The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

August 25, 2017

The Honorable Kevin Brady, Chairman
U.S. House Committee on Ways and Means
1102 Longworth House Office Building
Washington, D.C. 20515

The Honorable Richard Neal, Ranking Member
U.S. House Committee on Ways and Means
1139E Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Brady and Ranking Member Neal:

On behalf of The Hospital and Healthsystem Association of Pennsylvania (HAP), which represents approximately 240 member institutions, we appreciate this opportunity to provide input on how to reduce legislative and regulatory burdens on Medicare providers through the "Provider Statutory and Regulatory Relief Initiative."

HAP supports the efforts underway to identify areas for reduced burdens on Medicare providers, so that providers remain focused on directing their resources to providing high-quality patient care. In light of the accelerating transformation of the health care delivery landscape across the country and in Pennsylvania, it is critically important for the regulatory environment to keep pace and reflect these delivery system reforms.

As noted by other commenters, the regulatory burden faced by hospitals is unsustainable. In 2016, for example, The Centers for Medicare & Medicaid Services (CMS) and other agencies of the Department of Health and Human Services (HHS) released 49 hospital and health system-related rules, comprising almost 24,000 pages of text. This initiative promises to provide relief from these burdens.

Below are high-level summaries of regulatory and/or legislative reform priorities identified by our members. We also have submitted—via the subcommittees' website—more detailed information relating to many of these items within the specified template. We also incorporate, by reference, the more comprehensive list of priorities under separate cover by the American Hospital Association (AHA).

1) Take steps to reform the Anti-Kickback Statute, Stark Law, and other restrictions to permit and encourage hospitals to move away from fee-for-service (FFS) toward alternative payment models that pay for value, rather than the volume of care provided.

Congressman Patrick Meehan (R, PA-07) has developed a discussion draft—The Stark Law Modernization Act of 2017—that seeks to modernize the Stark Law and Anti-Kickback Statute for health care provider organizations participating in alternative payment models. HAP is currently in the process of providing suggestions in regard to how to improve this proposed legislation. HAP is supportive of steps included in this legislation and broader recommendations endorsed by the AHA and others for Congress to:

- ***Create an exception under Stark for any arrangement that meets a newly created Anti-Kickback safe harbor for clinical integration arrangements***
- ***Create an Anti-Kickback safe harbor for clinical integration arrangements that establishes the basic accountabilities for the use of incentive payment or shared savings programs among hospitals, physicians, and other providers***
- ***Create an Anti-Kickback safe harbor that permits hospitals to help patients achieve and maintain health***

Public policymakers also are calling for hospitals to coordinate care for their communities and make other improvements in delivering population health. To do that, hospitals need to integrate with physicians and other providers in their community to reward coordinated patient care. However, a restrictive Internal Revenue Service (IRS) ruling is standing in the way of hospitals meeting those demands. Specifically, a recent ruling stripped a commercial accountable care organization (ACO) of its charitable tax exempt status because they pursued a modern approach to clinically integrated health care.

The IRS should publish guidance affirming that tax-exempt hospitals may participate in a private sector accountable care organization without generating adverse tax consequences.

In this guidance, the IRS should publically acknowledge that when hospitals collaborate with health care providers in the community and other physicians with the goals of coordinating care and reducing health care costs, it should be considered under a safe harbor and protected from IRS regulations. Even though ACOs provide financial incentives for providers who implement value-based care, those incentives are primarily benefitting the patients through better population health management programs and patient-centered care.

2) Adjust the Medicare hospital readmission measure to reflect differences in socio-demographic status.

Readmissions are higher in communities that are economically disadvantaged, because a patients' likelihood of being readmitted is affected by access to resources that help them out of the hospital, such as affordable medicines, primary care physicians, and appropriate foods. As a result, the 21st Century Cures Act requires CMS to implement sociodemographic adjustment in the hospital readmissions penalty program starting in fiscal year (FY) 2019.

HAP urges CMS to ensure its implementation of a sociodemographic adjustment in the hospital readmissions penalty program is done in a transparent and fair manner, and that such adjustment is incorporated into its other quality measurement and pay-for-performance programs where necessary and appropriate.

