



September 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: 1678-P
P.O. Box 8013
Baltimore, MD 21244-1850

File Code: CMS–1678-P

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Ms. Verma:

The Healthcare Financial Management Association (HFMA) would like to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the 2018 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs (hereafter referred to as the Proposed Rule) published in the *Federal Register* on July 20, 2017.

HFMA is a professional organization of more than 38,000 individuals involved in various aspects of healthcare financial management. HFMA is committed to helping its members improve the management of and compliance with the numerous rules and regulations that govern the industry.

Introduction

HFMA would like to thank CMS for the opportunity to comment on its analysis and discussion of the Medicare reimbursement decisions addressed in the 2018 Proposed Rule. Our members would like to comment on the proposals related to:

- Alternative Payment Methodology for Drugs Purchased under the 340B Drug Program
- Proposed Changes to the Inpatient-Only (IPO) List
- Potential Revisions to the Laboratory Date-of-Service Policy
- Proposed New ASC Quality Measures

Below please find specific comments on the items listed above.

Alternative Payment Methodology for Drugs Purchased under the 340B Drug Program

CMS is proposing to reimburse separately payable Part B drugs acquired under the 340B program at Average Sales Price (ASP)-22 percent. Currently, almost all separately payable part B drugs are reimbursed at ASP+6 percent. CMS cites various reasons for this that include:

- Medicare expenditures on Part B drugs are rising due to underlying factors such as growth of the 340B program, higher-price drugs, or price increases for drugs.
- CMS's belief that changes to its current Medicare Part B drug payment methodology for 340B hospitals would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur.
- Beneficiaries should not be liable for a copayment rate that is tied to the current methodology of ASP+6 percent when the actual cost to the hospital to purchase the drug is much lower than the ASP for the drug.

HFMA members strongly oppose this proposal. As discussed below in detail, we do not believe that this policy will address the underlying issues that drive both increased Part B spending for the program or its beneficiaries. Further, we believe that if finalized, this policy will cause irreparable harm to safety net hospitals and the communities they serve.

Medicare Expenditures on Part B Drugs Are Rising, in Part, Due to the Growth of the 340B Program: The proposed rule states, "Medicare expenditures on Part B drugs are rising due to underlying factors such as growth of the 340B program, higher price drugs, or price increases for drugs," citing a 2016 Assistant Secretary for Planning and Evaluation (ASPE) issue brief.¹ However, the issue brief does not discuss the 340B program and only mentions any type of discount in the context of describing how the ASP is calculated. The report does state that biologics "grew from 39 percent to 62 percent of total spending. A significant share of this growth was attributable to price increases in these drugs rather than to growth in the number of users over time." To reiterate the point, the ASPE report *does not* present data linking these price increases to the 340B program.

