September 27, 2019

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

American Clinical Laboratory Association

RE: CY 2020 Outpatient Prospective Payment System Proposed Rule (CMS-1717-P)

Dear Administrator Verma,

The American Clinical Laboratory Association (ACLA) is pleased to submit these comments on the proposed rule addressing the Medicare Outpatient Prospective Payment System for CY 2020 and the laboratory date of service policy (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.

These comments focus on potential changes to the laboratory date of service policy and on proposed requirements for hospitals to make public a list of their "standard" charges.

A. Laboratory date of service policy

ACLA appreciates CMS's continued attention to the variety of challenges posed by the laboratory date of service (DOS) policy and its efforts to develop solutions that work for all stakeholders. The changes made in the CY 2018 Outpatient Prospective Payment System (OPPS) final rule[2] have been beneficial for laboratories that perform primarily or only molecular pathology tests and/or ADLTs, which includes some ACLA members. For these laboratories, the changes have improved patient access to these tests and have facilitated timely test results, allowing physicians to initiate appropriate treatment plans based on the results.

While the revised DOS policy has alleviated some of the problems with delayed access to precision diagnostic testing, some hospitals and laboratories (particularly larger laboratories with broad test menus) have experienced operational and implementation challenges since the current DOS policy was finalized in the 2018 final rule. For example, many hospitals do not have systems in place to extract from a Hospital Information System (HIS) all of the information needed for the laboratory to bill for a molecular pathology test or advanced diagnostic laboratory test (ADLT) performed on a specimen collected from a hospital outpatient (beneficiary demographics, complete contact information, beneficiary admission status at the time of specimen collection, whether the beneficiary is enrolled in fee-for-service Medicare or a Medicare Advantage plan, etc.). Patient admission status and billing information are not shared between the HIS and a Laboratory

[1] 84 Fed. Reg. 39398 (Aug. 9, 2019).
[2] 82 Fed. Reg. 52533 (Nov. 13, 2017).

Information System (LIS) regularly, and the patient admission status varies from hospital to hospital, based on cost centers (*i.e*., not just inpatient/outpatient, but also emergency, long-term care, observation). To provide this information to laboratories electronically, IT upgrades need to be requested and programmed on a hospital-by-hospital basis, at a cost to the hospital.

Additionally, a patient may have specimens collected at one time in the hospital for some tests for which the hospital must bill, because the DOS is the date of specimen collection, and other tests for which the hospital may not bill, because the DOS is the date of performance. Not all hospital billing systems can distinguish between these tests, so a manual work-around is the only solution. In some cases, this results in the hospital sending the laboratory patient admission status and billing information on a manual test requisition, which then is entered manually into the LIS, with results reported back to the hospital manually and the test billed manually. Information that is inputted manually is likely to be delayed and/or transmitted incorrectly.

A solution that would work for hospitals, large national and regional reference laboratories, and specialized molecular testing laboratories alike is one that minimizes the need for the hospital and laboratory to exchange patient information only about molecular pathology tests and ADLTs and that permits either the hospital or the performing laboratory to bill one of these tests, as long as both entities do not do so.

Below, we comment on potential revisions to the laboratory DOS policy, as set forth in the Proposed Rule, and propose an alternative solution.

1. Changing the test results requirement at 42 C.F.R. § 414.510(b)(5)(iv)

ACLA opposes CMS's proposal that the ordering physician would determine whether results of a molecular pathology test or ADLT are intended to guide treatment during a hospital outpatient encounter, either the hospital outpatient encounter during which the specimen was collected or a future hospital outpatient encounter.[3] This proposal would add to existing operational difficulties because it would require a hospital to communicate an additional data element to a performing laboratory and because the decision would be made on a specimen-by-specimen basis. Additionally, the multitude of factors an ordering physician may take into account to make that determination, coupled with a lack of incentive to make that determination and document it, is likely to lead to uneven and ultimately meaningless application of the rule.

