Submitted electronically via www.regulations.gov

September 1, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1678–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS-1678-P — Hospital Outpatient Prospective Payment System, Proposed Rule – Potential Revisions to the Laboratory Date of Service Policy

Dear Administrator Verma:

On behalf of the Coalition for 21st Century Medicine (C21), we appreciate the opportunity to submit our comments in response to the Centers for Medicare & Medicaid Services (CMS) Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule for Calendar Year 2018. In particular, we are writing in support of the agency's effort to modernize its Date of Service (DOS) billing policies for separately payable molecular pathology and Advanced Diagnostic Laboratory Tests (ADLTs) under Section 1834A(d)(5) of the Social Security Act that are performed on specimens collected from hospital outpatients. We agree with CMS that the current policy, as applied to these innovative tests, can create barriers to patient access to critical diagnostics and to the development of precision medicine, and that it is at odds with the agency's rationale for excluding these tests from laboratory packaging in the hospital outpatient setting.

C21 comprises many of the world's most innovative diagnostic technology companies, clinical laboratories, physicians, venture capital companies, and patient advocacy groups. C21's mission is to improve the quality of healthcare by encouraging research, development, and commercialization of innovative diagnostic technologies that will personalize patient care, improve patient outcomes, and substantially reduce healthcare costs. C21 has worked with CMS and Congress on this issue since 2005, and we appreciate the consideration that the agency has devoted to this topic in the Proposed Rule. We have included as an attachment recommended regulatory text to revise either the "under arrangements" regulations at 42 CFR 410.42 and 411.15(m) or the DOS regulations at 42 CFR 414.510.

I. Executive Summary

- C21 agrees with CMS that the DOS policy has had unintended negative consequences for patient access to timely diagnoses and treatments and that it is inconsistent with the agency's recent exclusion of molecular pathology tests, ADLTs, and certain multianalyte assays with algorithmic analysis (MAAAs) from laboratory packaging.
- We support CMS' efforts to modernize the DOS policy, and respectfully request that the agency finalize a revision to its regulations to allow the laboratory that performs the test to bill the Medicare program in certain specified circumstances.
- In particular, we recommend that the regulatory revision in the final rule apply to all molecular pathology tests, ADLTs, and MAAAs. Additionally, C21 recommends that this revised policy apply when the specimen is collected from the patient during a hospital outpatient encounter.
- We include recommended regulatory text to revise either: 1) the "under arrangements" regulations at 42 CFR 410.42 and 411.15(m) to exempt molecular pathology tests, ADLTs, and MAAAs performed on outpatient specimens from the requirement that only the hospital may bill for services furnished to a hospital outpatient; or 2) the DOS regulations at 42 CFR 414.510 to define the date of service as the date of performance for these tests.
- CMS may finalize either of these revisions under the Administrative Procedure Act (APA) as the public received sufficient notice of a proposed regulatory change in the Proposed Rule.

II. Summary of the Proposed Rule's Potential Revisions to DOS Policy

A. Background

As CMS sets out in the Proposed Rule, there are two separate regulatory requirements that, when read together, result in the unintended consequence of requiring hospitals to bill for clinical diagnostic laboratory tests that they do not perform.

1. Date of Service Regulations

The first of these requirements is the regulation at 42 CFR 414.510, which sets out the date of service for clinical laboratory tests. In 2001, CMS established the date of specimen collection as a uniform date of service for non-archived clinical laboratory tests.[1] In 2005, CMS defined an "archived" specimen as one stored for more than 30 days before testing, and established that the date of service for archived specimens is the date the specimen was obtained from storage.[2] CMS' stated purpose in establishing a uniform date of service for laboratory tests was to "promote program integrity and national uniformity, yet minimize the burden on laboratories."[3] However, as the agency notes in the Proposed Rule, the billing consequences of that change has led to unanticipated difficulties for hospitals, laboratories, and ultimately beneficiaries.