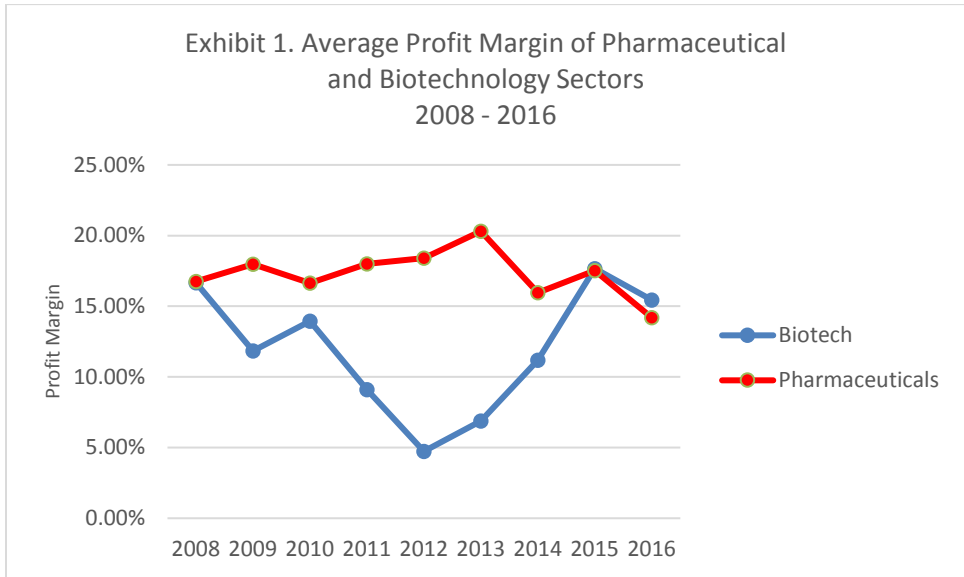
HFMA members, like CMS, are deeply concerned about the rapid growth in pharmaceutical prices. Hospital average annual inpatient drug spending increased by 23.4 percent between FY2013 and FY2015. During this same period, inpatient drug spending increased on a per-admission basis by almost 39 percent. Despite the inherent incentive in common fixed reimbursement systems like MS-DRGs to aggressively manage the formulary and use only medically necessary pharmaceuticals, growth in unit price—not volume—was primarily responsible for the increase in total inpatient drug spending.²

We note that during this time-period, net profit margins for biotechnology and pharmaceutical companies were approximately 12 and 18 percent respectively.³ As shown in Exhibit 1 below, this is in-line with both sectors' averages for the period from 2008 to 2016.

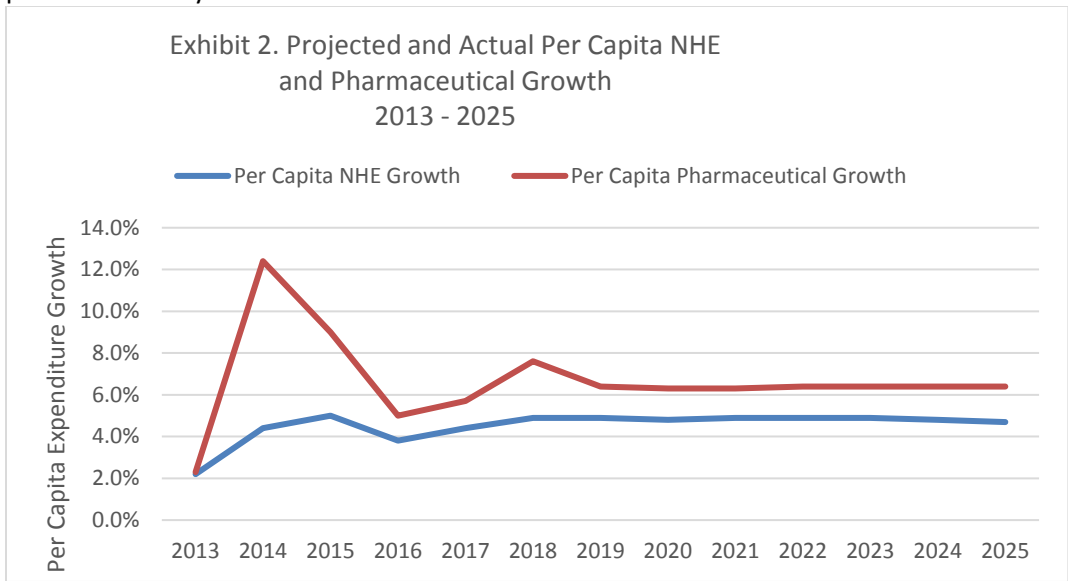
¹ <https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf>

² <http://www.aha.org/content/16/aha-fah-rx-report.pdf>

³ http://pages.stern.nyu.edu/~adamodar/New_Home_Page/data.html, HFMA analysis



Further, our members are concerned about future price increases. CMS’s Office of the Actuary projects that expenditures on retail pharmaceuticals (a rough proxy for drugs dispensed in hospitals and clinics) are projected to increase an average of 6.5 percent annually from 2018 to 2025.⁴ By contrast, as shown in Exhibit 2, total national health expenditures (NHE) are only projected to increase at an average of 4.9 percent annually.