It is worth noting that while CMS has taken steps to propose an adjustment for socioeconomic status in its recent Inpatient Prospective Payment System (IPPS) proposed rule, the proposed rule does not include detailed specifications necessary to comment fully regarding the methodology.

3) Adjust the Medicare Value-Based Payment (VBP) Methodology to adequately account for community and rural hospitals with low volumes.

In Pennsylvania, hospitals have been working very hard to drive down their infection rates. Some hospitals that have achieved superior performance in their infection rates, with zero infections quarter after quarter, have recently been negatively impacted by unintended consequences of the measurement methodology utilized by the VBP Program.

The methodology requires that hospitals have at least 1.0 predicted infections in order for an infection measure to count toward the Safety of Care Domain in the VBP calculation. For community hospitals that have virtually eliminated hospital-acquired infections, their predicted infection rate almost always falls below 1.0. Hospitals also must have a minimum of three measures being scored to obtain a Safety of Care Domain score. In the event that hospitals do not meet the minimum requirements in the patient safety domain, the other domains are proportionately reweighted to determine a total performance score. In a practical sense, hospitals that have been effective in driving down infection resulting in less than one predicted infection are penalized by the measure not being scored, rather than rewarded for their work.

CMS should revisit the volume threshold methodology related to the minimum of 1.0 predicted infections to account for and reward hospitals that have been successful in their efforts to drive down infection rates. Specifically, CMS should include an adjustment to the minimum number of predicted infections, decreasing the current 1.0 to 0.1 in current IPPS rulemaking.

4) Make future bundled payment programs voluntary.

Through the Center for Medicare & Medicaid Innovation (CMMI), CMS established a new mandatory bundled payment model for cardiac care and expanded a mandatory bundled payment model for comprehensive joint replacements. While it is important to offer opportunities to explore new payment models, CMMI engaged in regulatory overreach by making them mandatory. Hospitals should not be forced to bear the expense of participation in these complicated programs if they do not believe they will benefit patients.

CMS has recently proposed to cancel mandatory bundled payment models and make changes to an existing bundled payment initiative focused around joint replacements.

HAP applauds the Administration's proposal and urges that any new bundled payment programs be voluntary.

5) Expand Medicare coverage of telehealth services.

Hospitals are embracing the use of telehealth technologies because they offer benefits such as virtual consultations with distant specialists, the ability to perform high-tech monitoring without requiring patients to leave their homes, and less expensive and more convenient care options for patients. However, coverage and payment for telehealth services remain major obstacles for providers seeking to improve patient care. Medicare, in particular, lags far behind other payers due to its restrictive statutes and regulations.

Specifically, Medicare currently pays for telehealth services when the patient being treated is in a health professional shortage area or in a county that is outside any metropolitan statistical area, as defined by the Health Resources and Services Agency and the U.S. Census Bureau, respectively. The telehealth site must be a medical facility, such as a physician's office, hospital, or rural health clinic, and not the patient's home. Furthermore, Medicare will only pay for "face-to-face" interactive video consultation services in which the patient is present, and does not generally cover store-and-forward applications (the transmission of digital images) as they do not typically involve direct interactions with patients.

As CMS noted in the CY 2018 Physician Fee Schedule proposed rule (CMS 1676-P), statute specifies both the types of entities that can serve as originating sites and the geographic qualifications for originating sites. This restriction limits the delivery of medically necessary and potentially lifesaving services being delivered to patient beneficiaries. Expansion of telehealth services would improve care to patient beneficiaries and ultimately reduce total health care expenditures. By way of illustration, consider a patient in the intensive care unit of a community hospital. Telehealth would facilitate physician–driven clinical management and communication after hours improving clinical outcomes for the patient. In addition, expansion of telehealth services would improve patient access to specialists.

In light of these severe geographic constraints and other requirements, most Medicare beneficiaries are not eligible to use this service.

HAP urges Congress and the Administration to expand Medicare coverage, such as by a presumption that Medicare-covered services also are covered when delivered via telehealth unless CMS determines on a case-by-case basis that such coverage is inappropriate. This change should extend to the Medicare Advantage (MA) program so that MA plans can make services delivered via telehealth available more broadly to their Medicare enrollees.