Due to concerns about the negative impacts of its DOS Policy, CMS modified its approach in the CY 2007 Physician Fee Schedule Final Rule to create specialized rules for complex clinical

[1] 66 Fed. Reg. 58788, 58791-92 (Nov. 23, 2001).
[2] 70 Fed. Reg. 9,357 (Feb. 25, 2005).
[3] 66 Fed. Reg. 58788, 58791 (Nov. 23, 2001).

laboratory tests performed on specimens stored for 30 or fewer days. The agency distinguished tests that "would almost never affect the treatment regimen at the hospital" from those "directly related to not only the condition for which the patient is hospitalized, but [which] would typically be used for specific care during the hospital stay as well, if available during the hospital stay."[4] Under the CY 2007 revisions, CMS changed the date of service to the date of performance for tests on stored specimens ordered at least 14 days after a hospital encounter (if various other conditions were met). These changes, commonly known as the "14 Day Rule," created three possible dates of service for the same test for a Medicare beneficiary.

2. "Under Arrangements" Regulations

As CMS articulates in the Proposed Rule, the existing DOS policy has had unintended negative effects because of its interaction with separate regulations at 42 C.F.R. 410.42 and 411.15(m), which the agency terms its "under arrangements" regulations. These regulations generally provide that Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement with that entity to furnish the particular service. Due to the DOS Rule's interaction with these "under arrangements" provisions, when the specimen used in a laboratory test is collected during an outpatient encounter, the hospital—not the performing laboratory— often must bill Medicare.

B. Potential Revisions to DOS Policy

In the Proposed Rule, CMS notes stakeholder concerns about the unintended consequences of the DOS policy. In response to these concerns, the agency articulates two potential approaches to revising the DOS policy. The first would modify the date of service regulations at 42 CFR 414.510 to establish that in the case of certain specified test types that meet the criteria of section 1834A(d)(5)(A), the date of service is the date the test was performed only if:

- The physician orders the test following the date of a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- It would be medically inappropriate to have collected the sample from the hospital outpatient other than during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

The agency also notes that it is considering a variation on this revision that would apply only to ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Social Security Act.

CMS is also considering modifying the "under arrangements" regulations at 42 CFR 410.42 and 411.15(m) to except from hospital bundling those molecular pathology tests and ADLTs excluded from the OPPS packaging policy under 42 CFR 419.2(b). Under this approach, the date of service for laboratory tests would stay the same but the performing laboratory would be

[4] 71 Fed. Reg. 69624, 69706 (Dec. 1, 2006).

allowed to bill for a test even if the date of service is when the beneficiary was a hospital outpatient.

III. C21 Agrees that DOS Policy Must be Modernized

We agree with the agency that the existing DOS policy continues to be administratively burdensome for providers and patients and at odds with the billing requirements for commercial insurers, including Medicare Advantage plans. The billing jurisdiction complexities of the DOS policy hamper patient access to important diagnostic information and are inconsistent with the agency's approach to hospital outpatient payment for precision diagnostics.

A. Negative Impacts of DOS Policy on Beneficiaries

As CMS acknowledges, the existing DOS policy has created operational issues for hospitals and laboratories with respect to billing for non-packaged clinical diagnostic laboratory tests. In particular, the complexities of billing under the DOS policy can lead hospitals to delay ordering important tests. Treatment delays for advanced cancer patients have profound negative consequences for health outcomes. For example, the National Comprehensive Cancer Network (NCCN) guidelines advise molecular profiling in the treatment algorithm for Non-Small Cell Lung Cancer (NSCLC).[5] Traditionally a molecular profile is obtained via tissue, but liquid biopsy testing is performed when tissue is unavailable or has failed to produce a result. Because the molecular profile assists physicians with therapy selection, any delay to the testing process delays the initiation of therapy for that patient. These delays are highly detrimental to outcomes for advanced cancer patients who often present with very limited lifespans in the absence of treatment. Many professional society guidelines recommend that testing be performed as soon as possible, to the point of recommending that results be available within three days of diagnosis.[6]

