



May 9, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1670-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850.

File Code: CMS-1670-P

Re: Medicare Program; Part B Drug Payment Model; Proposed Rule

Dear Mr. Slavitt:

The Healthcare Financial Management Association (HFMA) would like to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the changes proposed to Medicare's reimbursement methodology for separately payable Part B drugs contained in "Medicare Program; Part B Drug Payment Model; Proposed Rule," published in the March 11, 2016, *Federal Register*.

HFMA is a professional organization of more than 40,000 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

On behalf of its members, HFMA would like to express its significant concerns over CMS's proposed changes in payment methodology for separately payable Part B drugs. HFMA members share CMS's concern over rapidly growing pharmaceutical costs. However, we do not believe the package of proposals put forward will be effective in achieving CMS's goals of reducing federal spending on pharmaceuticals while improving the efficiency of therapies delivered to patients. Further, we believe these proposals will result in significant unintended consequences which will ultimately increase overall spending while reducing Medicare beneficiaries' access to care without serving as an effective test of alternative value-based payment methodologies for Part B drugs. HFMA members' specific concerns include:

- CMS's articulation of the problem and the resulting solution identified
- CMS's legal authority to conduct a pilot of this scope
- Financial impact on providers
- Beneficiary access to care and cost sharing
- Unnecessarily increased administrative complexity

- Impact to CMS Shared Savings programs and other similar initiatives
- Applicability of pharmaceutical value-based payment models to the Medicare program

Each of these concerns is discussed in detail below. **Given the numerous issues with CMS's proposal, HFMA members strongly urge CMS to withdraw this proposed rule and work to implement solutions that more effectively address the root causes of rapid growth in pharmaceutical costs.**

CMS's Articulation of the Problem and the Resulting Solution Identified

Many Part B drugs, including drugs furnished in the hospital outpatient setting, are paid using the methodology in section 1847A of the Social Security Act. In most cases, this means payment is based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on. Under this methodology, expensive drugs receive higher add-on payment amounts than inexpensive drugs while there are no clear incentives for providing high-value care, including drug therapy.

CMS believes that the economic incentives embedded in the current payment system lead physicians in both office and hospital based settings to prescribe more expensive pharmaceutical therapies when lower-cost options would achieve similar results. This therefore purportedly contributes to rapidly escalating Medicare costs for Part B pharmaceuticals. In an attempt to correct what CMS views as misaligned economic incentives, it proposes a two-phase test to remove the incentive to prescribe more expensive therapies. In Phase I, which will start 60 days after the display of the final rule, CMS will continue paying a control group of providers under the current ASP + 6% methodology. A test cohort will be paid ASP + 2.5% + \$16.80. CMS maintains that the first phase will be budget neutral. It is important to note that the \$16.80 is an arbitrary value. It bears no relation to the cost of acquiring and handling Part B pharmaceuticals. It is merely a "plug" that, based on CMS's analysis, maintains budget neutrality across the Part B program. However, as discussed below, while there is budget neutrality across the program, the proposed rule arbitrarily shifts Part B payments across provider types based on a physician's specialty – not necessarily the physician's prescribing pattern. Sites of service and specialties that must use more costly Part B drugs in providing care to beneficiaries are penalized while those sites of service and specialties that do not utilize high-cost drugs in administering care are rewarded.

In Phase II, CMS, in selected primary care service areas, will test a variety of value-based purchasing tools for pharmaceuticals. HFMA will provide feedback on this aspect of the proposed rule later in this comment letter.

HFMA members agree with CMS that rapidly growing drug costs are a problem that need to be addressed. And, in theory, the construction of the current ASP +6% payment mechanism could be an underlying contributor to these rapidly growing costs. However, HFMA members question how significant a contributor the current ASP +6% payment methodology really is. First, there is little evidence that the current payment method is driving physicians to prescribe more expensive therapies when lower-cost alternatives exist. The few studies available are now several years old and focus on a few select conditions as opposed to proving a broad impact across multiple clinical conditions and classes of drugs.

