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August 12, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Verma:

On behalf of the AMGA, I want to express our appreciation for the opportunity to comment on the “Request for Information; Reducing Administrative Burden to Put Patients over Paperwork.”

Founded in 1950, AMGA represents more than 450 multispecialty medical groups and integrated delivery systems representing approximately 177,000 physicians who care for one in three Americans. Our member medical groups work diligently to provide innovative, high-quality, patient-centered medical care in a cost-effective manner.

AMGA supports policies that reduce the Medicare programs’ regulatory complexity so our member providers are better able to focus on providing the best possible patient care, rather than divert their attention toward regulatory compliance activities that do not improve the patient experience. Our overarching legislative and regulatory goals revolve around advancing the shift from fee-for-service (FFS) payments to reimbursement based on the value of the care provided. AMGA believes regulations should be designed and implemented so that providers are encouraged to innovate. Value-based models, such as Accountable Care Organizations (ACOs) and other Alternative Payment Models (APMs), are designed to remove the misaligned financial incentives that grew out of the FFS system, while also entrusting providers with the responsibility for the health of not just individual patients, but an assigned patient population. The regulatory framework governing these models of care delivery should reflect this key difference.

AMGA is pleased to offer these recommendations for your consideration.

Key Recommendations

Synchronize Rules and Regulations Across Medicare’s Accountable Care Organization

Programs: Payment waivers should be available for all levels within the Medicare Shared Savings Program (MSSP). Restricting these tools based on the level of risk is counterproductive to the goals of the program and hinders the ability of providers to develop care delivery models.

Encourage Use of Preferred Provider Lists: To improve the discharge process and foster care coordination, providers in value-based models of care should have the ability to develop and use preferred provider lists to inform patients of their options for post-acute care.

Waive Appropriate Use Criteria for Value-Based Models: As the incentives underlying the rationale behind the Appropriate Use Criteria (AUC) requirement are not present in value-based models of care, the requirement to consult clinical decision-support mechanisms should be lifted for providers who order advanced diagnostic imaging as part of a value-based model.

Streamline Quality Measurement Reporting: CMS should continue its work under the Meaningful Measures initiative to harmonize and scale down the amount of quality measures for all providers in value-based arrangements. Using a standard set of value measures will help reduce the variation in the measures that are reported and help eliminate unnecessary confusion and administrative burden. In fact, in 2018 AMGA's Board of Directors endorsed a set of 14 quality measures we believe are clinically meaningful to patients and providers.

Reduce Documentation Requirements for DMEPOS: CMS should evaluate its documentation requirements for ordering Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), as they do not reflect care delivery and workflow processes. Signature requirements should account for how items are prescribed and dispensed. The blanket requirement for a physician signature does not reflect how care is delivered.

Evaluate the Need for Advance Beneficiary Notice of Noncoverage: CMS should update its estimates of the burden associated with the Advance Beneficiary Notice (ABN) requirement and work with the provider community to determine if every test or procedure should be subject to the written notification.

Compensate Providers for Translation Services: CMS should clearly explain provider obligations for providing translation services and ensure providers are appropriately reimbursed for providing such services.

Remove Requirement for Physician Signature for Home Health Services: CMS should allow Nurse Practitioners (NPs) and Physician Assistants (PAs) to certify home health services without the need of a physician's signature.

Discussion

Synchronize Rules and Regulations Across Medicare's Accountable Care Organization Programs

Currently, the rules governing the Accountable Care Organizations (ACOs) within the Medicare Shared Savings Program (MSSP) shift depending on amount of financial risk the ACO accepts. Instead, providers that participate in these value-based arrangements should enjoy a consistent regulatory framework and have access to the tools that support their ability to deliver the highest quality care to their patients. The only meaningful difference among the levels of the MSSP's glide path should be the level of financial risk an ACO faces as it progresses.

CMS regulations that were developed and implemented in the FFS environment do not account for the significant investment that is required to engage in these population health models, including those that, for the time being, are in a shared-savings-only arrangement. With the

newly created glide path under the Pathways to Success regulations, ACOs will have a limited timeframe in a one-sided model before they transition to a model that includes an element of financial risk. As such, limiting waivers and beneficiary incentive opportunities to a subset of ACOs creates a situation that requires providers to adjust how they deliver care with no benefit to patients.