A recent study by the Moran Company illustrates these detrimental effects. The Moran Company was commissioned to assess the frequency of molecular pathology testing occurring 14 days after a hospital outpatient discharge based on the 2014 Carrier 5% Standard Analytic File and the 2013-2014 Outpatient 5% Standard Analytic File. Their findings indicated that 27% of molecular diagnostic testing services ordered for Medicare patients with a prior hospital outpatient discharge are performed more than 14 days after the outpatient procedure with the same diagnosis code. In the treatment of NSCLC specifically, EGFR testing is recommended by NCCN guidelines for stage IIIB and IV patients for whom targeted therapy doubles progression-free survival.[7] Delays in EGFR testing and treatment can result in worse patient outcomes, particularly when patients undergo chemotherapy in advance of targeted therapy due to delays in molecular testing.[8] The Moran Company observed 3,020 patients for whom an EGFR test was ordered greater than 14 days for the date of a hospital outpatient discharge, potentially delaying critical lung cancer treatment for these Medicare beneficiaries.

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[5] NCCN NSCLC Guidelines Version 3, 2017.

[6] *See* AMP/CAP/IASLC, 2016 Draft Molecular Testing Guidelines for Lung Cancer, Jun. 28, 2016, *available at* https://www.iaslc.org/sites/default/files/wysiwyg-assets/5-20160616capiaslcamplungguideline-2016draftrecommendations_ocpfinal.pdf.

[7] Sequist LV, et al. *J. Clin. Oncol.*, 2013; NCCN NSCLC Guidelines Version 5, 2017

[8] Zhou C, et al. *Annals of Oncology*, 2015; Schuler M, et al. *Annals of Oncology*, 2016

Molecular Pathology Lab Tests Following An Outpatient Procedure[9]
Data Source: 2014 Carrier 5% Standard Analytical File (SAF) and 2013-2014 Outpatient 5% SAF

	Same Diagnosis on Lab Claim and Prior Outpatient Claim	Different Diagnosis on Lab Claim and Prior Outpatient Claim	Total Count of Labs With Prior Outpatient Claims	Percent of Total Labs Linked to Outpatient Procedures
Total Molecular Pathology Labs Linked to Outpatient Procedures	*34,838*	*39,689*	*74,527*	*100%*
Molecular Pathology Labs <14 days from Outpatient Procedure	25,412	25,263	50,675	68%
Molecular Pathology Labs Between 14 to 30 Days	9,426	14,426	23,852	32%

As CMS notes in the Proposed Rule, these access limitations may disproportionately impact Medicare fee-for-service beneficiaries, as Medicare Advantage Plans and private payers allow laboratories to bill Medicare for tests that they perform no matter when a test is ordered or where the sample is collected. The existing DOS policy can also create inconsistent billing and coverage for tests performed by specialty laboratories. Laboratory tests are typically billed to the Medicare Administrative Contractor (MAC) in the region where the laboratory is located, which effectively sets a national coverage policy for the sole-source test.[10] The current DOS policy undermines this system by in some cases requiring a hospital to bill a MAC different from the one in which the laboratory is located, which may have a different coverage policy for the test, or none at all. This can lead to situations where the same laboratory test is covered by Medicare when ordered 15 days after an outpatient procedure, but not when ordered 13 days after the procedure. This impact on sole-source tests causes the burden of the DOS policy to fall especially heavily on small laboratories that offer innovative diagnostic products, an effect that hampers the development of precision medicine.

B. Existing DOS Policy Inconsistent with Hospital Outpatient Packaging Policy

The existing DOS policy has also become inconsistent with CMS' approach to hospital outpatient payment for precision medicine tests. As the agency points out in the Proposed Rule, in recent years CMS recognized that certain precision medicine tests that are not performed by a hospital necessitate a different payment approach than those tests that can be packaged with an outpatient service. In the CY 2014 HOPPS Final Rule, CMS excepted a range of molecular pathology test codes from outpatient packaging, reasoning that they "have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we . . . package."[11] In