HFMA’s members note that this proposal will do nothing to address the real problem (illustrated in Exhibit 2), the skyrocketing cost of pharmaceuticals. We question the assertion that scaling back the 340B program, as proposed or in other ways, will meaningfully reduce drug prices for patients, consumers, hospitals, and health plans. It’s estimated that 2016 sales at the 340B program price

⁴ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>, HFMA analysis

accounted for \$16.1 billion⁵ of the \$448.2 billion⁶ of U.S. prescription drug expenditures that year. Using CMS's proposed reduction of 22.5 percent to Medicare Part B payments as the average 340B discount, HFMA estimates the total price reduction to qualifying safety net hospitals resulting from the 340B program is approximately \$4 billion. **Even if the program were eliminated, assuming pharmaceutical companies reduced their prices to reflect the decreased need to cost-shift, HFMA estimates the maximum potential price reduction experienced by purchasers would be approximately 1 percent.** However, we strongly doubt that increased revenue resulting from elimination of the 340B program would be passed on by pharmaceutical companies to other purchasers in the form of reduced prices. In reality, scaling back the 340B program would hurt vulnerable patients and increase costs to the government in order to add to the already high profits of pharmaceutical companies. HFMA estimates that this could increase pharmaceutical companies' U.S. profit margins by as much as 4 to 6 percent annually.

Changes in Part B Drug Payments to 340B Hospitals Would Better Reflect Incurred Acquisition Costs: In the proposed rule, CMS states it is "proposing changes to our current Medicare Part B drug payment methodology for 340B hospitals that we believe would better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur." Further, CMS proposes that the reduced payments for separately payable drugs and biologicals purchased under the 340B program will be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act, and that the budget-neutral weight scaler is not applied in determining payments for these separately paid drugs and biologicals purchased under the 340B program. HFMA members find this argument problematic for three reasons.

First, Congress created the 340B program in 1992 to permit providers that care for a high number of low-income and uninsured patients "*to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.*" In 2016, the program accounted for less than 3.6 percent of drug purchases made in the United States. As discussed above, the estimated value of the 340B discount is approximately \$4 billion. This is a fraction of the total community benefit provided by safety net hospitals. Hospitals use 340B savings to stretch their limited resources and support programs that are improving and saving lives. Examples of such activities include, but are not limited to:

- Providing financial assistance to patients unable to afford their prescriptions
- Providing clinical pharmacy services, such as disease management programs or medication therapy management
- Funding other medical services, such as obstetrics, diabetes education, oncology services, and other ambulatory services
- Establishing additional outpatient clinics to improve access
- Creating new community outreach programs
- Offering free vaccinations for vulnerable populations

⁵ <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf>

⁶ <https://www.ashp.org/news/2017/06/26/14/28/pharmacy-journal-forecasts-drug-spending-for-2017>

In 2015, 340B hospitals provided \$23.8 billion in uncompensated care alone.⁷

If CMS presses forward with this policy, it will foist irreparable harm on the communities served by 340B safety net hospitals. A recent survey⁸ on the proposed rule's impact to safety-net providers fielded by the organization 340B Health finds that:

- **86 percent** of hospitals said that the proposed rule would affect their ability to provide clinical services, such as by having to **close clinics or limit infusion services**.
- **74 percent** of hospitals reported the proposed cuts would affect their provision of **pharmacy services, including staffing, drug discounts, and programs such as medication therapy management**.
- More than **two-thirds** of respondents reported the rule would **affect their ability to provide uncompensated care, which would directly impact access to care for low-income and rural individuals**.
- Nearly **half** of hospitals indicated that the proposed cuts would **impact quality of care and patient outcomes**.

