number of devices or procedures by instrumented chemistry analyzers, includes sample validation when performed, per date of service	$79.25	$71.83	$64.65
G0480	**Definitive drug test(s)** – Utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources, includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed*	$79.94	$114.43	$114.43
G0481	**Definitive drug tests –** 8-14 drug classes*	$122.99	$156.59	$156.59
G0482	**Definitive drug tests –** 15-21 drug classes*	$166.03	$198.74	$198.74
G0483	**Definitive drug tests –** 22+ drug classes*	$215.23	$246.92	$246.92

*** Drug class, including metabolites, listed below and include specimen validity testing, per patient encounter per day, for reference purposes.**

Drug Classes

Alcohol	Alcohol(s)
Ethyl Glucuronide	Alcohol Biomarkers
Kratom	Alkaloids, not otherwise specified
Amphetamines, Methamphetamines, Phentermine	Amphetamines
Citalopram, Duloxetine, Fluoxetine, Paroxetine	Antidepressants, serotonergic class
Amitriptyline	Antidepressants, Tricyclic and other cyclicals
Desipramine	Antidepressants, Tricyclic and other cyclicals
Imipramine	Antidepressants, Tricyclic and other cyclicals
Nortriptyline	Antidepressants, Tricyclic and other cyclicals
Bupropion, Venlafaxine	Antidepressants, not otherwise specified
Clozapine, Olanzapine, Quetiapine, Risperidone, Aripiprazole, Haloperidol	Antipsychotics, not otherwise specified
Secobarbital, Phenobarbital, Butalbital	Barbiturates
Benzodiazepines	Benzodiazepines
Buprenorphine	Buprenorphine
THC	Cannabinoids, natural
Spice	Cannabinoids, synthetic
Cocaine	Cocaine
Fentanyl	Fentanyls

Gabapentin	Gabapentin, non-blood
Heroin	Heroin Metabolite
Ketamine	Ketamine and Norketamine
Methadone	Methadone
MDMA	Methylenedioxyamphetamines
Methylphenidate	Methylphenidate
Codeine/Morphine	Opiates
Hydrocodone	Opiates
Hydromorphone	Opiates
Meperidine, Naloxone, Naltrexone, Dextromethorphan	Opioids and opiate analogs
Oxycodone	Oxycodone
Phencyclidine	Phencyclidine
Pregabalin	Pregabalin
Zolpidem	Sedative Hypnotics (nonbenzodiazepines)
Carisoprodol	Skeletal muscle relaxants
Cyclobenzaprine	Skeletal muscle relaxants
Tapentadol	Tapentadol
Tramadol	Tramadol
Bath Salts (Cathinones)	Drugs - stimulants, synthetic or substances, definitive, qualitative or quantitative, not otherwise specified