6) Allow flexibility for providers who want to share treatment space to address gaps in patient access to care.

Medicare permits hospitals to establish "provider-based" outpatient locations. This designation allows hospitals to treat certain departments and facilities located outside of the hospital campus as part of the hospital for billing purposes. Both the hospital and the provider-based locations must be licensed under the same CMS certification number and each outpatient location must be accredited as a hospital outpatient department. Provider-based locations must be administratively and financially integrated with the hospital, and hospitals must meet other stringent standards relating to public awareness, ownership and control, and administration and supervision to demonstrate that the location is fully integrated into the clinically operations of the hospital.

As Pennsylvania's hospital industry strives to deliver more efficient and cost-effective care, hospitals are investing in new care models and introducing new patient-centered service offerings. Many hospitals have moved their services to the community (by establishing "provider-based" locations) in order to remove geographic barriers to care. They co-locate services with other providers in order to offer a comprehensive range of medical services and better meet patient needs.

Recently, CMS issued several very restrictive interpretations of the Medicare Conditions of Participation (CoP) and provider-based payment rules that threaten appropriate reimbursement of essential provider-based services simply because these services are delivered in locations that share non-clinical spaces (i.e., entry ways, restrooms, registration desks or common areas) with other providers. Overly prescriptive interpretations of the sharing or "co-location" rules can create patient access or quality of care problems and subvert broader goals to provide more coordinated and patient-centered care at lower cost. A lack of transparency or seemingly inconsistent/changing interpretation leave the industry hamstrung as to how to best adapt current provider-based or plan future projects.

Pennsylvania hospitals are frustrated with the lack of consistency in the interpretation and enforcement of Medicare CoP and payment standards. A central office at CMS establishes certification protocols and policies, described in the online State Operations Manual, and

develops interpretive guidance on how compliance with the CoP standards should be assessed. The agency utilizes both accrediting organizations (AO) and state health agencies (SA) for its onsite survey activities, and expects those entities to adhere to CMS' standards interpretations. Particularly with respect to the shared space issue, Pennsylvania hospitals have experienced ambiguity with respect to the interpretation of standards between the central office at CMS, the regional office, and the SAs and AOs.

On a broader level, HAP believes CMS must:

- ***Ensure that CMS interpretive guidance is updated on a regular basis and encourage stakeholder engagement and review prior to release, and allow sufficient time for implementation.***
- ***Clarify the Medicare Survey and Certification program organization, management, and structure, and ensure closer oversight over survey contractors***
- ***Increase training and retraining of surveyors to promote consistent application of standards. Further, bring about a transparent process that will explain internal agency mechanisms in place to avoid variation in the interpretation of standards and citations.***

Specific to shared space, HAP urges CMS to allow (and codify in sub-regulatory guidance) flexibility for hospitals to share space to address gaps in patient access to care.

7) Ensure adequate reimbursement and appropriate flexibility for Provider-based Hospital Outpatient Departments.

Section 603 of the Bipartisan Budget Act (P.L. 114-74), enacted November 2, 2015, imposes site-neutral payment provisions for off-campus provider-based hospital outpatient departments (HOPD). The site-neutral policy mandates that items and services furnished at an off-campus provider-based department no longer be billed under the outpatient Medicare reimbursement system. Instead, the off-campus departments would be paid under the Medicare Physician Fee Schedule. A "grandfather clause" preserved payments for excepted off-campus provider-based HOPDs that were billing for Medicare outpatient services before a date certain, and the 21st Century Cures Act included provisions to address situations where hospitals were in a "mid-build" situation when the Act was passed.

The payment rule put forth last year sets "site neutral" Medicare reimbursement rates at 50 percent of the outpatient payment rate. Under the proposed rule this year, the payment rates would be reduced to only 25 percent of the outpatient rate.

CMS should revise the proposed applicable payment rates to appropriately reimburse for services provided by non-grandfathered HOPDs, and allow for maximum flexibility in relocation and change of ownership of grandfathered facilities.

8) Establish a policy mechanism to ensure that Medicare Administrative Contractors provide transparent notice of pre-payment denials and an opportunity to challenge denials.