[9] Moran Company, 2016.
[10] Medicare Claims Processing Manual, Ch. 1, § 10.1.5.4 ("Jurisdiction of claims for laboratory services furnished by an independent laboratory normally lies with the carrier serving the area in which the laboratory test is performed.").
[11] 78 Fed. Reg. 74826, 74939-42 (Dec. 10, 2013).

the CY 2016 and CY 2017 HOPPS Final Rules, CMS extended this rationale to exclude all new molecular pathology tests (including certain MAAAs) and ADLTs designated under the criteria of section 1834A(d)(5)(A), which was enacted under the Protecting Access to Medicare Act of 2014 (PAMA).[12]

Tests excluded from the laboratory packaging policy are paid separately from the hospital outpatient service under the Clinical Laboratory Fee Schedule (CLFS). However, under the existing DOS policy, these tests are still billed by the hospital when performed on a specimen collected from an outpatient and ordered less than 14 days after an outpatient procedure. This requirement is inconsistent with the rationale that the agency has articulated for excluding these precision medicine tests from laboratory packaging.

IV. Recommended Policy Revisions for the Final Rule

For the reasons set out above, we agree with CMS that the agency should modernize the current DOS policy to enable laboratories to bill Medicare directly for certain tests excluded from the OPPS packaging policy. In general, we support the approach articulated by the agency, under which laboratories would be permitted to bill Medicare directly for tests that meet specified criteria. We are recommending the following clarifications to the DOS policy articulated in the Proposed Rule, in order to promote the agency's objective of permitting the performing laboratory to bill for tests on hospital outpatient specimens that have a distinct pattern of clinical use that make them relatively unconnected to the outpatient service.

A. Updated DOS Policy Should Apply to Molecular Pathology Tests, ADLTs, and MAAA

C21 agrees that the performing laboratory should be required to bill for molecular pathology tests and ADLTs performed on specimens collected during an outpatient encounter. We believe that the inclusion of molecular pathology tests as well as ADLTs in the modification of the DOS policy is most consistent with CMS' laboratory packaging policy, under which both molecular pathology tests and ADLTs are excluded from packaging because of their distinct pattern of clinical use. Molecular pathology tests, MAAAs, and ADLTs are not routinely performed by hospital laboratories. If a hospital does perform the molecular pathology test, such as certain specialized hospital laboratories at academic medical centers, the hospital would remain the billing entity under a DOS policy revision, so there is no change to the current practice.

Moreover, C21 believes that CMS' revision to the DOS policy should encompass all ADLTs that qualify under section 1834A(d)(5). The current language in the Proposed Rule would apply just to those ADLTs that are designated under section 1834A(d)(5)(A), which includes only those tests that are analyses of multiple biomarkers of DNA, RNA, or proteins combined with an empirically-derived algorithm to yield a patient-specific result.[13] All ADLTs must be "offered and furnished only by a single laboratory,"[14] meaning that they cannot be performed by a hospital laboratory. Furthermore, as a practical matter, most tests that would be designated as an ADLT under Criterion B should also meet the separate definition of a molecular pathology test, so it is a relatively small universe of tests, if any, that will be impacted by this change.

[12] 80 Fed. Reg. 70298, 70348-50 (Nov. 13, 2015); 81 Fed. Reg. 79562, 79593-94 (Nov. 14, 2016).
[13] 42 CFR 414.502.
[14] 42 CFR 414.502.

Finally, we recommend that CMS' revision to the DOS policy also include all MAAAs. Currently, MAAA tests based on DNA or RNA are excluded from laboratory packaging in the outpatient setting as molecular pathology tests, but protein-based MAAAs are conditionally packaged. We believe that this bifurcated treatment of MAAA tests resulted from the definition of ADLTs in the Clinical Diagnostic Laboratory Test Payment System Proposed Rule implementing PAMA, which initially included only DNA- and RNA-based MAAAs. The final regulatory definition of ADLT as set forth at 42 CFR 414.502, however, includes protein-based MAAAs in accordance with the statutory language of section 1834A(d)(5), which expressly refers to "an analysis of multiple biomarkers of DNA, RNA, or proteins."