Further, in the face of Medicare Disproportionate Share Hospital (DSH), Medicaid DSH, and reductions in Medicare base payment rates coupled with a well-documented increase in administrative burden, finalizing this policy would further weaken safety net hospitals, threatening their ability to fulfill their core mission—provide access to care in disadvantaged communities. The median increase in pharmaceutical expenses resulting from this proposal is estimated by respondents to 340B Health's survey at between \$1 and \$2 million. However, based on HFMA's conversations with CFOs in academic medical centers, it was not uncommon for projected increases in pharmaceutical expense to exceed \$15 million.

If this is finalized, many of HFMA members in 340B safety-net hospitals stated that not only would they have to reduce programs that provide access to necessary pharmaceuticals and medical services for the indigent (as discussed above), but some organizations stated they would need to reduce staffing to maintain a sustainable margin. **HFMA members believe this outcome is deeply contrary to Congress's intent when it created the 340B program in 1992 and expanded it in 2010.** If Congress intended for funds from the 340B program to be spread across the Outpatient Prospective Payment System (OPPS), Part B in general, or used to create an additional funding mechanism through the OPPS, it would specifically direct the Health Resources & Services Administration (HRSA) to work with CMS to do so.

Second, HFMA members point out that the 340B program is a public health program administered by HRSA. This proposal is outside the jurisdiction of CMS. We strongly believe that if further authority were given to the Administration by Congress to promulgate regulations, it should only be done by HRSA. HFMA members reiterate that the 340B program is not a Medicare program, and Medicare does not subsidize 340B hospitals or pay them different rates. Rather, Medicare pays 340B hospitals the same predetermined payment rates it pays to other OPPS hospitals. Part of CMS's rationale for this payment policy is that 340B hospitals acquire the drugs for less than what Medicare pays for them. HFMA

⁷ <http://www.aha.org/advocacy-issues/testimony/2017/170718-340-hearing.pdf>

⁸ First Look: Part B Payment Cuts Survey, email from Jeff Davis, Legislative and Policy Council, 340B Health, sent Wednesday, August 23, 2017

members are concerned that, if this proposal is finalized, it creates a slippery slope to additional, arbitrary payment cuts for separately payable Part B drugs and other services. For example, ASP is calculated net of any price concessions such as volume discounts, prompt pay discounts, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those obtained through the Medicaid drug rebate program. Since it's an average, some hospitals, particularly in larger health systems, have access to discounts that others don't. Given this, would CMS attempt to reduce payment for separately payable drugs to hospitals and health systems that are able to avail themselves of drug pricing less than ASP? We believe this is contrary to the intent of the OPPS payment system for separately payable drugs but are concerned that this ill-considered policy could set a precedent.

Finally, CMS proposes to reallocate the estimated \$900 million in reduced payments for separately payable Part B drugs across the OPPS payment system. Given that MedPAC finds Medicare margins for not-for-profit hospitals in 2015 were -8.5 percent⁹, HFMA members do not dispute that outpatient payment rates need to be increased across the board to better reflect the cost of providing medically necessary services to Medicare beneficiaries. **However, we question the logic of taking money from not-for-profit safety net 340B hospitals and redistributing it randomly across the OPPS payment system.** CMS asks for feedback on three alternative methods for redistributing the \$900 million from the proposed reduction in payments to 340B hospitals for separately payable drugs. HFMA members do not believe there is a more effective, less administratively burdensome way to target funds to safety net hospitals to provide pharmaceuticals and care to indigent individuals.