A Medicare Administrative Contractor (MAC) is a private health care insurer that has been awarded a geographic jurisdiction to process Medicare Part A and Part B claims for Medicare FFS beneficiaries. CMS relies on a network of MACs to serve as the primary operational contact between the Medicare FFS program and the health care providers enrolled in the program. MACs perform many activities to include "pre-payment" reviews that function the same as audits but in the absence of full transparency.

In Pennsylvania, hospitals have experienced instances where a MAC has requested significant documentation to justify the provision of a medical services for patients with documented chronic and complex conditions. While this review function is important and legitimate, the process is onerous and overly burdensome. In fact, the services are automatically selected for review by the MAC based upon established edits in the claims adjudication system. Moreover, the information requested is significantly more burdensome and may include multiple years of data points, such as the original patient assessment that gave rise to the need for infusion therapy. Such documentation may reside in outpatient ambulatory records maintained by physicians and not the hospital, resulting in labor intensive efforts to gather and submit the information. In addition, pre-payment denials made by the MACs are issued based upon a line item basis that can only be found in the CMS Fiscal Intermediary Standard System (FISS) system. Providers spend a significant amount of time trying to determine which line of the claim was problematic, so the claim can ultimately be paid. In other words, hospitals submit information necessary to justify treatment, but they are not notified of pre-pay "denials" in an open and transparent manner.

HAP urges CMS to evaluate pre-payment denials made by a MAC, and evaluate policy changes that provide adequate transparency to providers, to facilitate an opportunity to challenge denials.

9) Hold Medicare Recovery Audit Contractors (RAC) accountable.

Medicare RACs are paid a contingency fee that financially rewards them for denying payment to hospitals, even when their denials are found to be in error. Hospitals in Pennsylvania have explained that this incentive may lead to overly aggressive recovery actions.

For example, in the program integrity field, regulatory violations are often grouped into two categories: overpayments and technical violations. While there is certainly overlap between the two categories, overpayments typically involve situations where the return of a claim is appropriate because medical necessity for the service has not been demonstrated, or another fundamental requirement of the service has not been met. Technical violations, on the other hand, are situations where it is clear that the service was rendered and medical necessity was established, but a technical violation nonetheless exists. For example, a claim may be denied because the physician signature was obtained a few hours too late. Despite the differences in the scope and seriousness of the violation, audit contractors are allegedly recovering full overpayments in all instances.

CMS should conduct a review of recovery processes and revise the RAC contracts to incorporate a financial penalty for poor performance by RACs, as measured by Administrative Law Judge appeal overturn rates.

10) Evaluate appropriateness of Inpatient Rehabilitation Unit documentation requirements and overpayment recovery actions.

Inpatient rehabilitation facilities (IRF) provide intensive rehabilitation services using an interdisciplinary team approach in a hospital environment. Admission to an IRF is appropriate for patients with complex nursing, medical management, and rehabilitative needs.

CMS requires that a Preadmission Screening—a detailed, comprehensive evaluation of the patient's condition and need for rehabilitation therapy and medical treatment—must be conducted by a licensed or certified clinician within the 48 hours immediately preceding the IRF admission. A rehabilitation physician must review, sign, and date the screening before the patient is admitted to the IRF. Providers also must perform a post-admission physician evaluation within the *first 24 hours after admission to the IRF* to document the patient's status on admission to the IRF, compare it to that noted in the preadmission screening documentation, and begin development of the patient's expected course of treatment and overall plan of care.

Both evaluations require extensive documentation and certification. If screenings are not completed within a prescribed time frame payment for IRF services are denied. Pennsylvania hospitals have explained that a minor gap in staffing or an error in physician workflow could result in a payment denial for a patient's entire inpatient rehabilitation stay.

CMS should either expand the time frames for completing the pre- and post-admissions screening or discontinue its practice of denying the payment for the entire IRF stay if assessments exceed the 48 and 24 hour time frames.

11) End onerous home health agency pre-claim reviews.

Under CMS' home health pre-claim review demonstration, home health agencies in five states were subjected to a mandatory Medicare demonstration launched in August 2016 that is testing a requirement for pre-claim review. Launched in Illinois in August 2016, but currently under a national pause, the demonstration added unnecessary and complex time and paperwork requirements, which, if fully implemented, would impact an estimated one million home health claims per year.

