Submitted electronically via www.regulations.gov

September 6, 2016

Mr. Andrew Slavitt, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–1656–P
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CY 2017 Medicare Program: Hospital Outpatient Prospective Payment System, Proposed Rule (CMS-1656-P) – Hospital Packaging Policy and Date of Service Rule for Clinical Diagnostic Laboratory Tests

Dear Administrator Slavitt:

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 (OPPS) Proposed Rule for Calendar Year 2017.[1] We are writing in support of CMS' proposal to expand the laboratory test packaging policy exception to also include Advanced Diagnostic Laboratory Tests (ADLTs). We believe, however, that the exception should be further expanded to include all Multianalyte Assays with Algorithmic Analyses (MAAA) protein based tests which are also not routinely performed by hospitals and are generally less tied to the hospital primary service than more routine laboratory tests.

In addition, we are writing on a related policy matter that is impacted by the agency's packaging policy proposal. Specifically, we are requesting that CMS update its "date of service" regulations at 42 C.F.R. § 414.510 so that hospitals are not required to bill for clinical diagnostic laboratory tests that are excluded from packaging and are performed by an independent laboratory.

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.

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[1] Centers for Medicare & Medicaid Services, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs for CY 2017; Proposed Rule, (CMS-1656-P), 81 Fed. Reg. 45,604, 45,604 (July 14, 2016) (hereinafter referred to as CY 2017 HOPPS Proposed Rule).

I. CMS Should Exclude All MAAA Test Codes From the Packaging Policy

A. Support for CMS' Packaging Policy Proposal and Rationale

Under CMS' current OPPS packaging policy, CMS packages payment for most common and routine clinical diagnostic laboratory tests that are ancillary to the primary service provided in the hospital outpatient setting.[2] In the CY 2014 Hospital OPPS Final Rule CMS excluded from the packaging policy molecular pathology tests.[3] In the CY 2017 Hospital OPPS Proposed Rule, CMS acknowledged that the current molecular pathology tests exception may be appropriately applied to other relatively new laboratory tests that have a *different pattern of clinical use* and are generally *less tied to a primary service* in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.[4] Based on this rationale, CMS is proposing an expansion of the laboratory packaging exception to also apply to all advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Act. In addition, CMS is proposing to assign status indicator "A" to ADLTs "once a laboratory test is designated an ADLT under the [Clinical Laboratory Fee Schedule (CLFS)]."[5] The "A" status indicator will allow the test to be paid under the CLFS.

We strongly support CMS's proposal to exclude all ADLTs from the packaging policy, and we agree that the packaging of advanced diagnostic laboratory tests is inconsistent with the agency's goals in using payment bundles in the OPPS. The Proposed Rule states:

> *Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of the hospital resources.*[6]

As CMS has recognized, the particular characteristics of an ADLT make it a poor fit for this packaging rationale. In establishing the definition of an ADLT, Congress recognized that there is a new class of advanced laboratory tests that is distinct from the common laboratory tests routinely performed in the hospital. Under the statutory definition, an ADLT must be offered and furnished only by a single laboratory.[7] Additionally, these advanced diagnostic laboratory tests typically provide targeted information for the treatment of specific conditions, and are not ordered as part of the usual course of a treatment during a hospital visit.

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[2] CY 2017 HOPPS Proposed Rule at 45,628 (July 14, 2016).
[3] *Id*. (citing 78 Fed. Reg. 74839 through 74942).
[4] *Id*.
[5] *Id*.
[6] 81 Fed. Reg. at 45627
[7] § 1834A(d)(5)(A) of the Act.