CMS has heard from stakeholders that hospitals "are having difficulty developing the systems changes necessary to provide the performing laboratory with the patient's hospital outpatient status, beneficiary demographic information, and insurance information, such as whether the beneficiary is enrolled in original fee-for-service Medicare or a specific Medicare Advantage plan."[4] This proposal would exacerbate existing problems that hospitals have with conveying information to performing laboratories for billing purposes. Under this proposal, the ordering physician would have to make a subjective determination about the future use of the molecular pathology test or ADLT and record that information somewhere in the beneficiary's medical record. The hospital would need to develop a mechanism to ensure that the ordering

[3] 84 Fed. Reg. 39601.
[4] *Id*. at 39600.

physician actually makes that determination for each molecular pathology test and ADLT subject to the date of service rule at 42 C.F.R. § 414.510(b)(5) (but only for these tests, as ordering physicians generally do not have to make this determination for other tests). The hospital then would have to extract that information from the beneficiary's medical record and reflect it in the billing system and take care not to bill for a test that is not intended to guide treatment during the current or a future hospital outpatient encounter. It would add this data element to the other data elements it must convey to the performing laboratory.

Hospitals currently struggle to transmit information to performing laboratories that they already collect for other purposes (*e.g.*, beneficiary demographics). This proposal would add to that difficulty by requiring a hospital to train each ordering physician on his or her obligation to declare that a molecular pathology test or ADLT will or will not guide hospital treatment, now or in the future, to create or alter an EHR template to capture the new information, and to implement a new system to ensure that the determination is being made and that the hospital does not inadvertently bill for a service that is unrelated to hospital outpatient care. The new information it captures in an EHR template would have to be exported to the billing system—but only for these molecular pathology tests and ADLTs. Collecting this information also would tend to undermine the agency's successes in its "Patients Over Paperwork" initiative, which aims to shift more of clinicians' time and our healthcare system's resources from needless paperwork to high-quality care that improves patient health.[5]

We also are concerned about the ordering physician's subjective determination about the purpose of the molecular pathology test or ADLT. Among the many factors CMS points to as influencing a test's relationship to a hospital outpatient encounter are the beneficiary's current diagnosis or lack thereof, the procedures that the beneficiary may have, and the beneficiary's current and previous medical history—if the physician is aware of all of this information.[6] If a beneficiary does not yet have a diagnosis, or if the physician is not familiar with the beneficiary's medical history, it may be difficult or impossible for an ordering physician to determine whether the test would be used to guide future hospital outpatient treatment. It is likely to lead to uneven application of the criterion at 42 C.F.R. § 414.501(b)(5)(iv). And there are other criteria an ordering physician may apply, some of which may be influenced by a hospital's desire to avoid billing for a test, rather than by beneficiary characteristics. Based on experience with other policies that require a treating physician to make a subjective determination about the nature of a Medicare beneficiary's treatment (*e.g.*, observation status and its effect on application of the "two midnights" rule), we are concerned about the soundness of this approach for making a billing determination.

Further, laboratories often struggle to obtain necessary documentation to submit or complete claims. For example, when a laboratory is subject to a Comprehensive Error Rate Testing ("CERT") audit, the laboratory must submit documentation to the CERT auditor to support the medical necessity of the testing performed. Typically, it is the ordering physician who possesses that documentation in the beneficiary's medical record, yet oftentimes the physician does not respond to the laboratory's repeated requests for documentation. This results in payment recoupments for legitimate services and increased administrative costs to submit appeals. We have

[5] *See* Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork, 84 Fed. Reg. 27070 (Jun. 11, 2019).
[6] *Id*. at 39601.

similar concerns with this proposed revision, as the laboratory is unlikely to be able to get documentation of the physician's determination of the test's use.

Because this proposal would add to current operational difficulties, rather than ameliorate them, and because of our concerns with the ordering physician's subjective determination and lack of incentive to provide documentation to a performing laboratory, we strongly oppose this proposal.

2. Limiting the laboratory DOS exception at 42 C.F.R. § 414.510(b)(5) to ADLTs

In comments on the CY 2018 OPPS proposed rule, ACLA stated our opposition to limiting the application of this DOS policy to ADLTs. That remains our position. Many of the issues that apply to ADLTs also apply when two laboratories offer a molecular pathology test, rather than only a single laboratory. An ADLT may be offered and furnished by only one laboratory, but whether more than one laboratory offers a molecular pathology test, it still is a highly specialized test and a coverage policy may have been issued only by the MAC in whose jurisdiction the performing laboratory is located. CMS reasons that there are a number of FDA-approved kits for certain molecular pathology tests that a hospital can purchase, allowing the hospital to perform the test.[7] That is the case for certain molecular pathology tests, but it is by no means the default, and the existence of some molecular pathology test kits should not drive billing policy for all molecular pathology tests. That a hospital could perform and bill for molecular pathology tests should not drive billing policy for tests it does not perform.