Protein-based MAAA tests have the same clinical pattern of use as their counterpart DNA- or RNA-based MAAA tests, and in many cases address the same types of clinical questions. As with DNA- and RNA-based MAAA tests, protein-based MAAAs are not tied to the primary outpatient service in the hospital and are never performed in the hospital laboratory. The rationale for allowing independent laboratories to bill Medicare directly for molecular pathology tests and ADLTs thus applies equally to protein-based MAAA tests. Some laboratories may seek ADLT designation for their MAAAs, but those that choose not to do so should not be excluded from this change. As above, this change will only impact a relatively small universe of tests, as only five protein-based MAAA tests are not excluded from the packaging policy at present (codes 81490, 81503, 81535, 81538 and 81539).

B. Removal of Test Order Date Requirement

We also recommend certain clarifications to the agency's suggested approach to ensure that tests are not excluded from the revision of the DOS policy due to sample type. The potential revision discussed in the Proposed Rule would allow the performing laboratory to bill for a test only if the physician "**orders the test following the date"** of a hospital outpatient's discharge. This language is suitable for tests performed on tissue samples, which are typically ordered after the specimen is collected. However, this language would exclude tests performed on liquid samples, such as blood or urine, which are generally ordered on or before the date of specimen collection because these sample types are not routinely stored and must be shipped immediately for testing. With advances in technology, tests are increasingly performed on blood and other liquid samples, and some molecular pathology tests can be performed on tissue, blood, or urine samples, providing the same clinical result to the physician no matter the sample type. In other cases, liquid biopsy testing is used to obtain a molecular profile recommended by guidelines when tissue is unavailable or has failed to produce a result. These liquid-based tests meet all of the same criteria as their tissue-based counterparts, and the rationale supporting the changes now contemplated by CMS apply equally to liquid-based tests as to tissue-based tests.

The following examples illustrate the problematic effects of retaining the order date requirement. A patient may see their physician for an office visit in a hospital owned clinic. The physician orders a blood-based molecular pathology test to help determine future treatment, and since the patient is already in the hospital, the patient goes directly to the hospital laboratory for a blood draw. The hospital laboratory sends the sample to an independent laboratory to perform the test. The test is not related to the outpatient visit, is not performed by the hospital, and has a different pattern of clinical use, but the potential revision language in the Proposed Rule would still require the hospital to bill for the test because the order occurred on or before the collection date.

It is also common for physicians to order a test such as a blood-based molecular pathology test during an office visit. Several days later, the patient goes to the hospital laboratory, is checked in as an outpatient, and receives the blood draw. The sample is sent to the independent laboratory for testing. In this case, the order happened before the sample collection, and since the patient was an outpatient at the time of the draw, the hospital would still be required to bill for the test under the potential revision language. In both of these cases, maintaining the order date requirement could lead to delayed treatment decisions for patients requiring liquid biopsy testing, worsening patient outcomes as discussed above.

To avoid these negative clinical results and mitigate any inconsistency among tests, we recommend that the agency remove the requirement that for the performing laboratory to bill for a test, the test must be ordered following the date of a hospital outpatient's discharge.

C. Clarifications to "Appropriate Specimen Collection" Language

The other modification we are recommending also seeks to prevent the inadvertent exclusion of separately payable tests performed on liquid samples from the revision of the DOS policy. Under the potential revision discussed in the Proposed Rule, another condition required for the performing laboratory to bill is that "it would be **medically inappropriate** to have collected the sample from the hospital outpatient other than during the hospital outpatient encounter." This language mirrors section 414.510(b)(2)(i)(C) of the existing 14 Day Rule. CMS has always interpreted this language to permit the performing laboratory to bill for tests performed on liquid specimens that could have been collected outside the hospital but for which it would have been impractical not to have taken the specimen at the same time as the procedure. The agency should avoid any language that could create incentives for hospitals to require outpatients to go elsewhere for specimen collection, which would present access issues for patients with limited mobility.

We believe the best approach is to replace the "medically inappropriate" language with the requirement that it "was **medically appropriate** to have collected the sample from the hospital outpatient during the hospital outpatient encounter."