Reducing Cost Sharing for Beneficiaries Receiving 340B Drugs: Part of CMS's rationale for reducing payment to 340B hospitals for separately payable drugs is that "such changes would allow Medicare beneficiaries (and the Medicare program) to pay less when hospitals participating in the 340B program furnish drugs to Medicare beneficiaries that are purchased under the 340B program." While HFMA members generally support efforts to reduce beneficiary cost sharing, we question the effectiveness of this proposal relative to the negative impact on access to care that this will impose on indigent patients. First, MedPAC finds that 86 percent¹⁰ of Medicare beneficiaries have either Medigap coverage or Medicaid, which covers their cost sharing. For the 14 percent of patients who receive separately payable drugs at 340B hospitals, many (given their socioeconomic situation and their burden of illness) qualify and receive charity care discounts for their cost sharing. Nearly three-quarters of the respondents to 340B Health's survey indicated that they provide some form of beneficiary copayment assistance for their low-income Medicare patients. This is the exact intent of the 340B program.

Further, because the \$900 million in payment cuts will be redistributed via the conversion factor, this policy change will increase cost sharing for all other OPPS services. And as a result, it will have no impact on premiums for Medigap plans and may actually shift costs to state Medicaid programs. **Therefore, HFMA members believe the anticipated reductions in cost sharing will not directly benefit Medicare beneficiaries.**

Given the flaws discussed above with CMS's proposed reduction in payment for separately payable drugs to 340B hospitals, CMS should rescind its proposal. Moreover, the law governing the 340B

⁹ http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch3.pdf?sfvrsn=0

¹⁰ MedPAC, June 2016 Databook, Section 3, p. 27.

program is limited as to what constraints may be placed on the program by the Executive Branch. Congress is the only authority to make changes to the current program and recent actions by congressional committees show that they intend to do so. Recently, the Energy and Commerce Committee sent a letter to HRSA stating its concerns about the rapid growth and lack of oversight in the 340B drug discount program and requested that HRSA audit the program. Following the letter, the Committee's Subcommittee on Oversight and Investigations held a hearing to examine the program with testimony from HRSA, the Governmental Accountability Office, and the Department of Health and Human Services, Office of Inspector General. The letter and hearing are only the beginning of the work that Congress has indicated it intends to perform on this vital program, with possible legislation in the near future. We believe it is the intention of Congress to gradually reform the program and this proposed rule would severely hamper its ability to investigate and develop legislation to improve the program.

Appending a Modifier to All Separately Payable Part B Drugs Not Acquired through the 340B Program: If this proposal is finalized, CMS states it "intends to establish a modifier, to be effective January 1, 2018, for hospitals to report separately payable drugs that were not acquired under the 340B program." However, it provides no additional detail, stating that it intends to provide additional detail in the final rule or through a sub-regulatory process. **If the proposal (or some version of it that requires a modifier for non-340B separately payable claims to be paid at ASP+6) is finalized, HFMA members find this unacceptable.**

Currently, we are unaware of any software systems available to automate this process. And once these systems are available, it will require significant staff time and financial resources to implement correctly. For example, Texas hospitals are required to append a modifier to Medicaid claims in which the patient has received a 340B drug. On average, HFMA members in Texas hospitals and health systems estimate it took their organizations over four months to develop the IT systems and processes to correctly append a modifier onto Medicaid claims with 340B drugs. And this will add to hospitals' administrative burdens, diverting scarce IT resources and human capital away from other more pressing projects without actually improving the quality of care provided to patients. **If CMS persists in finalizing this proposal, HFMA members believe the rule needs to be delayed by at least 12 months to allow hospitals time to implement the systems necessary to append the modifier onto claims for non-340B separately payable drugs.** Given the high cost of many of these drugs, we do not believe it is appropriate for CMS to ask hospitals to hold these claims until systems can be implemented.

Proposed Changes to the Inpatient-Only (IPO) List

Removing Total Knee Arthroplasty (TKA) from the IPO List: CMS proposes to remove TKA, CPT Code 27447, from the Medicare IPO list for CY2018. This would allow the procedure to be performed as an outpatient surgery paid under the OPPI for patients who are healthy enough not to require an inpatient stay. Currently, CMS is not proposing to allow Medicare reimbursement when TKA procedures defined as CPT Code 27447 are performed in an ASC. HFMA's members conditionally supported CMS's proposal in the CY2017 proposed OPPI rule.