For CMS's theory that physicians are choosing more expensive therapies to increase revenue to hold, the prescribing physicians would need to have a direct economic interest in the site of service where the Part B drugs are administered. For hospital-based clinics, that link is tenuous, at best. In many instances,

the physicians practicing in these settings are not employed by the hospital but are community physicians who have privileges to provide care at the hospital. Further, compensation packages for physicians employed by hospitals vary significantly across health systems and specialties. However, most use relative value units (RVUs) as the basis. RVUs are a measure of productivity, not profitability. While hospital physician compensation packages typically do factor in margin, it is a relatively small component so as not to penalize employed physicians for providing care to the indigent and those insured by Medicare and Medicaid. Because physicians practicing in hospitals are removed from both the cost and revenue impact of their choice of therapies, in many instances they are likely unaware of the fully loaded (drug price that includes acquisition and handling expenses) cost differentials between different pharmaceutical options. This traditionally has been viewed as a positive, as it allows the physician to choose best therapy for the patient without being influenced by the margin impact to the organization.

Furthermore, for CMS's proposed rule to have the desired effect, there must be therapeutic substitutes for higher-cost drugs. This underlying assumption in CMS's proposed rule is not necessarily true for many disease states. We have come to understand from conversations with pharmacists who work with our members that in many instances – particularly for a variety of cancers – there is only one clinically effective therapeutic agent available. For these conditions, CMS's proposed rule is nothing more than a rate cut, which will be discussed further in the section on provider margin impacts. **For this reason, if CMS elects to move forward with this pilot, HFMA members request that any Part B drug that does not have a lower-priced clinical equivalent be removed from the Model. Regardless of which Primary Care Service Area (PCSA) the prescribing practice is located in, these drugs should continue to be reimbursed at ASP+6%.** While CMS intends for the Pre-Appeals Payment Exception Review Process to handle these issues in Phase II, there is no similar mechanism for Phase I. Even if there were, HFMA members believe that this will be insufficient to handle the volume of appeals and ultimately only serve as an administrative barrier to Medicare beneficiaries receiving medically necessary care.

Even if the current ASP+6% payment methodology is a significant contributor to rapidly rising drug costs, HFMA fails to see how the proposed changes in Phase 1 alter the incentives to prescribe more expensive therapies. All things being equal in terms of acquisition and handling costs, mathematically 2.5% of a \$1,000 drug still yields more profit than a \$500 drug. Further, many of our members have voiced concern that \$16.80 +2.5% of the ASP will not cover the cost to acquire, store, and handle many of the drugs they use in providing care to Medicare beneficiaries.

HFMA has long supported accurate reimbursement for services provided to Medicare beneficiaries that covers the cost of an efficient provider to deliver medically necessary care.¹ **In an effort to more accurately compensate providers for their acquisition and handling costs (as intended by the 6% add-on payment), HFMA believes that CMS needs to calculate the actual cost for these activities across related groups of drugs and use this as the basis for payment. Our members have recommended the following as possible categories: oral administration, injectables, chemotherapy, and specialty pharmaceuticals.**

Ultimately, if CMS is looking to staunch the growth in spending for Part B pharmaceuticals it needs to work directly with the pharmaceutical manufacturers to address price inflation. To that end, the

¹ <https://www.hfma.org/Content.aspx?id=1017>

Medicare Payment Advisory Commission (MedPAC) has recently discussed the possibility of an ASP price inflation cap. MedPAC staff suggest that this ASP inflation cap could be operationalized through a manufacturer rebate to Medicare (or some other means) when the ASP for a drug increases faster than a specified inflation benchmark. MedPAC staff point out that such a cap would protect against the potential for a dramatic increase in the Medicare payment rate for a product and also could potentially generate savings for drugs with ASP growth above the inflation benchmark. While HFMA shares the concern voiced by several Commissioners that an inflation cap could incentivize drug manufacturers to protect their revenues by setting a very high launch price for new drugs, we believe that there are ways to address this as well, given Medicare’s substantial potential negotiating power. **We encourage CMS staff to explore this option and, if it has merit, work with Congress to gain the necessary authority to implement such a program.**