B. The Packaging Policy Exclusion Should Encompass all MAAA Test Codes, including Protein-Based MAAA Test Codes

Although we are encouraged by CMS' proposal to expand the exception to the hospital packaging policy, we continue to be concerned that the current exception policy does not exclude all MAAA test codes. In 2016, CMS expanded the policy to apply to all new molecular pathology test codes, which included numerous MAAA tests based on DNA or RNA, but not proteins. In the CY 2017 Hospital OPPS Proposed Rule, CMS acknowledged comments received in response to CMS' CY 2016 Proposed Rule that "argued that CMS' rationale for excluding molecular pathology tests from the laboratory test packaging policy also applies to certain CPT codes that describe some new multianalyte assays with algorithmic analyses (MAAAs)."[8] CMS stated that "[a]fter further consideration, we agree with these commenters . . .."[9] However, CMS has again applied the packaging exception in a manner not supported by its rationale by applying it to some MAAA test codes but not to others that are protein-based assays, even though both sets of tests fall within the rationale for exclusion. In Addendum B to the CY 2017 Proposed Rule the protein-based MAAA tests have been assigned status indicator "Q4" meaning that they are "*conditionally packaged laboratory tests*" that may be "*Paid under OPPS or CLFS*" while other DNA- and RNA-based MAAA tests have been assigned status indicator "A," meaning that they are paid for separately based on the CLFS.[10]

We do not believe there is any policy justification for treating protein-based MAAA tests differently from DNA- or RNA-based MAAA tests. Protein-based MAAAs are used the same way as DNA- or RNA-based MAAA tests and molecular pathology tests in the clinical setting, providing the same type of clinical information to physicians. They are also used in some cases to address the same types of clinical questions. All of these MAAA test codes are not routinely ordered for all patients and they are often not tied to the primary outpatient service in the hospital. Furthermore, as with other MAAA test codes, a protein-based MAAA test's sample is typically sent from the hospital to the sole-source independent laboratory for processing and the tests are typically performed *outside* the hospital setting by a single independent laboratory. Altogether, protein-based MAAA's, like other MAAAs, clearly fit into the rationale for excluding molecular pathology tests from the packaging policy.

Additionally, excluding protein-based MAAAs from packaging is consistent with the current Agency proposal as ADLTs and MAAAs are similar in definition. The statutory definition of an ADLT at § 1834A(d)(5)(A) of the Act states that the test is "an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result." This definition is similar to the AMA-CPT definition of a MAAA, which includes:

> "procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays and non-nucleic acid based assays (e.g. proteins, polypeptides, lipids, carbohydrates). Algorithmic

[8] 81 Fed. Reg. at 45628.
[9] Id.
[10] See 2017 NPRM, Addendum B.-Proposed OPPS Payment by HCPCS Code for CY 2017, available at https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1656-P-OPPS-Data-Addendum-B-and-2-Times-Rule.zip.

analysis, using the results of these assays as well as other patient information (if used) is then performed and reported typically as a numeric score(s) or probability."

Accordingly, there is no justification for treating protein-based MAAAs different from ADLTs that meet the criteria of § 1834A(d)(5)(A) of the Act.

We recommend that CMS clarify that the packaging proposal to apply to all MAAA test codes, regardless of whether the underlying analysis focuses on DNA, RNA, or proteins.

II. The Date of Service for Tests Excluded From the Packaging Policy Should Be The Date the Test is Performed

In the CY 2017 OPPS Proposed Rule, CMS acknowledged that molecular pathology tests and ADLTs should be excluded from the general laboratory packaging policy and should be paid for separately on the CLFS. In conjunction with this proposal, we respectfully request that CMS revise the Date of Service Rule, at 42 C.F.R. § 414.510, to ensure that these and other similar tests that are excluded from packaging can appropriately be billed by the independent laboratory that performs the test. Clarifying that the "date of service" for these tests is the date on which the test is performed would allow for the laboratory that performs the test to bill for the test.

