American
Clinical Laboratory
Association

September 27, 2019

Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CMS-1715-P

Dear Administrator Verma,

The American Clinical Laboratory Association (ACLA) is pleased to submit these comments on the proposed rule addressing the Medicare Physician Fee Schedule (PFS) for CY 2020 and other issues (Proposed Rule).[1] ACLA is a non-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional specialty, end-stage renal disease, hospital, and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion annually to the nation's economy.

Our comments focus on proposed revisions to the Physician Self-Referral Advisory Opinion process and regulations, the agency's proposed policies for opioid use disorder treatment services furnished by opioid treatment programs and by physician offices, and the agency's policy on coinsurance for colorectal cancer screening.

A. Physician Self-Referral Advisory Opinion Process

ACLA is pleased that CMS is considering changes to the process it uses for issuing advisory opinions on compliance with the Physician Self-Referral Law (Stark Law). In the two decades since the advisory opinion process was implemented in regulation, the agency has issued just 15 advisory opinions, which amounts to less than one opinion per year. (In contrast, the Office of Inspector General (OIG) issued 14 Anti-Kickback Statute advisory opinions in 2018 alone.) Currently, CMS accepts only those questions involving specific existing or planned arrangements and not those related to interpretation, hypotheticals, or proposed business arrangements.[2] This limits the usefulness of the advisory opinion process tremendously.

We support CMS's proposal to modify the timeframe by which the agency is to issue an advisory opinion after receiving a request, establishing a 60-day timeframe that would be tolled during any time periods in which the request is being revised or additional information compiled and presented by the requestor.[3] However, we do not support this change being made only in regulations and not in practice. The agency has been unable to meet the current 90-day timeframe for issuing an advisory opinion, often taking years to respond to a request with a completed advisory opinion. CMS has not said how it intends to meet this shorter proposed timeframe for

[1] 84 Fed. Reg. 40482 (Aug. 14, 2019).
[2] 42 C.F.R. § 411.370(b).
[3] 84 Fed. Reg. 40729.

issuing advisory opinions, or how its practice will differ such that the new timeframe will not be merely aspirational.

Related to the agency's proposal to shorten the timeframe for issuing an advisory opinion is its proposal to change the fees for the cost of the advisory opinion.[4] CMS proposes to adopt an hourly fee of $220 for preparation of an advisory opinion, or $440 per hour for an expedited advisory opinion (if the agency decides to establish an expedited pathway). ACLA believes that the hourly rate for CMS to prepare a Stark Law advisory opinion should be the same as the hourly rate for the OIG to prepare an Anti-Kickback Statute advisory opinion, which currently is $176 per hour, because the resources required to prepare each should be similar. We would support the establishment of a higher hourly rate for an expedited advisory opinion. We believe that a requestor should be able to establish a "triggering dollar amount," similar to the process used when the OIG issues its advisory opinions, so that a requestor will be informed when the work on the advisory opinion is at or near a predetermined budget limit. A requestor of a Stark Law advisory opinion should not pay any hourly fee for work that CMS does not complete by the expiration of the regulatory timeframe. This serves to ensure that a requestor is getting its value from the hourly rate and that the agency is incentivized to meet its own established timeframe.

CMS is proposing to modify its regulation on matters that qualify for an advisory opinion,[5] such that a request for an advisory opinion must "relate to"—rather than "involve"—an existing arrangement or one into which the requestor plans to enter.[6] It is not clear what impact this would have on the scope of matters that qualify; we would support this modification if it expanded the types of questions that could be included in an advisory opinion request.

Finally, ACLA strongly supports proposed modifications to 42 C.F.R. § 411.387, Parties affected by advisory opinions.[7] Currently, the regulation states an advisory opinion does not apply in any way to any individual or entity that does not join in the request for the opinion, and individuals or entities other than the requestor(s) may not rely on an advisory opinion. We are grateful that the agency recognizes the restrictiveness of its long-standing position that an advisory opinion may be relied on only by the requestor—and the disconnect between that approach and the reality of how those other than requestors use and rely on advisory opinions. We support CMS's proposal that it would not pursue sanctions against any individual or entities that are parties to an arrangement that the agency determines is indistinguishable in all material aspects from an arrangement that was the subject of a favorable advisory opinion. Another entity then could structure an arrangement in a manner it knows has been determined not to violate the Stark Law and benefit from the agency's analysis and interpretation of an arrangement that is materially identical. We also support CMS's proposal to state in regulations that individuals and entities may reasonably rely on advisory opinions as non-binding guidance that illustrates the application of the Stark Law and regulations to specific facts and circumstances. This would recognize a practice that has been common for years—and indeed is the reason that the agency publishes advisory opinions on its website, rather than providing them solely to a requestor.