HAP supports the Administration's current pause on this onerous demonstration and urges CMS to instead consider more targeted policies, such as education and other interventions that only focus on agencies and/or claims with high payment error rates. Home health agencies with no payment or fraud issues should face no additional compliance interventions.

12) Eliminate the home health services face-to-face requirement for attending physicians.

Medicare pays for home health services only if certain requirements are met. These requirements include certain documentation in the patient's medical record, a narrative from the attending (certifying) physician justifying the provision of care at home and recertification at certain points in time. The process is flawed and onerous. For instance, the certifying physician typically does not do the discharge rounds, and others who are licensed to perform these functions may not have actually cared for the patient, which is a requirement of the face-to-face encounter. The burden of satisfying requirements to demonstrate home bound status and skilled needs is significant, and if these requirements are not met, the claim is denied notwithstanding the medically necessary and clinically justified skilled services provided. Moreover, the home health care provider does not have a means to ensure physician compliance with the content of their patient progress notes while obligated to provide for the clinical needs of the patient in terms of skilled nursing and therapy services.

CMS should reconsider the process for establishing payment of home health services and align requirements with hospital and physician workflows. The order for home health care skilled services with an appropriate supporting diagnoses should be sufficient consistent with other services ordered by a licensed provider. Furthermore, the content of the medical record showing services provided such as a joint replacement should be sufficient to justify medically necessary skilled services.

13) Permit hospitals to provide Medicare patients quality information relating to post-acute providers, to allow an "informed choice."

Under new payment models, hospitals face financial penalties if their Medicare patients are readmitted following release. As a result, hospitals have an incentive to steer patients who require care after discharge to higher-quality post-acute providers, where they are less likely to need hospital readmission.

Due to restrictive Medicare Conditions of Participation, however, hospital staff provide lists of post-acute providers that contain only minimal information because patient choice laws appear to forbid hospitals from influencing the selection process. While federal statutes protect the right of Medicare patients to choose their own providers, nothing in the law prevents hospitals from helping patients make an informed choice.

CMS should modify Medicare's conditions of participation to allow hospitals to provide patients information on the quality of post-acute care providers and assist patients in making an informed choice of care providers.

Adopting a less strict approach would allow patients to make better, more-informed choices that would lead to improved outcomes for both patients and hospitals.

14) Protect the ongoing financial viability of long-term care hospitals by permanently rescinding the 25 Percent Rule.

Long-term care hospitals (LTCH) furnish extended medical and rehabilitative care to individuals with clinically complex problems, such as multiple acute or chronic conditions, that need hospital-level care for relatively extended periods. To qualify as an LTCH for Medicare payment, a facility must meet Medicare's conditions of participation for acute care hospitals and have an average inpatient length of stay greater than 25 days. LTCHs serve a critical role within the Medicare program by treating the sickest patients who need long hospital stays.

In recent years, Congress created a two-tiered payment system, under which LTCHs are paid a LTCH level rate for patients with higher severity of illness levels, and a lower, "site-neutral" rate (comparable to general acute care hospitals) for patients with a lower medical acuity. This change has resulted in a 54 percent reimbursement reduction, on average, to one out of two current cases.

In addition, LTCHs operate under what is known as the 25 Percent Rule, which reduces LTCH payments for patients transferring from a general acute-care hospital to an LTCH and who exceed a 25 percent referral threshold. Currently, the policy is partially implemented at a more lenient level due to multiple Congressional interventions that have temporarily blocked full implementation.

HAP is opposed to the 25 Percent Rule because it would materially reduce payments for care provided to patients who meet the statutory criteria for a full LTCH PPS rate. Moreover, given the scale of LTCH cuts under site-neutral payment, implementing the 25 Percent Rule payment penalties would unjustifiably exacerbate the instability and strain on the field, which would threaten access for the high-acuity, long-stay patients that require LTCH-level care. Finally, and perhaps most importantly, in light of the site-neutral payment implementation, the 25 Percent Rule has become outdated, excessive, and unnecessary.

HAP strongly endorses the CMS' recent proposal to implement a 12-month moratorium on the full 25 Percent Rule, beginning October 2017. More importantly, HAP urges CMS to use its authority to permanently rescind the unnecessary 25 Percent Rule.