A. Date of Service Rule Background

Under CMS' "date of service" policy dating back to 2001, the general rule is that the "date of service" for clinical laboratory tests is the date the specimen is collected.[11] The original policy provided for an exception where the laboratory test used a stored specimen – in such cases, the date of service is the date the specimen was obtained from the storage.[12] In 2006, CMS addressed issues with the date of service policy, including the concern that it created "unintended consequences, especially in situations in which a specimen is taken in a hospital setting, but then later used for a test after the patient has left the hospital."[13] CMS codified in regulations at 42 C.F.R. § 414.510 that the "date of service" for clinical laboratory tests is "the date the specimen was collected," unless an exception applies. The exceptions detailed the circumstances under which the date of service for a clinical laboratory test would be the date the test was performed and when it would be the date the specimen was obtained from storage.[14] For example, the date of service may be the date the test was performed, if: the test is performed on a stored specimen, the specimen was stored for less than or equal to 30 calendar days from the date it was collected, *and*

(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,

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[11] Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services; Final Rule, 66 Fed. Reg. 58792 (Nov. 23, 2001).
[12] See also CMS, Program Memorandum AB–02–134 (October 4, 2002), at p. 2-3 (allowing contractors discretion in making determinations regarding the length of time a specimen must be stored to be considered archived).
[13] Id.
[14] 71 Fed. Reg. at 69706 (Dec. 1, 2006) (discussing 42 C.F.R. § 414.510).

(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.[15]

CMS noted at that time that it was interested in receiving additional information and stated that the Agency "*will continue to review this policy in the future to ensure that our goal of appropriately recognizing hospital and post-hospital care is achieved*."[16]

In 2010, recognizing that the current Date of Service Rule creates barriers and administrative complexities for hospitals and physicians in ordering complex diagnostic laboratory tests performed by independent laboratories, Congress included Section 3113 in the Affordable Care Act. This provision mandated the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration, a two-year demonstration project to examine the impact of the Date of Service Rule on complex diagnostic laboratory tests. A primary goal of the Demonstration was to increase access to tests within 14 days of discharge from a hospital by allowing the independent laboratories to bill for the tests rather than bundling them into hospital payment. The final report on the demonstration project was released by CMS in January 2014 but did not include any policy recommendations.[17] We believe it is an appropriate time for the agency to review and revise the Date of Service Rule.

B. Hospitals Should Not Bill For Tests That They Do Not Perform

The complexity of the Date of Service Rule has become increasingly problematic when combined with Medicare's hospital bundling rule, which requires a hospital to bill for all services with a date of service on the day of an outpatient procedure, whether they are bundled in the OPPS bundle or not. The result of these two regulations is inconsistent with the manner in which all other provider services are billed in Medicare. Typically, the provider of a diagnostic service (radiologist, pathologist, etc.) bills for the service they render. It is also inconsistent with the general policy in the private insurance market and among Medicare Advantage plans, in which diagnostic services performed outside of the hospital are billed by the entity performing the service.

Hospitals are increasingly required to bill for clinical laboratory tests that the hospital does not perform and where the test is not tied to the primary hospital service except that the sample was collected during the hospital service. For instance, novel clinical diagnostic laboratory tests, unlike other services that are packaged into the payment bundles, are to be reimbursed separately and distinctly from the other services based upon their CLFS rate. Hospitals do not negotiate the rates of these services, and requiring the hospital to bill for them effectively creates a "buy-and-

[15] 42 C.F.R. § 414.510(b)(2)(i). (Emphasis added).
[16] Id.
[17] See Report to Congress on the Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration, Final Report (2015) available at https://innovation.cms.gov/files/reports/tccdlt-finalrtc.pdf.

bill" scenario whereby the hospital is incurring administrative burden and expense to bill for services that it does not perform in the fraction of patient cases where the test is indicated. The consequence of this policy is that hospitals may seek to bill all payers – Medicare and private insurers – for these services in order to create a standard administrative process across all patient cases and to recoup some revenue from private insurers against the added administrative expense.

Due to the financial risk and administrative burden associated with billing for tests that are unrelated to the primary hospital service and are performed by another entity, numerous academic medical centers as well as community hospitals have informed us that they do not want to bill for advanced diagnostic laboratory tests that are performed by independent laboratories. We are concerned that, as a result of the Date of Service Rule, some hospitals may be delaying testing for certain Medicare patients until 14 days after discharge or forgoing ordering a test altogether. The Date of Service Rule, as currently written, negatively impacts the quality of care offered to and received by Medicare beneficiaries.