[4] *Id*.
[5] 42 C.F.R. § 411.370(b).
[6] 84 Fed. Reg. 40728.
[7] *Id*. at 40730.

B. Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs

Our comments on CMS's proposal to implement Sec. 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)[8] focus on proposed reimbursement for the non-drug component of a bundled payment for opioid use disorder (OUD) treatment services that are furnished by an outpatient treatment provider (OTP) to an individual during an episode of care.[9] We believe that CMS should modify the proposed non-drug component of the bundle to accommodate more frequent point-of care presumptive testing, and it should allow for payment outside of the non-drug component of the bundle for presumptive testing using instrumented chemistry analyzers and for definitive testing.

1. Background

CMS is proposing that an episode of care for OUD treatment services would be a contiguous 7-day period, which is similar to the structure of the TRICARE bundled payment to OTPs for medication-assisted treatment with methadone. Reflecting the definition of "opioid use disorder treatment services" in the Social Security Act, CMS proposes that OUD treatment services would include "toxicology testing," at a frequency of once per month.[10] (The term "toxicology testing" is not defined elsewhere in the Social Security Act or in existing regulations.) To be eligible for Medicare payments for OUD treatment services, an OTP would need to have a current valid certification from the Substance Abuse and Mental Health Services Administration (SAMHSA) and meet federal opioid treatment standards at 42 C.F.R. § 8.12. These standards include the provision of drug abuse testing services.[11] OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment not in excess of 30 days, the OTP must perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program is to perform initial and monthly random tests on each patient.[12]

Drug abuse testing typically includes presumptive testing and/or definitive testing. Presumptive testing allows for an initial determination of whether a patient may have certain drugs in his or her system. When results are needed immediately, the testing can be performed at the point-of-care with a CLIA-waived presumptive test readable by optical observation only (*e.g.*, cup, dipstick, cassette). It also can be performed in a CLIA-certified laboratory using instrumented chemistry analyzers, when a lower substance detection cut-off is necessary and test results are not needed immediately. The clinical setting and the treating clinician's risk assessment for the patient determines whether the simpler CLIA-waived presumptive test is medically appropriate, or whether it is necessary for a sample to be sent to an outside laboratory for testing. In addition to presumptive testing, a CLIA-certified laboratory may perform definitive testing when it is medically necessary for a treating clinician to be able to identify specific medications, illicit

[8] Pub. L. 115-271.
[9] 84 Fed. Reg. 40518.
[10] SSA § 1861(jjj)(1).
[11] 42 C.F.R. § 8.12(f)(6).
[12] 84 Fed. Reg. 40521.

substances, and metabolites in a patient sample. It also is used when several opioids are present in the urine of a patient prescribed a single opioid and the clinician needs to know whether the presence of other opioids is consistent with metabolism of the prescribed opioid or if the patient is using more than one drug class. Definitive testing methods include gas chromatography coupled with mass spectrometry (GC-MS) and liquid chromatography coupled with mass spectrometry (LC-MS).

2. CMS should increase the frequency for point-of-care toxicology testing.

Based on the proposed OUD treatment services episode of care reimbursement for the non-drug component of the bundle, and based on CMS's modeling of the bundle on TRICARE's methods, CMS appears to be proposing that "toxicology testing" included in the non-drug component of the bundle would mean a point-of-care CLIA-waived presumptive test readable by optical observation, performed once per month.[13] CMS should modify its proposed bundle to align more closely with clinical standard of care to include at least weekly point-of-care toxicology testing, rather than monthly, and increase reimbursement for the bundle accordingly.

