AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

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VIA ELECTRONIC MAIL
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Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-8013

Re: CMS-9928-NC, CMS' Request for Information on Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act

Dear Mrs. Verma:

On behalf of the Adventist Health Policy Association (AHPA), we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Request for Information (RFI) on Reducing Regulatory Burdens Imposed by the *Affordable Care Act* (ACA). Our organization represents the policy perspective of five Seventh-day Adventist health systems that include 82 hospitals and more than 300 other health facilities in 17 states and the District of Columbia.

AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to urban areas of California. CMS seeks comment on creating a more patient-centered health care system that adheres to the key principles of affordability, accessibility, quality, innovation and empowerment.

We believe that we can provide an objective and sound policy voice in response to CMS' RFI. After reaching out to our member hospitals, we identified eight issue areas where regulatory reform could be achieved. Although most of these areas do not relate to the ACA, we believe that they align with CMS' overall goal of reducing the administrative burden placed on health care providers. Below are the eight issue areas in which we provide comments.

- Hospital Readmissions Reduction Program
- Hospital Outpatient Provider-Based Departments
- De Minimus Rotations of Hospital Residents
- Stark Modernization
- Anti-Kickback Safe Harbor
- Group Reporting under the Medicare Access and CHIP Reauthorization Act of 2015
- Guiding Patients to the Best Provider
- Immediate Jeopardy

Hospital Readmissions Reduction Program

In FY 2012, as required by Section 3025 of the ACA, CMS created the Medicare's Hospital Readmissions Reduction Program (HRRP). The HRRP financially penalizes hospitals who have higher than expected risk-standardized 30-day readmission rates for the following conditions: Acute Myocardial Infarction (AMI), heart failure, pneumonia, Chronic Obstructive Pulmonary Disease (COPD), hip/knee replacement and Coronary Artery Bypass Graft (CABG) surgery.

While reducing readmissions is important to improve the quality of care, AHPA believes that the HHRP should be revised to address the following issues:

- The inclusion of readmissions unrelated to the initial admission in the determination of the HRRP penalties.
- The lack of risk-adjustment for key social risk factors that influence the likelihood of readmission.
- Aggregate penalties under the readmissions formula remain constant even when national readmission rates decline.

All-Cause Readmissions Measure

Currently, CMS penalizes hospitals for all-cause readmissions, even those that are not preventable or associated with the care delivered by the hospital. For example, if a patient fractures his leg after being hospitalized for pneumonia and is readmitted, that would count toward a readmission penalty.

AHPA believes that hospitals should not be held accountable for unplanned, unrelated admissions. Many readmissions are outside of a hospital's control and may be unavoidable due to a variety of factors, such as the natural progression of a disease or even a patient's noncompliance with its medical treatment. Avoidable, unplanned readmissions related to the original admission—such as an infection after receiving a surgical procedure in the hospital—are included in the HRRP and should be the focus of hospital improvement efforts.

Accounting for Social Risk Factors

The HRRP program currently does not account for social risk factors that may influence patient outcomes, such as the lack of available support resources in the community, the lack of caregivers in the home, or the ethnicity and educational background of the patient. This policy places hospitals that treat a disproportionate share of vulnerable populations at a significant financial disadvantage. For example, hospitals that care for low-income patients tend to incur higher readmissions penalties because patients in these communities are more likely to have limited access to treatments that would ensure recovery.

As mentioned in our comments to CMS on the FY 2018 Inpatient Prospective Payment System (IPPS) proposed rule, we strongly believe that accounting for social risk factors is crucial to the transition from volume to value-based care. Adjusting for these factors encourages providers to examine the health of patients beyond the walls of a hospital or health care facility. It also provides CMS with a mechanism to better track the impact of social risk factors on health care outcomes and potentially identify best practices. This will likely help improve patient outcomes for vulnerable populations. Adequate risk-adjustment for social risk factors would also help lessen the practice of "cherry-picking," in which providers reject the sickest and most vulnerable patients out of fear of being penalized for having poor quality scores.

Readmission Penalties

Currently, the aggregate penalties for the readmissions formula remain constant even when national readmission rates decline. **AHPA believes that there should be a fixed target for readmission rates so that penalties go down when industry performance improves.** This recommendation was shared by the Medicare Payment Advisory Commission (MedPAC) in its June 2013 report to Congress. We believe that this approach to calculating hospitals' readmission penalties would help achieve CMS' goal of reducing readmission rates without unfairly penalizing hospitals.