CMS’s Legal Authority to Conduct a Pilot of this Scope:

Section 1847a of the Social Security Act mandates that physicians and hospitals be paid ASP+6% for certain Medicare Part B Drugs. CMS cites section 1115a of the Social Security Act as its authority in making the proposed, significant changes to reimbursement for Part B Drugs. HFMA members are concerned that CMS, if it has not exceeded the statutory authority under Section 1115a, has stretched the boundaries of what Congress intended in granting CMS waiver authority. CMS, in the proposed rule, even goes so far as to describe the Part B Payment Model as a “national payment model,” which begs the question of what other payment policies CMS could implement on a time-bound basis and use under Section 1115a to justify.

Specific to the Part B Payment Model, HFMA members do not believe that the proposed two-phase program meets the criteria for selection at 1115A(b)(2)(A) which states:

(A) In general.—The Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title. The models selected under this subparagraph may include, but are not limited to, the models described in subparagraph (B).

Despite a dearth of evidence that there are “deficits in in care leading to poor outcomes or potentially avoidable expenditures,” the model broadly targets all Medicare beneficiaries who receive Part B drugs. As discussed above, the limited number of studies that have examined this issue have been narrowly focused on conditions like lung and prostate cancer. However, there is no evidence that this is an issue impacting quality or contributing to potentially avoidable expenditures across a wide range of conditions or impacting all Medicare beneficiaries. **HFMA believes that, given the lack of evidence of a broad-spectrum problem, CMS, if it elects to move forward with the Model, is legally compelled to re-scope the Model to only conditions where there is some existing evidence that the current ASP+6% payment methodology is impacting quality or contributing to potentially avoidable expenditures.**

Additionally, one of the keys to evaluating the success of this intervention will be to determine the impact on the quality of care beneficiaries receive. CMS briefly addresses the need to understand the impact on quality as part of its discussion of the Evaluation of the Part B Drug Model. However, the

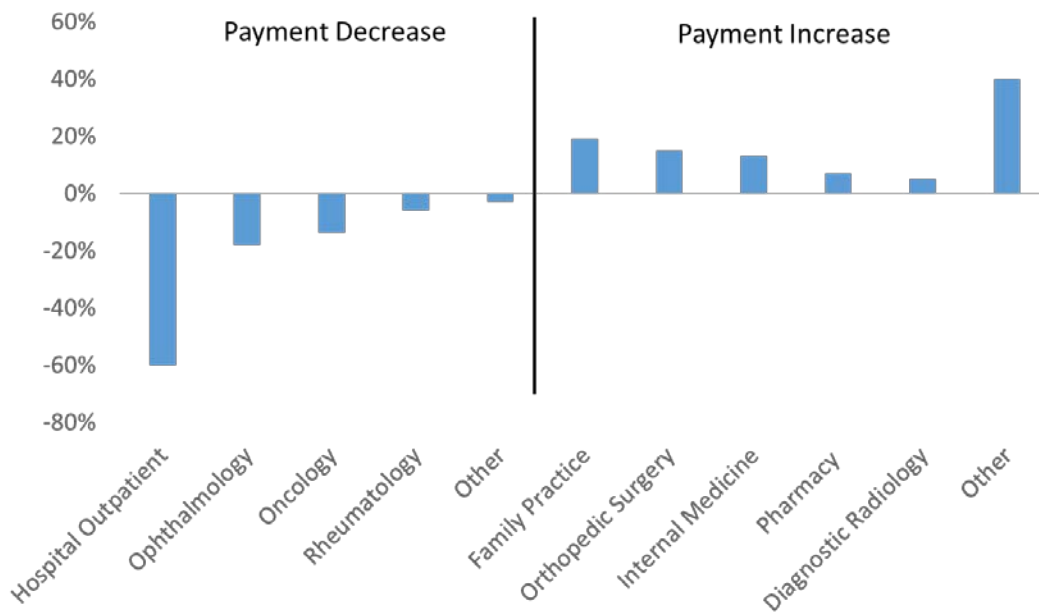
discussion around CMS’s quality measurement approach is left wanting. The proposed rule contains no details as to how CMS will determine what, if any, effect on quality the Model will have on the broad spectrum of conditions experienced by Medicare beneficiaries who receive Part B drugs. Further, as discussed below, HFMA members believe that an unintended consequence of the Model will be to limit beneficiary access to care. The steps CMS will take to monitor this foreseeable unintended consequence are not discussed at all in the proposed rule. **If CMS insists on moving forward with this Model, HFMA strongly believes that it needs to publish for comment a detailed description of the process it will use to evaluate the impact the Model will have on both beneficiary outcomes and access to care.**