V. Recommended Revised Regulatory Text

In the Proposed Rule, CMS solicits comments on two options to revise the regulations to address the administrative burden presented by the date of service policy. C21 respectfully recommends that CMS finalize the regulatory revisions set out in either Appendix A or B below. The revisions in Appendix A would revise the agency's under arrangements regulations at 42 CFR 410.42 and 411.15(m). The revisions in Appendix B would revise the DOS regulations at 42 CFR 414.510. For the reasons set out below, we believe that either approach would be workable. Based on the comments in Section IV above, the attached regulatory language we propose in both Appendix A and Appendix B makes certain slight adjustments from the potential revisions that the agency described in the Proposed Rule as being under consideration.

A. Changes to Under Arrangements Regulations

The most direct approach to resolving billing jurisdiction issues created by the existing DOS policy is to revise the "under arrangements" regulations at 42 CFR 410.42 and 411.15(m). Revising the under arrangements regulations to exclude molecular pathology tests, ADLTs, and

MAAAs performed on specimens collected from hospital outpatients would permit the performing laboratory to bill Medicare for these tests. This approach would clearly address the billing jurisdiction issue, and would maintain uniformity in date of service for laboratory tests, which was the agency's objective in making the date of service the date of specimen collection in 2001. Specifically, this approach would avoid establishing a date of service for tests performed on outpatient specimens that differs from the one for inpatient specimens, and instead would only revise the billing regulation for tests performed on outpatient specimens to align with CMS' existing outpatient packaging policy.

Moreover, excluding these tests from the under arrangements provisions would be consistent with CMS' past precedent of excluding other services. The under arrangements regulations currently include exceptions for certain types of physician, nurse practitioner, and other services that are not performed by the hospital outpatient department. Notably, these particular types of services are generally paid separately from the hospital service, similar to non-packaged laboratory tests that are paid on the CLFS.

In particular, CMS has noted in past rulemakings that the under arrangements regulations require the bundling of clinical diagnostic laboratory tests only when they are performed during an outpatient encounter. In the CY 2000 HOPPS Final Rule, the agency addressed an association's question on the bundling of laboratory tests, stating that:

> All diagnostic tests that are **furnished by a hospital, directly or under arrangements, to a registered hospital outpatient during an encounter at a hospital** are subject to the bundling requirements. The hospital is not responsible for billing for the diagnostic test if a hospital patient leaves the hospital and goes elsewhere to obtain the diagnostic test.[15]

This language supports the view that the agency did not intend hospitals to bill for tests performed on outpatient specimens after the encounter. Revising the under arrangements provisions to avoid bundling molecular pathology tests, ADLTs, and MAAAs performed on outpatient specimens would align with this original approach and eliminate the unintended consequences of the existing DOS policy.

B. Changes to Date of Service Regulations

An alternative approach is to update the DOS regulations at 42 CFR 414.510. This revision would follow CMS' precedent for addressing the unintended billing consequences of designating the date of specimen collection as the date of service. As discussed above, for CY 2007 the agency revised its DOS policy to establish the exception now known as the "14 Day Rule". This was done by adding 42 CFR 414.510, with its exceptions to the general DOS policy at 414.510(b)(2). Revising 414.510 to add a new section 414.510(b)(5), as set out in Appendix B, would follow that historic approach.

[15] 65 Fed. Reg. 18434, 18440 (Apr. 7, 2000) (emphasis added). In the same rulemaking, in response to a question about the treatment of diagnostic tests furnished by "outsourced" hospital departments that operate as free-standing providers of outpatient services on hospital grounds, the agency made clear that "[a] free-standing entity, that is, one that is not provider-based, may bill for services furnished to beneficiaries who do not meet the definition of a hospital outpatient **at the time the service is furnished**. Our bundling requirements apply to services furnished to a 'hospital outpatient,' as defined in § 410.2, during an 'encounter,' also defined in § 410.2." *Id*. at 18440-41.