For example, the Social Security Act requires traditional Medicare beneficiaries to have an inpatient hospital stay of no fewer than three consecutive days to qualify for Medicare coverage of care in a skilled nursing facility (SNF). This rule, which does not apply to home health or inpatient rehabilitation stays, dates back to the inception of the Medicare program. CMS should waive this requirement for all providers participating in the MSSP. Ensuring that patients move along the care continuum and receive treatment in the most appropriate setting, as determined by their health needs, is imperative. The 3-Day Rule hinders timely and appropriate care, impedes care coordination, heightens the risk of iatrogenic harm from extended hospital stays, and is a burden on beneficiaries and their family caregivers.

CMS has exercised its waiver authority to lift the requirement in select models that are at performance-based risk, including the BASIC and ENHANCED tracks of the MSSP and the Next Generation ACO demonstration (NextGen). Today, under pay-for-value arrangements, the 3-Day Rule has become, as MedPAC has noted, “antiquated.” CMS should waive the three-day qualifying inpatient stay for beneficiaries who receive care from MSSP providers so care can be provided in a SNF at the most appropriate time as determined by clinicians, not regulation.

Additionally, current Medicare regulations limit the use of telehealth services and remote monitoring. However, the MSSP and the NextGen program allow participants to apply for waivers that permit more flexibility with telehealth services. This expansion of telehealth services only applies to ACOs in performance-based risk models. Restricting the availability of the waivers to two-sided models does not help patients engage with their physicians. AMGA supports waiving the geographic limitations for telehealth use for all providers participating in the MSSP.

Encourage Use of Preferred Provider Lists

Under current Medicare regulations, patients who are discharged from an acute care facility and are in need of post-acute care (PAC) are only provided information about the available providers in their area. Hospital discharge planners must take into account the patient’s preferences and beneficiary choice when providing this information, but Medicare regulations prohibit hospital discharge planners from recommending specific PAC providers. The quality and efficiency of care that is provided in a PAC facility should factor into options that are presented to the patient. While patients have access to information regarding the quality of care provided in PAC facilities via the Medicare.gov website, the literature does not clearly indicate that this information moves the beneficiary to choose a higher quality PAC provider.¹

In a value-based system of care, clinicians should have access to every possible tool to ensure a beneficiary receives the most efficient and highest quality care. Providing a beneficiary with a preferred provider offers them more information and improves care transparency. Currently,

¹ Medicare Payment Advisory Commission. June 2018 Report: Medicare and the Health Care Delivery System. Chapter 5: Encouraging Medicare beneficiaries to use higher quality post-acute care providers.

certain Center for Medicare & Medicaid Innovation demonstrations, such as the NextGen model, allow providers to present patients with a list of preferred PAC providers that meet certain quality criteria, including a minimum star rating. This policy should be extended beyond the NextGen demonstration to all providers participating in value-based programs. Preferred provider lists help ensure Medicare beneficiaries receive care in a higher-quality care setting. This proposal also begins to redress the longstanding problem associated with the confusing and fragmented discharge planning process, helps reduce hospital readmissions, incentivizes PAC providers to improve their quality of care, lowers the risk of potential iatrogenic harm, and helps reduce spending growth. Additionally, PAC continues to be an area where providers can improve and ensure that the facilities they use are efficient and offer high-quality care. Preferred provider lists can aid in the ability to further coordinate a patient's care across the care continuum as providers work to build relationships with these organizations.

While some providers currently are creating their own preferred provider networks, there is some reluctance on the part of hospital discharge planners to highlight these choices due to concerns regarding restricting beneficiary choice.² Clearly allowing providers that have or are developing relationships with PAC facilities to create and share these lists with patients would enhance the quality of care and eliminate confusion on what the regulations permit. Without the worry of encroaching on beneficiary choice, providers would then be able to focus on quality improvement efforts with their PAC partners. Beneficiaries would maintain their choice of provider under this policy and would not be obligated to receive care from a specific PAC provider. Preferred provider lists simply offer information to beneficiaries so they may make an informed decision. Beneficiaries are still free to make their own decisions regarding their care once they are discharged from the hospital.