15) Rescind the 60 Percent Rule or, at a minimum, restore compliant codes for IRFs under the rule.

Of all the IRF regulations that deserve careful consideration, the IRF 60 Percent Rule is particularly worthy of reconsideration. By requiring IRFs to derive at least 60 percent of the patient case mix from a list of 13 specific medical conditions, the 60 Percent Rule narrowly defines IRFs by the patients they treat. While decisions pertaining to where patients receive post-acute care should be made based upon patients' rehabilitative, medical, and nursing needs and their physicians' judgment as to where those needs are optimally met, the 60 Percent Rule functions to displace those decisions and largely determines which patients are able to be treated at an IRF, and which are not. The conditions that qualify toward the 60 percent threshold are largely based upon outdated data and information from the 1970s and do not reflect many of the innovative and value-based care practices that are the hallmarks of modern rehabilitative practice.

HAP strongly believes the 60 Percent Rule should be rescinded.

Absent a complete rescission of the policy, changes should be made to the application of the rule. During the transition to ICD-10-CM, CMS reduced the number of conditions that qualify toward compliance under the IRF 60 Percent Rule. Yet certain codes that qualified under ICD-9-CM were inadvertently omitted as a result of the conversion to ICD-10-CM.

HAP supports the Administration's current proposal to restore some of those codes so they again count toward the 60 Percent Rule presumptive compliance test. However, we urge CMS to also consider adding those codes that were omitted from the proposed restoration.

16) Cancel Stage 3 of the "meaningful use" program.

Pennsylvania hospitals and stakeholders are working together to implement health IT that improves patient quality and reduces health care errors and costs.

However, hospitals face extensive, burdensome and unnecessary "meaningful use" regulations from CMS that require significant reporting on the use of electronic health records (EHR) with no clear benefit to patient care. These excessive requirements are set to become even more onerous when Stage 3 begins in 2018. They also will raise costs by forcing hospitals to spend large sums upgrading their EHRs solely for the purpose of meeting regulatory requirements.

HAP urges the Administration to cancel Stage 3 of meaningful use by removing the 2018 start date from the regulation. The Administration also should institute a 90-day reporting period in every future year of the program, and gather input from stakeholders on ways to further reduce the burden of the meaningful use program from current requirements.

17) Remove the current barriers to sharing patient information for clinically integrated care and allow treating providers to access their patients' substance use disorder records.

The Health Insurance Portability and Accountability Act (HIPAA) regulations currently restrict the sharing of a patient's medical information for "health care operations" like quality assessment and improvement activities, including outcomes evaluation. The challenge that this strict regulatory prohibition poses in the integrated care setting is that frequently patients do not have a relationship with all of the providers among whom information should be coordinated.

A clinically integrated setting and each of its participating providers must focus upon and be accountable for all patients. Moreover, achieving meaningful quality and efficiency improvements in a clinically integrated setting requires that all participating providers be able to share and conduct population-based data analyses.

The HIPAA medical privacy regulation enforced by the Office for Civil Rights should permit a patient's medical information to be used by and disclosed to all participating providers in an integrated care setting without requiring that individual patients have a direct relationship with all of the organizations and providers that technically "use" and have access to the data.

In addition to the barriers to sharing medical information for "health care operations," requiring individual patient's consent for access to addiction records from federally funded substance use treatment programs, as current requirements do, is an obstacle to an integrated approach to patient care. It also may unknowingly endanger a person's recovery and his or her life. Pennsylvania has established barriers under state law, but federal obstacles also exist.

The Administration should fully align requirements for sharing patients' substance use records with the requirements in the HIPAA regulation that allow the use and disclosure of patient information for treatment, payment, and health care operations. Doing so would improve patient care by ensuring that providers and organizations who have a direct treatment relationship with a patient have access to his or her complete medical record.

Thank you for your consideration of HAP's comments regarding opportunities to reduce Medicare regulations and mandates, and to improve care for individuals served by this important program.

If you have any questions, please contact me at (202) 863-9287 or Jeffrey Bechtel at (717) 561-5325.

Sincerely,

Laura Stevens Kent
Vice President
Federal Advocacy