Financial Impact on Providers

The proposed rule estimates that the effect of Phase I will further decrease payments to hospitals by .3%. Based on MedPAC’s most recent analysis, hospital Medicare margins in 2014 were -5.8%. It projects these margins will fall to -9% based on current law, not including the changes considered in this proposal. This analysis also doesn’t factor in the financial impact on 340B hospitals that will occur if the Health Resources and Services Administration’s 340B Drug Pricing Program Omnibus Guidance (hereafter HRSA Mega-Guidance) is implemented as written. Given the multitude of payment cuts hospitals are facing (particularly safety net hospitals), HFMA is deeply concerned about the financial impact this proposal has on hospitals and health systems.

Further, we are concerned that the proposed rule arbitrarily shifts Part B payments across different types of providers. Based on analysis by Avalere, the chart below shows how the proposed rule shifts payments across providers and sites of service.

Chart I: Share of Payment Decrease/Increase under Proposed Part B Rule by Provider Specialty or Site of Service²



² <https://www.washingtonpost.com/news/wonk/wp/2013/04/03/cancer-clinics-are-turning-away-thousands-of-medicare-patients-blame-the-sequester/>

Avalere's analysis finds that \$480 per day is the drug price cut-point between higher and lower reimbursement. Specifically, drugs that cost providers more than \$480 per day will result in lower reimbursement under the model while those that cost more than \$480 will result in higher payments.

Given the unlikelihood of the Model to solve the problem CMS is targeting coupled with the arbitrary redistribution of reimbursement that will impact access (discussed below), HFMA believes that CMS should withdraw the proposed rule. In the prior sections, we have outlined a number of proposals that we believe will accurately reimburse providers for the costs of acquiring and handling Part B drugs, remove the alleged incentives to prescribe higher-cost drugs when clinically effective lower-cost substitutes exist, and slow the overall growth in Part B drug expenditure. We would encourage CMS to pursue these policies as opposed to the current proposal, which is unlikely to achieve its policy goals, and penalizes or rewards specialties and settings arbitrarily based on the cost of drugs they typically prescribe.

Impact on Beneficiary Access and Cost Sharing

HFMA is deeply concerned about the impact on both beneficiary access to care and the related impact on cost sharing. The physician practices (primarily ophthalmology, oncology, and rheumatology) negatively impacted by the proposed reduction in payment as a result of Phase 1 will not have the financial wherewithal to continue providing care to Medicare beneficiaries in the freestanding clinic setting. Similar to what occurred with the implementation of the Medicare budget sequester, this proposed rule will drive another round of freestanding clinics in the impacted specialties to determine that providing care to Medicare patients in their offices is not financially sustainable. Patients who would have received care closer to home will be forced to seek care from a provider-based setting. Assuming capacity is available in provider-based settings, not only is this inconvenient for the Medicare beneficiary, but it will drive both higher Medicare expenditures and patient cost sharing.

However, CMS should not assume that all hospitals will be able to absorb these patients into their oncology or other clinics. As discussed above, hospital outpatient departments, already operating on negative Medicare margins, will bear the brunt of this unjustified reduction in payment for Part B drugs. For qualifying hospitals, the financial impact will be compounded and the ability to serve not only Medicare but all of its patients will be greatly impaired if the provisions in the HRSA Mega-Guidance are finalized. As an example of the impact, several of our members at teaching hospitals have called into question their ability, if this rule is finalized, to continue providing "salvage therapy" to Medicare beneficiaries whose prior courses of cancer therapy have been unsuccessful but who would like to continue pursuing treatments.