At this juncture, HFMA members do not support CMS's proposal. Our support in response to the inquiry in the proposed 2017 OPPI rule was directly predicated on adequate adjustment of the MS-DRG payment and target prices for Lower Extremity Joint Replacement (LEJR) episodes. HFMA

members are deeply disappointed the CY2018 proposed rule provided no discussion of how CMS will adjust payments and target prices to reflect this significant policy shift.

TKA is a high-volume inpatient procedure, accounting in 2014 for approximately 57 percent of the discharges included in MS-DRG 470 (Major Joint Replacement or Reattachment of Lower Extremity w/o MCC). Using publicly available CMS data, HFMA estimates that in 2014, over 261,000 TKAs were performed. The total allowed amount for these discharges was approximately \$3.9 billion. Further, to provide a sense of the significance of TKA discharge volume, HFMA estimates that if CPT Code 27447 were assigned its own MS-DRG, it would be the third most commonly billed MS-DRG, ahead of MS-DRG 291 (Heart Failure and Shock w/ MCC) (201,431, approximately \$2.2 billion allowable). For illustrative purposes, if only 7 percent of TKAs migrated into the outpatient setting it would decrease discharges by approximately 18,000 cases for MS-DRG 470. The number of impacted discharges is greater than the individual volumes for more than 600 MS-DRGs.

Our members are concerned that TKA procedures for healthier patients will be shifted into an outpatient setting, leaving sicker, more costly patients to have their procedures performed in the inpatient setting. The “weight” for MS-DRG 470, like all MS-DRGs, is a blended historical average of all Medicare patients who have this procedure. Under the scenario described above, it will be approximately two years before MS-DRG weights are based on claims experience that incorporates this policy. In the interim, hospitals will be under-reimbursed for providing a medically necessary service to Medicare beneficiaries. Given the potential volume of discharges impacted, HFMA believes CMS must proactively adjust the weight for MS-DRG 470 to reflect this policy shift.

In addition to repricing the MS-DRG itself, CMS will need to account for this policy shift in LEJR episode target prices by adjusting for projected changes in the number of “outlier” cases, increased use of post-acute sites of service, and a potential increase in readmissions rates for patients who continue to have TKA procedures performed in the inpatient setting. HFMA members believe cases fitting the following criteria could be removed from the existing data set to determine the correct MS-DRG weight and episode pricing, if CMS eventually decides to implement this policy:

- A. Cases with no co-morbidities listed on the claim or that have a low-risk HCC score
- B. Short length of stay (two days)
- C. No institutional post-acute care utilization
- D. No readmissions

Additionally, when CMS moves forward with this policy, we believe it will need to monitor and possibly adjust readmissions rates used in the Hospital Readmissions Reduction Program and posted on the Hospital Compare website. We are concerned that differential rates of adoption of performing TKA as an outpatient surgery across and within regions could potentially skew readmission rates.

HFMA agrees with CMS that physicians will need to develop evidence-based patient selection criteria to identify patients who are appropriate candidates for an outpatient TKA procedure as well as exclusionary criteria that would disqualify a patient from receiving an outpatient TKA procedure. Therefore, once CMS is able to adequately address issues related to MS-DRG payment rates, episode target prices, and quality measures and removes TKA from the IPO list, HFMA supports a temporary moratorium on recovery audit contractor (RAC) site-of-service reviews. However, instead of 24 months,

our members believe the moratorium periods will need to be at least 36 months to allow consensus to develop around appropriate evidence-based patient selection criteria.