Waive Appropriate Use Criteria for Value-Based Models

Under the Protecting Access to Medicare Act, CMS will require physicians to consult specified AUC before ordering advanced diagnostic imaging services in order for the furnishing provider to receive Medicare reimbursement. Practitioners who order advanced diagnostic imaging services for Medicare beneficiaries will be required to consult a qualified Clinical Decision Support Mechanism (CDSM), which is an electronic portal through which AUC is assessed. CMS has indicated that the purpose of the AUC program is to enable physicians or providers to order the most appropriate test for the patient.³ AMGA contends the AUC requirements add an unnecessary step that delays the provision of care and neither improves quality nor lowers the cost of care. AMGA appreciates the statutory requirement underlying the program and recommends that CMS use its waiver authority as broadly as possible to exempt practitioners who deliver care in value-based models from the AUC program, as physicians participating in these models have no incentive to increase the volume of services provided. Under a value-based system, the selection of the best imaging for the most favorable outcome is already the principal criteria for the physician or practitioner ordering the image. CMS also should delay the 2020 testing period, as the agency has yet to begin its provider education efforts for the new requirements.

² Medicare Payment Advisory Commission June 2018 Report: Medicare and the Health Care Delivery System. Chapter 5: Encouraging Medicare beneficiaries to use higher quality post-acute care providers.

³ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AUCDDiagnosticImaging-909377.pdf>

Outside of alternative payment models, CMS also could meet the AUC requirements by aligning the program with the Medicare Access and CHIP Reauthorization Act (MACRA), which could eliminate some administrative and regulatory burden. In a FFS model under MACRA, inappropriate advanced imaging use is already reflected in the MIPS score of the provider. CMS previously recognized the need to align the Protecting Access to Medicare Act (PAMA) with MACRA when it finalized AUC Consultation through a qualified CDSM as a high-weight Improvement Activity. Given that further reforms likely would require congressional action, CMS should delay the 2020 testing period to provide additional opportunity to incorporate the program into MIPS.

Streamlining Quality Measurement Reporting

Quality measurement is intended to aid providers in improving health care, from both a provider and patient perspective. While CMS has made progress towards centering quality measures on holding providers accountable for patient health outcomes and ensuring quality measures are important to providers and patients under the Meaningful Measures Initiative, there still remains a need to focus quality measurement. Current quality reporting continues to be burdensome, contributing to burnout and added costs for providers. Research has indicated that annually U.S. physician practices in four common specialties spend more than \$15.4 billion and, on average, 785 hours per physician to report quality measures.⁴ Additionally, our own members have reported the cost and burden associated with measure reporting. For example, a 2017 AMGA survey found that for every 100 physicians our members employ, 17 information technology (IT) professionals were needed to support them. These costs are much better spent on caring for patients, not maintaining an expensive IT infrastructure.

Given the immense provider burden with very little added value, the Medicare program should reduce the number of quality measures for all value-based providers and move to a more outcomes-based system supported by claims data. Policymakers should work to harmonize and scale down the amount of existing quality measures for all providers in value-based arrangements. Using a standard set of value measures will help reduce the variation in the measures that are reported and help eliminate unnecessary confusion and administrative burden.

Beyond Medicare, our member groups submit data to different insurance companies in different formats, creating a massive administrative burden and further diverting resources away from providing critical care to our patients. Commercial payers generally follow what the Medicare program does, so as Medicare continues to work to ensure quality measures actually measure meaningful outcomes, commercial payers will hopefully follow.

Worth noting are the 14 quality measures that AMGA's Board of Directors endorsed in 2018. The 14 measures were selected to address the flaws with the current quality measurement and reporting system, which suffers from duplicative measures and a lack of data standardization. Our board members believe these measures, which are a mix of process and outcome measures, are clinically meaningful to both patients and providers and will lead to a more simplistic and cost-reducing quality measurement reporting system.

⁴ Casalino, L.P., et al. US physician practices spend more than \$15.4 billion annually to report quality measures. Health Affairs. 2016.

Reduce Documentation Requirements for DMEPOS

Chapter 5 of the Medicare Program Integrity Manual requires a detailed written order (DWO) for non-drug DMEPOS to include the physician or practitioner signature. Based on this requirement, National and Local Coverage Determinations require that a physician complete and sign a DWO for DMEPOS items, including diabetes test strips. While staff may complete the order, the manual states that the treating physician/practitioner must review the order and “personally sign and date the order.” Our members report the signature requirement for diabetes supplies creates needless delays and confusion about the regulations.