Given the unlikelihood of the Model to solve the problem CMS is targeting, coupled with the high likelihood of negatively impacting beneficiary access and cost sharing, HFMA believes that CMS should withdraw the proposed rule.

Unnecessarily Increased Administrative Complexity

If CMS elects to move forward with the proposed rule, HFMA members are concerned with two components of the rule that will significantly increase administrative complexity and overhead cost without improving the quality of care delivered to Medicare beneficiaries.

- 1) CMS analysis showed that almost all claims for an individual provider or supplier were billed within a single PCSA, which limits, but does not eliminate, situations where practices are exposed to multiple payment interventions under the Model. However, where a provider's or supplier's practice spans multiple PCSAs, this issue will be particularly problematic. **Therefore, if the rule is finalized, HFMA believes that in these limited instances where a provider's or supplier's practice spans multiple PCSAs, CMS should allow the provider or supplier to pick which PCSA it should be "assigned to" for purposes of the Model.**
- 2) CMS anticipates using a G-code that providers and suppliers billing in geographic areas assigned to this approach (ASP+2.5 percent + flat fee) would use to bill for the flat-fee portion of the payment. CMS in the proposed rule states that it will use units of the G-code to monitor for overuse of lower cost drugs as a result of this policy. However, HFMA members believe that CMS could do this by monitoring the units of drugs reimbursed rather than counting separate G codes. Providers and suppliers are currently not required to bill a separate G-code to receive the +6% of ASP and our members do not believe that the marginally improved ability for CMS to monitor changes in utilization will be outweighed by the administrative costs that providers will bear in making sure the code is added to all applicable claims. CMS will know which drugs and PCSAs are subject to this payment methodology so this step is redundant. **Therefore, HFMA members believe CMS should drop the requirement that providers who are in PCSAs that are receiving ASP +2.5% +\$16.80 bill a separate G code to receive the flat fee payment, if it elects to move forward with the Model.**

Impact to CMS Shared Savings Programs and Other Similar Initiatives

HFMA strongly supports CMS's efforts to test alternative payment models. However we are concerned about the Part B Payment Model's interaction/overlap with the Oncology Care Model (OCM), Medicare Shared Savings Programs, Pioneer ACO Program (Pioneer), Next Gen ACO, Bundled Payment for Care Improvement (BPCI), Comprehensive Care for Joint Replacement (CJR), and other models where CMS sets a per-beneficiary expenditure target for a defined set of services for a defined period of time and then reconciles actual provider payments to them, resulting in a settlement to/from the Program. If CMS elects to move forward with the Part B Payment Model, we believe CMS needs to remove the OCM and confirm that CMS will not adjust the target expenditure "benchmarks" set for the remaining programs referenced.

Given the significant overlap between the OCM and the Part B Payment Model, HFMA members believe that practices volunteering to participate in the OCM should be excluded from the Part B Payment Model. Beyond the administrative complexity, we question CMS's stated ability to isolate the impacts of the interventions in the OCM from the impacts on patient outcomes and overall expenditure brought about by the change in financial incentives as a result of the Model.

HFMA members support CMS's approach outlined in the proposed rule section entitled, "Most Shared Savings Programs and Models," starting on page 13248. We agree with CMS that it should not exclude beneficiaries impacted by the Model from the Medicare Shared Savings Program. Given the number of beneficiaries who receive separately reimbursed Part B drugs, we believe this could reduce the number of beneficiaries attributed to an organization, which, for some models, has implications for whether or not an organization can participate in a given program. **HFMA asks that CMS list in the final rule all**

programs that will not have beneficiaries removed from them if the beneficiary also receives one or more Part B drugs under the Model.