Under CMS's proposal, a Medicare beneficiary receiving OUD treatment services from an OTP would have far more limited access to presumptive testing than a Medicare beneficiary receiving active substance use disorder treatment or monitoring in other contexts. In recognition of the value of presumptive testing to making treatment decisions, most Medicare Administrative Contractors (MACs) cover presumptive testing pursuant to Local Coverage Determinations (LCDs) at least once per week for beneficiaries in substance use disorder treatment or monitoring, especially in the first 90 days of active treatment.[14] Other MACs do not specify testing frequency and require that the testing frequency must be consistent with the clinical need for testing, based on the treating clinician's assessment of the patient.[15] (The same LCDs cover definitive testing in some cases once per week, in other cases one to three times per month, and in other cases yet without a stated frequency limit.) The MACs developed their LCDs for drugs of abuse testing with stakeholder input and based on peer-reviewed research.

CMS should take advantage of the MACs' experience with drugs of abuse testing and the vetting the LCDs have received and modify the proposed non-drug component of the bundle to accommodate point-of-care CLIA-waived presumptive testing performed one to three times per week. It also should adjust reimbursement for the non-drug component of the bundle to increase

[13] To price the non-drug component of the bundled payments, CMS is proposing to use a crosswalk to the non-drug component of the TRICARE weekly bundled rate for services furnished when patient is prescribed methadone. *Id.* at 40535. The TRICARE weekly bundled rate assumes use of dipstick tests.

[14] *See*, *e.g.*, L35724 (Palmetto GBA); L36668 (Noridian Healthcare Solutions LLC); L36037 (National Government Services, Inc.).

[15] *See*, *e.g.*, L35006 (Novitas Solutions, Inc.) ("The patient's medical record must include an appropriate testing frequency based on the stage of screening, treatment, or recovery; the rationale for the drug/drug classes ordered; and the results must be documented in the medical record and used to direct care."); *see also* L34645 (Wisconsin Physician Service Insurance Corporation) ("Drugs, or drug classes for which testing is performed, should reflect only those likely to be present, based on the patient's medical history, current clinical presentation, and illicit drugs that are in common use. Drugs for which specimens are being tested must be indicated by the referring provider in a written order.")

this testing frequency.[16] The SAMHSA certification standards that call for monthly drug abuse tests for those in long-term detoxification should be considered a floor, not a ceiling. Those Medicare beneficiaries being treated by OTPs should have access to the same frequency of medically-necessary testing as other Medicare beneficiaries treated in other contexts.

3. CMS should allow for payment of presumptive testing using an instrumented chemistry analyzer and for definitive testing that is outside of the non-drug component of the bundle.

While we believe it is appropriate to include simple point-of-care tests in the bundle—because access to immediate test results can be an important component of opioid use disorder treatment—CMS must recognize that laboratory-performed presumptive testing using an instrumented chemistry analyzer and/or definitive testing oftentimes are medically necessary for patients being treated for opioid use disorders. It should pay separately for these types of testing.

The proposed reimbursement for non-drug component of the bundle for the most basic episode of care is only $100.46. But current Medicare CLFS reimbursement for presumptive testing using an instrumented chemistry analyzer is $64.65,[17] and current Medicare reimbursement for definitive testing ranges from $114.43 to $246.92, depending on the number of drug classes tested. Reimbursement for presumptive testing using an instrumented chemistry analyzer is roughly two-thirds of the proposed non-drug component reimbursement for an episode of care, and reimbursement for definitive testing in almost all cases would exceed the proposed non-drug component reimbursement for an episode of care. Proposed payment for the non-drug component of the bundle cannot possibly accommodate presumptive testing using an instrumented chemistry analyzer or definitive testing, even when a clinician determines it is medically necessary for a particular patient.

It is appropriate for CLIA-waived point-of-care presumptive testing to be included in the non-drug component of the bundle, but CMS also must facilitate medically necessary presumptive testing using instrumented chemistry analyzers and definitive testing for a patient being treated by an OTP—and pay adequate reimbursement to the laboratories that perform them. We believe the most straightforward way to accomplish this is for these test to remain outside of the non-drug component of the bundle and to be billed directly by the performing laboratory (or another appropriate entity).

C. Bundled Payments under the PFS for Substance Use Disorders

CMS is proposing to create HCPCS G-codes to describe monthly bundles of substance use disorder services furnished outside of an opioid treatment program that are similar to the proposed bundles furnished by an opioid treatment program and that are paid under the PFS. Under this

[16] Currently, the Medicare Clinical Laboratory Fee Schedule (CLFS) reimbursement rate for a CLIA-waived point of care presumptive drug test described by CPT code 80305 is $12.60.