Hospital Outpatient Provider-Based Departments

In Fiscal Year 2001, CMS issued regulatory guidelines to providers who function as single entities but own and operate multiple Hospital Outpatient Provider-Based Departments (HOPDs), locations and facilities.[1] Under the guidelines, CMS specified criteria that HOPDs need to meet to obtain Provider-Based status. One of the regulations specifically requires that HOPDs supply documentation that clearly identifies the facility as being part of the main provider. Examples of documentation that fall under the requirements include patient registration forms, letterhead, advertisements, signage and websites. AHPA believes that the current provider-based regulations are outdated and do not recognize the efficiencies associated with operating as a health care system. Because CMS requires each HOPD to identify their main provider on *all* forms, when any update needs to be made, each HOPD within a health care system needs to update their corresponding form. In a large health care system, this could mean updating 40 forms instead of a single form. Due to these regulations, health care systems are unable to standardize certain forms, such as patient consent forms. This creates additional compliance responsibilities and administrative burden. Therefore, **AHPA recommends that CMS provide flexibility to HOPDs regarding the requirement to identify, in all patient forms, the main provider associated with the facility.**

For hospitals with several HOPDs, having to change each HOPD form and letterhead can increase overhead costs. We agree with CMS that a facility's general documentation, including signage and advertisement, should clearly identify the main provider's name. This allows patients to visibly recognize the facility they are entering to receive health care services and helps avoid confusion. However, if most facility's signage reflects the name of the main provider, but not all of the forms the HOPD uses, CMS should provide flexibility to allow HOPDs that are part of a health care system to standardize only certain forms for purposes of efficiency. While not all forms would have the name of the health care system, all other documentation would clearly identify the name of the main provider associated with the HOPD. We are concerned that the current requirements increase administrative burden among HOPDs and incur unneeded costs to providers.

De Minimis Rotations of Hospital Residents

To date, many hospitals are limited in their ability to start a Graduate Medical Education (GME) program because of an unintended Per-Resident Amount (PRA) cap that is triggered when a hospital hosts residents for training rotations. As part of their training, residents participating in GME programs rotate to non-teaching hospitals to gain experience in various specialties and in serving different populations. However, due to informal interpretations by CMS, non-teaching hospitals are having their PRA cap

[1] Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (April 18, 2003). Retrieved at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/a03030.pdf.

triggered when hosting residents, no matter how short the rotation is. This impedes the ability of hospitals to start a residency program of their own in the future and penalizes hospitals that want to host residents.

AHPA recommends that CMS specify, through regulatory guidance, that neither a hospital's PRA nor its cap-building window be triggered by the presence of a small number of residents performing brief rotations at a hospital. We also urge the Agency to lift the PRA cap for those hospitals who had it inadvertently triggered because of hosting residents. Many residency programs are based in settings in which the clinical experience available to the residents is limited. To provide broad clinical experience, residency programs ideally have their residents do rotations at other institutions. Due to CMS' PRA restriction, rural communities can miss out on opportunities for residents to experience practicing in rural settings at a time when these hospitals are in desperate need of trained physicians. Residents are also, essentially, precluded from an educational exposure that may be necessary to ensure a comprehensive clinical experience.

AHPA is confident that CMS has the statutory authority to conclude that de minimis rotations do not trigger a cap. In the *Balanced Budget Act of 1997* (BBA), Congress capped for the first time the total number of residency positions that Medicare would support for new programs. However, Congress did not define what constitutes a new residency program or dictate a methodology for determining cap adjustments for new programs. These decisions were left for CMS to address through rulemaking. The BBA states:

> "The Secretary shall, consistent with the principles [in the same subsection governing resident caps], prescribe rules for the application of [resident caps] in the case of medical residency training programs established on or after January 1, 1995."[2]

Throughout the years, CMS has exercised the authority granted by the BBA to interpret the cap rules for new GME programs. For example, in 2012, CMS extended the cap-building period for new programs from three to five years. This change was not the result of legislative action. In extending the cap-building period, CMS stated that the Agency was seeking to address "concerns about teaching hospitals having insufficient time to 'grow' their new residency training programs and to establish an appropriately reflective permanent FTE resident cap."[3]

Stark Modernization

Congress enacted the Stark Law to prohibit physicians from referring Designated Health Services (DHS) payable by Medicare or Medicaid to any entity with which the physician had a financial relationship. While the law was created with the intention of curbing overutilization of resources inherent in a Fee-For-Service (FFS) environment, the regulation has become increasingly outdated and costly to providers. As we shift to a value-based system, Stark Law continues to penalize providers and impede hospitals and physicians from coordinating care across the continuum.

AHPA recommends that CMS create a Stark regulatory exception for clinical integration arrangements. Many of the Stark Law rules are incompatible with value-based payment models that both Congress and CMS are promoting. This is highlighted by the fact that regulatory waivers have been

[2] 42 U.S.C. § 1395ww(h)(4)(H)(i).
[3] 77 Federal Register. 53258, 53416 et seq. (August 31, 2012). Retrieved at: https://www.gpo.gov/fdsys/pkg/FR-2012-08-31/pdf/FR-2012-08-31.pdf.

issued for innovative payment and service delivery models such as the Medicare Shared Savings Program (MSSP), the Bundled Payments for Care Improvement Initiative (BPCI) and the Accountable Care Organization (ACO) Program. The extent of these waivers inherently show the conflict between payment reform and the current regulatory model.