Further, CMS does not propose a separate reconciliation process or modification to the reconciliation process for beneficiaries involved in shared savings programs. **HFMA generally supports this approach with the caveat that it is interpreting this statement to mean that CMS will also not adjust (either prospectively or retrospectively) target expenditure benchmarks for any CMS or CMMI program that relies on a reconciliation process to determine financial outcomes for participating providers. HFMA asks that CMS confirm that this interpretation is accurate in the final rule.**

Applicability of Pharmaceutical Value-Based Payment Models to the Medicare Program

CMS proposes to test value-based payment models such as reference pricing, indications-based pricing, and outcome-based pricing in Phase II of the model “no sooner than January 1, 2017.” CMS has stated that its goal is to have “both phases of the model in full operation during the last three years of the proposed five year duration...” which implies that Phase II will start, at the latest, on the two-year anniversary of the Model. While all of the value-based pricing mechanisms CMS discusses in the proposed rule have been experimented with in the private sector, they have not been deployed on a nationwide basis, as is contemplated under the two applicable test arms in the proposed rule.

HFMA members generally support the concept of value- and outcomes-based payment for healthcare services. **However, at this time we do not support experimenting with value-based pharmaceutical payments on a broad scale in the fee-for-service Medicare program as is proposed.** HFMA members believe that too little is known about how to effectively deploy these tools within the confines of the Medicare program, how CMS plans to operationalize these tools – including the impact they will have on providers, and most importantly how these tools will impact beneficiaries’ timely access to medically necessary Part B Drugs. Before CMS implements these mechanisms in a national test model, our members believe CMS needs to deploy these tools in smaller tests. Some of the key questions to answer as part of smaller scale tests include:

- 1) How do value-based pharmaceutical strategies work in an “open formulary” model? While there is growing experience with these mechanisms in the private sector, private health plans typically manage their pharmaceutical benefit more aggressively than Medicare.
- 2) How will the impact on quality and access to care for beneficiaries be measured?
- 3) For outcomes-based pricing mechanisms, how will outcomes data be collected? If there is a significant administrative burden on the provider to submit additional clinical information to document the outcome, how will the provider be reimbursed for the additional administrative work?
- 4) How will reference pricing be implemented in situations where the prescribing physician is not an employee of an organization billing for the Part B drug? For example, it is not uncommon for a physician ordering services in a hospital outpatient department to have privileges to practice at the hospital, but not be employed by that hospital or a subsidiary corporation. Under this very common scenario, there are no financial implications to the physician for ordering a more expensive drug under a reference pricing methodology. The hospital ultimately has purchased and will be paid for the Part B drug administered. Given this mis-alignment of incentives, as CMS implements reference pricing, HFMA believes it is more appropriate for CMS to require rebates

from the manufacturers of low-value drugs as opposed to reducing the Medicare reimbursement to providers for these drugs.

Our members appreciate CMS's attempt to collect additional data to answer these and other outstanding questions as part of the proposed rule's comment period. However, we believe it is inappropriate to also attempt to implement Phase II on a national scale under the time frame posited in the proposed rule when CMS has so many outstanding questions about how to deploy value-based pricing for Part B drugs that need to be publicly addressed.

Finally, CMS proposes to use a sub-regulatory process to implement the various value-based strategies it wants to test through the model. The proposed rule states that CMS will:

"...finalize the implementation of specific tools for specific HCPCS codes after soliciting public input on each proposal by posting on the CMS Web site, and we would allow 30 days for public comment. We would provide a minimum of 45 days public notice before implementation."

Given the potential impact these tools will have on the therapeutic pathway for specific conditions, HFMA members believe it is highly inappropriate to use a sub-regulatory process to announce and request comment for the various tools CMS is contemplating in Phase II of the Model. Our members believe that in order for there to be a full and transparent discussion of these tools, the Federal Register notice and comment process needs to be used.

HFMA looks forward to any opportunity to provide assistance or comments to support CMS as it attempts control pharmaceutical costs, improve patient outcomes, and more accurately reimburse providers for the overhead costs associated with acquiring and handling Part B pharmaceuticals. 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 40,000 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.