[17] CPT code 80307, Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (*e.g.*, utilizing immunoassay [*e.g.*, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (*e.g.*, GC, HPLC), and mass spectrometry either with or without chromatography, (*e.g.*, DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service.

proposal, payment for medically necessary toxicology testing would not be included in the bundle and would continue to be billed separately under the Clinical Lab Fee Schedule.[18] For the reasons set forth above, we support CMS's proposal that this critical testing would remain outside of the bundle for other substance use disorder treatment services.

D. Coinsurance for Colorectal Cancer Screening

CMS invites comment on whether it should consider establishing a requirement that the physician who plans to order colorectal cancer screening for a beneficiary notify the beneficiary in advance that a screening procedure could result in a diagnostic procedure if polyps are discovered and removed, and that coinsurance may apply.[19] CMS has issued regulations governing payment for colorectal cancer screening tests under which it pays 100 percent of the Medicare payment amount established under the applicable payment methodology for the setting for providers and suppliers, and beneficiaries are not required to pay Part B coinsurance.[20] In addition to screening tests, which typically are furnished to patients in the absence of signs or symptoms of illness or injury, Medicare also covers various diagnostic tests.[21] When these services are furnished as diagnostic tests rather than as screening tests, patients are responsible for the Part B coinsurance (normally 20 percent) associated with these services.

ACLA urges CMS to act within its authority to clarify in regulations or guidance that Medicare's colorectal cancer screening process includes both the initial screening test and any follow-up colonoscopy that is medically necessary for completing a screening for a beneficiary. Cost-sharing currently is waived for a beneficiary who undergoes an initial colorectal cancer screening exam, including colonoscopy if no biopsy is performed and no lesion or growth is removed during the procedure (*i.e.*, the screening finds a "clean colon"). Conversely, cost-sharing is *not* waived for a beneficiary for a follow-up colonoscopy needed to complete the screening process after an initial positive test, even if the patient is found to have a "clean colon" (*i.e.*, no biopsy is performed, and no polyp or lesion is removed during the colonoscopy). A payment policy that results in disparate financial impacts on beneficiaries for essentially the same procedure is illogical, and it may discourage use of less invasive and less resource-intensive testing methods, decrease screening participation for patients preferring a non-invasive testing option, and inhibit screening completion for patients requiring a two-step screening process. The risk of dying of colorectal cancer is seven times higher for patients who do not adhere to provider recommendations to follow-up on an abnormal initial screening test with a colonoscopy than it is for those who do complete the process.[22] We strongly recommend that CMS use this final rule as an opportunity to issue a clarification to mitigate the negative impacts of its current policy.

[18] 84 Fed. Reg. 40542
[19] *Id.* at 40557
[20] 42 C.F.R. § 410.152(l)(5).
[21] 42 C.F.R. § 410.32.
[22] Doubeni CA *et al.* Modifiable failures in the colorectal cancer screening process and their association with risk of death. Gastroenterology. 2019;156:63-74.

E. Estimated Impacts Related to Proposed Changes for Office/Outpatient E/M Services for CY 2021

CMS estimates that, depending on case mix, CY 2021 pathology reimbursement could decrease as much as eight percent, due to changes in coding and payment for evaluation and management services. Because the PFS is required by statute to be budget-neutral, implementation of increases in the RVUs of evaluation and management services potentially lead to decreases in specialties such as pathology, radiology, and anesthesiology that generally do not bill office or outpatient evaluation and management codes.[23] We urge CMS to join ACLA and other stakeholders to ask Congress to address the adverse impacts of this budget neutrality requirement, including inaccurate valuation of services and potential beneficiary access issues resulting from inadequate reimbursement. Laboratories that provide clinical laboratory services reimbursed under the Clinical Laboratory Fee Schedule (CLFS) already are facing steep reimbursement cuts as a result of the implementation of Sec. 216 of PAMA, and these cuts to the valuation of pathology services will exacerbate those effects.

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Thank you for your consideration of ACLA's comments.

Sincerely,

Sharon L. West
Vice President, Legal and Regulatory Affairs
American Clinical Laboratory Association

[23] 84 Fed. Reg. 40887.