Solicitation of Comments on the Possible Removal of Partial and Total Hip Arthroplasty (PHA/THA) Procedures from the IPO List: HFMA members currently do not support the removal of PHA and THA from the IPO list. Our concerns are similar to the issues discussed above with CMS’s proposal to remove TKA. We believe CMS must address issues related to MS-DRG pricing and LEJR target price setting to account for lower acuity cases transitioning into the outpatient setting. The volume of cases potentially impacted is significant, as illustrated in Exhibit 3.

Exhibit 3. 2014 Volume of PHA/THA Cases and Impact of an Illustrative 3 Percent Shift in Cases to the Outpatient Setting

CPT Code	Description	2014 Volume	2014 Medicare Allowable	Illustrative 3% Shift in Cases	
				Volume Impact	Allowable Impact
27125	Total Hip Arthroplasty	137,853	\$ 2,067,670,146	4,136	\$ 62,030,104
27130	Partial Hip Arthroplasty	55,141	\$ 827,068,059	1,654	\$ 24,812,042

Further, unless CMS prospectively reprices the MS-DRG to reflect changes as a result of TKA cases shifting to the outpatient setting, it should allow this policy change to be fully reflected in the MS-DRG payment and LEJR target price before it removes PHA and THA from the IPO list. **We believe that CMS should wait a minimum of four years to allow for changes in practice patterns.**

Potential Revisions to the Laboratory Date-of-Service (DOS) Policy

HFMA commends CMS for addressing the issue of overly complex laboratory billing for hospitals and performing laboratories. **Our members believe the future exception should be applied to both molecular pathology tests and advanced diagnostic laboratory tests (ADLTs).** Both types of tests are different from regular laboratory tests and are technologically advanced. These tests are important tools that guide patient treatment plans. Many hospitals currently lack the in-house technical expertise and Clinical Laboratory Improvement Amendments (CLIA) licensure to perform molecular pathology tests and thus send them out to a performing laboratory. ADLTs, by definition, are performed by sole or proprietary labs.

Our members would like to point out that the molecular pathology kits referenced by CMS are different from those used for waived clinical laboratory tests. These kits require the hospital to have the highest licensure level from CLIA, as well as obtain specialized training for correct use and interpretation of the results. Most hospitals are not likely to have either the expertise or the technology to use these kits. To ensure appropriate access to these tests by rural and community hospitals, as well as academic and specialty hospitals, the exception should apply to both molecular pathology and ADLTs.

The DOS exception must apply to ADLTs and molecular pathology laboratory tests ordered for hospital inpatients, as well as hospital outpatients, as proposed by CMS. It would be a significant administrative burden on hospitals that collect specimens, and laboratories that furnish and bill the tests, to track tests ordered for outpatients in a way that is inconsistent with those obtained from inpatients.

Consistency is also important to CMS's ability to evaluate data on patient outcomes. Laboratory tests ordered for hospital inpatients do not have the tests' HCPCS codes on the inpatient claim. CMS therefore cannot track patients who have had these tests ordered for them using claims data, or evaluate how advanced testing contributes to cancer care and other advanced treatments and to the total cost of care. To preserve insight into data on survival and outcomes, two key categories of information need to be accounted for: (1) accurate information on the timing of the test, and (2) the test HCPCS codes for patients for whom the tests are ordered (whether inpatient or outpatient). For this to happen, the DOS exception policy must be consistent with regard to hospital inpatients and outpatients.

In terms of the DOS of the molecular pathology or ADLT, CMS has proposed the following:

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

Except for the first requirement, HFMA members agree with what CMS has proposed. We believe it is problematic to meet this criterion when considering current clinician workflow in ordering laboratory tests. To help clarify our concern, and our alternate suggestion, we have given some background information below.

In almost all instances, orders for ADLT or molecular pathology preceded the inpatient stay or outpatient encounter. Also, the initial diagnosis could be made during the inpatient stay and an order for biopsy and tissue testing could be made during the encounter. Postponing an order for testing until after post-discharge is not in keeping with how clinicians conduct their workflows.