Once a beneficiary has been diagnosed with diabetes mellitus, the need for a signed prescription order for a glucometer and test strips delays access to supplies that the patient often will use multiple times per day. The number of times a patient tests his or her glucose level, however, will fluctuate based on individual conditions. This often results in patients exhausting their supplies early, necessitating them to contact their DMEPOS supplier, who in turn must receive a new signed order from the physician. This requirement creates work and delays for the patient, the supplier, and the physician.

This signature requirement also precludes AMGA’s member organizations from including diabetes testing strips in a standing order. Standing orders and protocols allow patient care to be shared among non-clinician members of the care team, including medical assistants and nurses. While standing orders often are based on national clinical guidelines, practices customize these guidelines to account for their own patient population or care environment. The rationale for the signature requirements is not commensurate to the administrative burden it creates for AMGA’s members, their patients, or their DMEPOS supplier partners.

Evaluate the Need for Advance Beneficiary Notice of Noncoverage

Section 50 of the Medicare Claims Processing Manual establishes the standards for use by providers and suppliers, including laboratories, in implementing the ABN, form CMS-R-131. While AMGA and its members recognize and support the need for beneficiaries to understand what Medicare does and does not cover, there is no minimum threshold that must be met before notice is required. ABN constitutes a significant paperwork burden for providers. CMS recognized this problem when it sought comment in May 2007 on changes to the ABN form. In a request for information in 2007, based on the available data at the time, CMS estimated that the annual cost of delivering ABN was roughly \$326 million, or about \$69 annually per notifier—the physician, provider, practitioner, or supplier that delivers the ABN.⁵ CMS in 2016 revised these estimates and reported that the cost had increased to \$440 million and about \$286 per notifier.⁶

This represents a significant cost to the provider community. Beyond the monetary expense, the requirements of a written notice to inform beneficiaries of potential liability, regardless of the amount, creates an administrative burden for providers. CMS should update its estimates of the burden associated with the ABN requirement and work with the provider community to determine if every test or procedure should be subject to the written notification. For example, an expected cost above a certain threshold could trigger the requirement. Additionally, rather

⁵ Supporting Statement for the Advance Beneficiary Notice of Noncoverage Contained in 42 CFR §411.404 and §411.408.

⁶ Supporting Statement for the Advance Beneficiary Notice of Noncoverage Contained in 42 CFR §411.404 and §411.408 (updated with 2016 data).

than provide a written ABN, the provider could document within the encounter note that the beneficiary's potential financial responsibility was discussed.

Compensate Providers for Translation Services

Federal law and regulations mandate that clinicians ensure that beneficiaries have meaningful access to health care and any needed translation services. While this largely is enforced through regulations promulgated by the Department of Health and Human Services Office of Civil Rights, the rules and subregulatory guidance impose a significant financial and administrative burden on our members. AMGA and our members agree that translation services are important and should be provided as appropriate; however, these services are not reimbursed. As a result, our providers face an unfunded mandate. Should the translation services be provided during an Evaluation and Management visit, our members report that their costs for delivering the care will exceed allowable reimbursements. This creates an untenable financial situation for providers. AMGA recommends that CMS work with the provider community to clarify the expectations for providing translation services and to develop a reimbursement mechanism to ensure that providers can continue to deliver necessary services.

Remove Requirement for Physician Signature for Home Health Services

Currently, a physician signature is required in order for a patient to receive home health services. Even when an NP or PA is the primary clinician caring for the patient, these practitioners must seek approval from a physician. While this requirement may have served an important purpose by ensuring appropriate referrals or reducing the potential for fraud and abuse, requiring a physician signature can create a massive burden for physicians with little value added and can lead to care delays for patients. In fact, this requirement has contributed to the immense workload that our member groups' primary care physicians, who rely heavily on these non-physician practitioners on their care team, already face. Additionally, a patient's care can be delayed if it takes physicians some time to get to the many orders that they must sign daily. As such, we believe CMS should use its authority to waive the physician signature requirement. Our member groups practice care in a team-based environment and non-physician practitioners are a part of this care process. Allowing NPs and PAs to complete these orders will contribute to the goals of team-based care, reduce strain on physicians, and ensure that patients receive the right care at the right time.

We thank CMS for consideration of our comments. Should you have questions, please do not hesitate to contact AMGA's Darryl M. Drevna, senior director for regulatory affairs, at 703.838.0033 ext. 339 or at ddrevna@amga.org.

Sincerely,



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