As noted above, we are recommending technical clarifications to the DOS policy articulated in the Proposed Rule, in order to promote the agency's objective of permitting the performing laboratory to bill for tests on hospital outpatient specimens that have a distinct pattern of clinical use that make them less connected to the outpatient service. We believe that the order date of a test is irrelevant to CMS' goal of separating those tests that are performed outside the hospital on specimens collected from hospital outpatients and that have such a pattern of use. These revisions would achieve the objective of requiring the performing laboratory to bill for tests that are less connected with the outpatient service, irrespective of sample type.

C. CMS Can Finalize Regulatory Revisions to the DOS Policy

CMS has the authority to finalize one of the potential revisions it discusses in the Proposed Rule under the APA. It is well-established policy that agencies must publish "either the terms or substance of the proposed rule or a description of the subjects and issues involved."[16] The agency must then "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments."[17] Courts interpret this language to mean that a final rule must be the "logical outgrowth" of the proposed rule. The DC Circuit explains that "a final rule is a logical outgrowth of a proposed rule only if interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period,"[18] and states that "insightful comments may be reflective of notice and may be adduced as evidence of its adequacy."[19]

In the Proposed Rule, the agency devotes three full pages of Federal Register text to the DOS issue, and goes into some detail on each of the potential revisions considered. CMS explicitly states that "[w]e would consider finalizing the modifications described in this section."[20] Together with the significant numbers of insightful public comments that CMS has received on the DOS policy, these factors enable parties to anticipate that a change in that policy is possible.

VI. Conclusion

In conclusion, C21 supports CMS' efforts to modernize the DOS policy for clinical laboratory tests. We encourage CMS to finalize a revision to its DOS policy that will enable the performing laboratory to bill Medicare for molecular pathology tests, ADLTs, and MAAAs that are performed outside the hospital on specimens taken from hospital outpatients and that have a pattern of clinical use that makes them less connected to the primary service in the hospital outpatient setting. This can be accomplished by means of a revision to the under arrangements regulations at 42 CFR 410.42 and 411.15(m), or to the DOS regulations at 42 CFR 414.510.

[16] 5 USC 553(b)(3).
[17] 5 USC 553(c).
[18] *Intl Union, UMW v. MSHA*, 407 F.3d 1250, 1259 (D.C. Cir. 2005).
[19] *Horsehead Resource Dev. Co. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994); *see also New York v. United States EPA*, 413 F.3d 3, 44 (D.C. Cir. 2005) (finding no inadequacy of notice where "the EPA received extensive comments on all aspects of the rule.").
[20] 82 Fed. Reg. 33650.

Thank you for considering our comments. Please contact me at (650) 243-6363 or via electronic mail to john@veracyte.com should you have any questions or if we can provide you with further information.

Sincerely,

John W. Hanna
Chair, Reimbursement Workgroup
The Coalition for 21st Century Medicine

Appendix A: Changes to "Under Arrangements" Regulations

C21 recommends that CMS finalize a regulatory revision that would add the following new paragraph (8) to 42 CFR 410.42(b) in highlighted text:

§410.42 Limitations on coverage of certain services furnished to hospital outpatients.

(a) General rule. Except as provided in paragraph (b) of this section, Medicare Part B does not pay for any item or service that is furnished to a hospital outpatient (as defined in §410.2) during an encounter (as defined in §410.2) by an entity other than the hospital unless the hospital has an arrangement (as defined in §409.3 of this chapter) with that entity to furnish that particular service to its patients. As used in this paragraph, the term "hospital" includes a CAH.

(b) Exception. The limitations stated in paragraph (a) of this section do not apply to the following services:

(1) Physician services that meet the requirements of §415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in §410.69.

(7) Services furnished to SNF residents as defined in §411.15(p) of this chapter.

(8) Molecular pathology tests, advanced diagnostic laboratory tests that meet the criteria of section 1834A(d)(5) of the Act, or a test that is a multianalyte assay with algorithmic analysis, only if:

(i) The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 C.F.R. 410.2);

(ii) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

(iii) The results of the test do not guide treatment provided during the hospital outpatient encounter; and

(iv) The test was reasonable and medically necessary for the diagnosis or treatment of an illness or injury.