The 14-day DOS exemption currently in place is problematic in that laboratory orders are delayed, which can delay care. Community hospitals, or other small hospitals that send these tests to outside laboratories to be performed, have to consider the timing of a delay, since it can determine whether the hospital is the one paying for the cost of these tests, or, conversely, the performing lab is able to bill separately. Patient care could be delayed because the clinician would order a test 14 days or more from the biopsy date. This ensures the performing lab can bill for separate payment. We know it is not CMS's intent to encourage this, so we wanted to ensure that the issue was raised.

Instead of CMS's existing policy, HFMA members recommend that when ordering molecular pathology or ADLT tests, a clinician should certify that the results do not inform the treatment that is provided during the hospital inpatient or outpatient encounter. Such a certification could be confirmed by the performing laboratory when it bills the tests with a modifier. If the laboratory DOS coincides with the dates of a hospital inpatient or outpatient encounter, CMS would see the applicable modifier and make an exception when the test is a molecular pathology or ADLT and pay the performing laboratory separately. Clinicians would follow their standard clinical workflow when ordering tests, and not require

that the orders be post-discharge, but that results are not needed for treatment during an inpatient or outpatient hospital encounter.

CMS would then have separate performing laboratory claims with molecular pathology and ADLT tests for all patients who receive them and could link the tests with the ordering clinicians and patients, and evaluate outcomes and survival rates over time; data that are crucial for developing best practices. Therefore, we ask CMS to exclude molecular pathology and ADLTs from hospital inpatient and outpatient encounters and permit separate billing based on test performance dates for all furnishing laboratories.

Proposed New ASC Quality Measures

CMS proposes to add the following three new quality measures to the ASC Quality Reporting (ASCQR) Program.

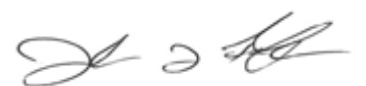
- Toxic Anterior Segment Syndrome (ASC-16): The measure will be submitted in CY2021 (performance year 2019). The measure has not been approved by the National Quality Forum (NQF).
- Hospital Visits after Orthopedic ASC Procedures (ASC-17): The data collection period would be the two calendar years prior to the applicable payment determination year, so the first payment determination (CY 2022) would be based on data from CY 2019 and CY 2020. ASCs would not need to submit any additional data directly to CMS as it is claims-based. The measure will be presented to the Measures Application Partnership (MAP) this fall and has not been approved by the NQF.
- Hospital Visits after Urology ASC Procedures (ASC-18): This measure will be presented to the MAP this fall and has not yet been endorsed by the NQF.

Given that none of these measures has been approved by the NQF, HFMA members do not support including them in the ASCQR Program.

HFMA looks forward to any opportunity to provide assistance or comments to support CMS's efforts to refine and improve the 2018 OPPS. As an organization, we take pride in our long history of providing balanced, objective financial technical expertise to Congress, CMS, and advisory groups.

We are at your service to help CMS gain a balanced perspective on this complex issue. If you have additional questions, you may reach me or Richard Gundling, Vice President of HFMA's Washington, DC, office, at (202) 296-2920. The Association and I look forward to working with you.

Sincerely,



Joseph J. Fifer, FHFMA, CPA
President and Chief Executive Officer
Healthcare Financial Management Association



About HFMA

HFMA is the nation's leading membership organization for more than 38,000 healthcare financial management professionals. Our members are widely diverse, employed by hospitals, integrated delivery systems, managed care organizations, ambulatory and long-term care facilities, physician practices, accounting and consulting firms, and insurance companies. Members' positions include chief executive officer, chief financial officer, controller, patient accounts manager, accountant, and consultant.

HFMA is a nonpartisan professional practice organization. As part of its education, information, and professional development services, HFMA develops and promotes ethical, high-quality healthcare finance practices. HFMA works with a broad cross-section of stakeholders to improve the healthcare industry by identifying and bridging gaps in knowledge, best practices, and standards.