3. Excluding blood banks and blood centers from the laboratory DOS policy at 42 C.F.R. § 414.510(b)(5)

ACLA supports CMS's proposal to exclude blood banks and blood centers from the laboratory DOS policy, such that the DOS for laboratory testing performed by blood banks and centers on specimens collected from a hospital outpatient during a hospital outpatient encounter would be the date of specimen collection when the testing is performed for blood compatibility testing purposes.

4. Alternative policy proposal

ACLA favors a DOS policy solution that is flexible enough to accommodate changes in both the use of molecular pathology tests and ADLTs and in their performance. While the current DOS policy included in the CY 2018 OPPS final rule has been successful in improving access to timely, actionable results for these tests, a permanent solution also must address the many operational difficulties presented by some hospitals and performing laboratories having to exchange patient and billing information for this small subset of tests.

Below is a proposal under which a hospital and a performing laboratory would affirm their agreement that the hospital will bill for a molecular pathology test or ADLT that meets the other criteria already set forth in 42 C.F.R. § 414.510(b)(5); if the hospital and performing laboratory do

[7] *Id*. at 39602.

not agree to this condition, the date of service would be the date of performance and the performing laboratory would bill for the test. Text that ACLA proposes adding to the regulation is in bold print below:

> (5) In the case of a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test at § 414.502, the date of service of the test must be the date the test was performed only if—
>
> > (i) The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
> >
> > (ii)The specimen was collected from a hospital outpatient during an encounter (as both are defined in § 410.2 of this chapter);
> >
> > (iii) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
> >
> > (iv) The results of the test do not guide treatment during the hospital outpatient encounter; ~~and~~
> >
> > (v) The test was reasonable and medically necessary for the treatment of an illness; **and**
> >
> > **(vi) The hospital and the performing laboratory have not agreed that the hospital will bill for the test.**

The hospital and its partner performing laboratory would reach an agreement as to whether the hospital or the laboratory will bill for a molecular pathology test or ADLT, in a manner that is suitable in the context of their relationship to each other. Like the "under arrangements" provision in the statute and as reflected in regulations, the agreement could be reduced to writing by the parties, but it would not have to be. And, as with all services, hospitals and performing laboratories would be responsible to ensure that only one of them bills for a particular molecular pathology test or ADLT, not both.

Our proposal balances the real need for a solution that is administratively workable for all laboratories and hospitals against the possibility of a hospital billing for a test that may or may not guide treatment during a hospital outpatient encounter. In any event, the laboratory test will never be wholly divorced from hospital treatment, as the specimen will have been collected from a hospital outpatient during an outpatient encounter.

An alternative way to view a hospital billing for a test that does not guide treatment during a hospital outpatient encounter is to consider the hospital laboratory to be acting as a referring laboratory under Sec. 1833(h)(5)(A)(ii)(III) of the Social Security Act (SSA). Conceptually, the hospital would be acting like an independent laboratory that refers a test for a patient to a reference laboratory.

When a hospital bills for a test described in 42 C.F.R. § 414.510(b)(5) that would not guide hospital treatment, it would be reasonable for CMS to extend the "referring laboratory" exception in SSA § 1833(h)(5)(A)(ii)(III) in that one circumstance to the hospital laboratory. Sec. 1833(h)(5)(A) states that payment for a clinical diagnostic laboratory test may be made only to the person who performed or supervised the test, unless an exception applies. Sec. 1833(h)(5)(A)(ii)(III) allows payment to be made to the referring laboratory for a test performed by a reference laboratory if not more than 30 percent of the clinical diagnostic laboratory tests for which such referring laboratory receives requests for testing during the year in which the test is performed are performed by another laboratory. The terms "referring laboratory" and "reference laboratory" are not defined in the Social Security Act, and CMS has not issued any regulations to implement this provision of the SSA. Rather, it has established the parameters for submission of claims for referred tests in Ch. 16, § 40.1 of the Medicare Claims Processing Manual (MCPM). It is CMS's current policy that "claims for referred laboratory services may be made only by suppliers having specialty code 69, *i.e.*, independent clinical laboratories."[8] The policy could be amended to accommodate this circumstance only.

The agency said that "because of the administrative issues raised by stakeholders regarding the implementation of the laboratory DOS exception at § 414.510(b)(5), we believe a cautious and incremental approach to making changes to the laboratory DOS policy is warranted."[9] This would be a "cautious and incremental approach" that would address the rule's operational challenges but that would not entirely upend the agency's referring laboratory policy.