This revision would also require adding the following corresponding subparagraph (vii) to 42 CFR 411.15(m)(3):

§411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

* * * *

(m) Services to hospital patients—

(1) Basic rule. Except as provided in paragraph (m)(3) of this section, any service furnished to an inpatient of a hospital or to a hospital outpatient (as defined in §410.2 of this chapter) during an encounter (as defined in §410.2 of this chapter) by an entity other than the hospital unless the hospital has an arrangement (as defined in §409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients. As used in this paragraph (m)(1), the term "hospital" includes a CAH.

(2) Scope of exclusion. Services subject to exclusion from coverage under the provisions of this paragraph (m) include, but are not limited to, clinical laboratory services; pacemakers and other prostheses and prosthetic devices (other than dental) that replace all or part of an internal body organ (for example, intraocular lenses); artificial limbs, knees, and hips; equipment and supplies covered under the prosthetic device benefits; and services incident to a physician service.

(3) Exceptions. The following services are not excluded from coverage:

(i) Physicians' services that meet the criteria of §415.102(a) of this chapter for payment on a reasonable charge or fee schedule basis.

(ii) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act, that are furnished after December 31, 1990.

(iii) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(iv) Certified nurse-midwife services, as defined in section 1861(ff) of the Act, that are furnished after December 31, 1990.

(v) Qualified psychologist services, as defined in section 1861(ii) of the Act, that are furnished after December 31, 1990.

(vi) Services of an anesthetist, as defined in §410.69 of this chapter.

(vii) Molecular pathology tests or advanced diagnostic laboratory tests that meet the criteria of section 1834A(d)(5) of the Act, or a test that is a multianalyte assay with algorithmic analysis, only if:

(I) The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 C.F.R. 410.2);

(II) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

(III) The results of the test do not guide treatment provided during the hospital outpatient encounter; and

(IV) The test was reasonable and medically necessary for the diagnosis or treatment of an illness or injury.

Appendix B: Recommended Changes to DOS Regulations

In the alternative, C21 recommends that CMS finalize a regulatory revision that would add the following new paragraph (5) to Section 42 C.F.R. 414.510(b):

The date of service for either a clinical laboratory test or the technical component of physician pathology service is as follows:

(a) Except as provided under paragraph (b) of this section, the date of service of the test must be the date the specimen was collected.

(b)

(1) If a specimen was collected over a period that spans 2 calendar days, then the date of service must be the date the collection ended.

(2) In the case of a test performed on a stored specimen, if a specimen was stored for—

(i) Less than or equal to 30 calendar days from the date it was collected, the date of service of the test must be the date the test was performed only if—

(A) The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;

(B) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(C) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(D) The results of the test do not guide treatment provided during the hospital stay; and

(E) The test was reasonable and medically necessary for the treatment of an illness.

(ii) More than 30 calendar days before testing, the specimen is considered to have been archived and the date of service of the test must be the date the specimen was obtained from storage.

(3) In the case of a chemotherapy sensitivity test performed on live tissue, the date of service of the test must be the date the test was performed only if—

(i) The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

(ii) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(iii) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(iv) The results of the test do not guide treatment provided during the hospital stay; and,

(v) The test was reasonable and medically necessary for the treatment of an illness.

(4) For purposes of this section, "chemotherapy sensitivity test" means a test identified by the Secretary as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. The Secretary identifies such tests through program instructions.

(5) In the case of a molecular pathology test or an advanced diagnostic laboratory test that meets the criteria of section 1834A(d)(5) of the Act, or a test that is a multianalyte assay with algorithmic analysis, the date of service must be the date the test was performed only if:

(i) The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 C.F.R. 410.2);

(ii) It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

(iii) The results of the test do not guide treatment provided during the hospital outpatient encounter; and

(iv) The test was reasonable and medically necessary for the diagnosis or treatment of an illness or injury.