Furthermore, with more hospitals acquiring and consolidating with physician practices in recent years, the negative impact of this rule is increasing. For example, tests to predict therapy response in non-small cell lung cancer are often ordered by a physician in an office visit. If a physician's office is affiliated with a hospital, the patient may be sent to the hospital-affiliated laboratory for serum specimen collection, but the specimen is then sent to the sole-source independent laboratory for the test to be performed. The testing results are sent directly to the ordering office-based physician. In such cases, the patient is only considered a hospital outpatient because of the physician's affiliation with the hospital.

Another example involves thyroid tumor biopsies to distinguish which patients have a malignancy and require surgery. These are not typically collected in the hospital outpatient setting. Again, as consolidation increases, biopsies that may have historically been obtained in an office-based setting are being increasingly collected and billed as hospital outpatient procedures. Clinical diagnostic laboratory tests for thyroid tumors are indicated for only a minority of patients that undergo a biopsy. The pathology evaluation of these biopsies is performed and billed by the hospital, but in the 1 in 10 cases referred for a subsequent molecular test, typically, several days after the outpatient service, that test is performed by an independent clinical laboratory. Requiring these clinical diagnostic laboratory tests that are performed by independent laboratories to be billed by hospitals can limit treatment options for beneficiaries in the Medicare fee-for-service program as compared to privately insured patients.

C. Date of Service Rule Leads to Inconsistent Application by MACs

A related complication with the Date of Service Rule relates to the important role played by the Medicare Administrative Contractors (MACs) in coverage determination for novel diagnostic tests. The clinical diagnostic laboratory tests excluded from packaging are not routinely performed on all patients who present with a given indication. They are typically indicated for a narrow patient population for which they are reimbursed. These narrow indications – as outlined in local coverage determinations (LCDs) by the MACs – typically are defined by specific diagnosis codes and/or levels of patient risk for disease as documented by a previous pathology

diagnosis, radiologic exam, or physician-assessed risk. Those LCD policies define the appropriate clinical use of these resources.

The Date of Service Rule, as it currently operates and interacts with hospital billing rules, results in inconsistent application of MAC coverage policies of clinical laboratory diagnostic tests from region to region nationwide. Laboratory tests are typically billed to the MAC in the region in which the laboratory is located. When the test is billed by the hospital, however, it may be billed to a separate MAC in the region in which the hospital is located, and that region may have different policies from the MAC where the laboratory is located. As a result, a test may be covered by Medicare if it is ordered 15 days after the specimen is collected, but may not be covered by Medicare if it is ordered 13 days after the specimen is collected, even though the test is performed in the same laboratory. Such a policy is administratively burdensome and results in confusion not only for the laboratories and hospitals, but for the MACs, as well. Even when processing claims that fall within the 14 day period, there are some MACs that apply the coverage policy of the region in which the hospital is located and other MACs that apply the coverage policy of the region in which the laboratory is located.

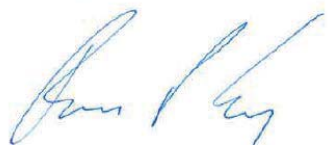
For these reasons and in light of the packaging policy proposal included in the CY 2017 Hospital OPPS Proposed Rule, we believe this is an appropriate time for CMS to update its Date of Service Rule. The regulations at 42 C.F.R. § 414.510 should be modified so that the date of service for clinical laboratory diagnostic tests that are excluded from packaging is the date on which the test is performed, thus allowing such tests to be billed by the independent laboratory performing the tests.

III. Conclusion

In conclusion, we support CMS' proposal to expand its laboratory tests packaging policy exception for molecular pathology tests to apply to ADLTs and we urge CMS in the final rule to extend this exception to all MAAA test codes, including protein-based tests. In addition, we urge CMS to update its Date of Service Rule by providing in regulations at § 414.510 that the date of service for clinical laboratory diagnostic tests excluded from packaging is the date on which the test is performed.

Thank you for considering our comments. Please do not hesitate to contact me at (202) 261-7398 or at bcarey@foleyhoag.com should you have any questions or if we can provide you with any further information.

Sincerely,



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