Our proposal would be a permanent solution to this issue that would be permissible under the SSA, work for all stakeholders, preserve the improvements to patient access under the current DOS policy, and accommodate changes in the way that molecular pathology tests and ADLTs are developed, commercialized, and used. If CMS does not accept this proposal, it should extend the current policy of enforcement discretion through the end of CY 2020, rather than implement a policy now that is likely to extend or even exacerbate laboratories' and hospitals' operational difficulties. This additional amount of enforcement discretion would allow the agency to include this issue in the CY 2021 OPPS proposed rule and solicit stakeholder input on another solution.

B. Proposed requirements for hospitals to make public a list of their standard charges

CMS is proposing new regulations to implement Sec. 2718 of the Public Health Services Act, entitled "Bringing Down the Cost of Health Care Coverage."[10] In part, the agency proposes requirements for hospitals to make public online in a machine-readable file the standard charges (both gross charges and payer-specific negotiated charges) for all items and services (both individual items and services as well as service packages) provided by the hospital.[11] The data elements would include: a description of each item or service; the corresponding gross charge that applies to each item or service; the corresponding payor-specific charge that applies to each item or service, associated with the name of the third-party payor; the code used for billing for each

[8] MCPM, Ch. 16, § 40.1.1.
[9] 84 Fed. Reg. 39602.
[10] 42 U.S.C. § 300gg-18(e).
[11] 84 Fed. Reg. 39582.

item or service (*e.g.*, CPT code); and the revenue code (as applicable).[12] A hospital would be required to update the list at least annually.

The agency also proposes requirements for hospitals to make public online a limited amount of standard charge data for a limited set of "shoppable" items and services the hospital provides (at least 300 such items and services), in a form and manner that is more "user-friendly".[13] Several common laboratory tests are included in the list. The data elements for this list would include: a plain language description of each shoppable service; the payor-specific negotiated charge that applies to each shoppable service, associated with the name of the third-party payor; a list of all the associated ancillary items and services that the hospital provides with the shoppable service; the location at which each shoppable service is provided by the hospital, including whether the payor-specific negotiated charge for the shoppable service applies at that location in the inpatient setting, the outpatient setting, or both; and any primary codes used by the hospital for purpose of billing for the shoppable service (*e.g.*, CPT code). This list also would be updated at least annually. A hospital that fails to report the required information would be subject to civil monetary penalties up to $300 per day, which the agency says "are sufficiently harsh to incentivize compliance but not so severe as to be punitive."[14]

Like many other stakeholders, ACLA is concerned about the usefulness to consumers of much of the information that hospitals would be required to make public. ACLA does believe that providers and suppliers should help patients understand what their potential financial liability may be for services they obtain, which may help patients become savvier health care consumers. However, under this proposal, the information that may be useful to a patient would be overwhelmed by torrents of information that is not relevant to patients and may be all but undecipherable to them. In addition, we share others' concerns about the unintended consequences of the agency requiring private entities to disclose their negotiated contract terms to the public and the adverse impact that may have on providers' negotiating power and on competition.

ACLA is surprised that the agency characterizes a civil monetary penalty of up to $300 per day as "sufficiently harsh to incentivize compliance." Of course, civil monetary penalties are tools to incentivize compliance only when they are imposed. In Sec. 216 of the Protecting Access to Medicare Act (PAMA), Congress authorized civil monetary penalties of $10,000 per day for an applicable laboratory's failure to report applicable information timely to the agency for purposes of establishing reimbursement rates for clinical diagnostic laboratory tests, or for each misrepresentation or omission of data.[15] Only 21 hospital outreach laboratories reported any applicable information to the agency during the initial data reporting period[16]—a fraction of the number that should have reported applicable information then—yet CMS imposed no civil monetary penalties on any laboratory for failure to report. In this case, it remains to be seen

[12] *Id.* at 39582.
[13] *Id.*
[14] *Id.* at 39592.
[15] 42 U.S.C. § 1395m-1(a)(9).
[16] *See* Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System at 3 (Sept. 22, 2017), *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf.

whether the agency is committed to getting price transparency information and using it—and consequently chooses to enforce the reporting requirement.

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Thank you for your consideration of ACLA's comments.

Sincerely,

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American Clinical Laboratory Association