To continue to make the shift to value-based care, hospitals must be able to financially align themselves with shared incentives, shared resources and seamless technology. For example, in rural settings that have limited providers, a hospital physician may have a limited pool of Post-Acute Care (PAC) providers to refer from. Having shared information and incentives will better allow these providers to coordinate care. However, Stark Law impedes such alignment and innovation. Stark Law also places unreasonable constraints on how hospitals may finance the infrastructure needed to support a physician in diagnosing and ordering treatments for a patient. For example, without the ability to finance Electronic Health Records (EHRs), a patient's treatment and diagnosis may be hampered. Due to current laws, hospitals cannot partner with physicians to finance these needed tools.

Moreover, under the Stark Law and the Medicare Conditions of Participation (CoPs), hospitals cannot provide any incentive to physician partners to be more efficient in the ordering of services. Even hospitals that operate in a consolidated, employment-only model are severely constrained in their ability to coordinate and incentivize their physicians to practice high quality, evidence-based medical care. We believe that this is contrary to CMS' goal of transitioning to a value-based system.

AHPA recommends that CMS, through rulemaking, interpret the Stark Law in a way that enables providers to have a high degree of confidence that their claims comply with the statute. As a strict liability statute, the Stark Law's breadth, complexity and inscrutability has created a minefield for the health care industry. Whether the complete scope of needed reforms can be accomplished without legislative action is doubtful, but we think CMS has the authority to significantly improve the current situation. It can implement the Stark Law, through rulemaking and published interpretations, in a way that is consistent with the goals of health care reform. CMS should interpret the statute so that well-intentioned and diligent health care providers are not penalized with overpayment and liability.

Specifically, we request that CMS clarify the definitions of volume and value standards, fair market value and commercial reasonableness. The volume and value standards constrain any arrangements that seek to compensate physicians for cost-efficient care and use of resources in the inpatient and outpatient settings, including such simple actions as compliance with an evidence-based clinical protocol. By definition, a reduction in costs for patient care reimbursed on a prospective fixed basis (whether Diagnosis Related Group or Ambulatory Payment Classification) results in increased profits (or reduced loss) for that episode of care. Thus, any sharing of those savings with physicians arguably results in compensation that varies with or takes into account the "value" of the referral. Since physicians control the great majority of patient care inputs, any meaningful attempt to constrain costs must incentivize them.

Importantly, the very vagueness and ambiguity in the critical terms "fair market value," "take into account volume or value," and "commercial reasonableness," combined with the enormous potential for disallowed claims and False Claims Act damages and penalties, make prudent providers extremely wary of adopting innovative compensation methodologies. Given the strict-liability structure of Stark, providers cannot rely on expert counsels' advice and have no assurance that CMS, the Office of the Inspector General (OIG), the Department of Justice (DOJ), or a relator will not challenge any innovative compensation methodology. Moreover, providers have the burden of proof that they comply with the

conditions in the exceptions. Simply put, given the ambiguity of critical terms, the exceptions are not reliable protection, thereby chilling adoption of innovative arrangements.

AHPA also recommends that CMS extend regulatory waivers to commercial plans. The Center for Medicare and Medicaid Innovation (CMMI) and the OIG have the authority to expand both the Medicare MSSP and the CMMI program waivers to corresponding coordinated care arrangements with commercial plans that are aligned with the aims of the MSSP and CMMI payment models. Now that ACOs engage in both Medicare and commercial markets, the government should allow waivers to be applied to commercial relationships as well. This would incentivize greater physician participation in ACOs and other CMMI programs, which would be consistent with the principles applicable to these Medicare programs.

Anti-Kickback Safe Harbor

Congress enacted the Anti-Kickback Statute to prohibit the exchange of anything of value that serves to induce (or reward) the referral of federal health care program business. Since its enactment, Congress has made several exceptions to the statute by authorizing CMS to define payments and business practices that will not be considered a kickback.

To encourage the transition to value-based care, AHPA recommends that CMS create an Anti-Kickback safe harbor for clinical integration arrangements involving incentive payment or shared savings programs among hospitals, physicians and other providers. With the move toward value-based care, a hospital's responsibility for patient care no longer begins and ends in the hospital setting or any other site of care provided by the hospital. Instead, it expands beyond the walls of a hospital and through the continuum of care. However, current laws such as the Anti-Kickback statute, impede hospitals from providing such assistance. We believe CMS could work with the OIG to ensure that arrangements under this safe harbor are transparent and well monitored. For example, any performance standards that providers use to govern collaboration (e.g., required care protocols, metrics used to award performance bonuses) could be required to be consistent with accepted medical standards and reasonably fit for improving patient care. Performance under integration arrangements could also be internally reviewed to guard against adverse effects.

AHPA also urges CMS to create an Anti-Kickback safe harbor that permits hospitals to help patients achieve and maintain health. Currently, the general prohibition on providing anything of value to "induce" the use of services paid for by the Medicare program also applies to assistance to patients. With health care becoming more consumer-centric, we believe there is a need to create more programs that encourage patient's active engagement in their wellbeing. In December 2016, the OIG recognized this need by implementing new safe harbors for certain patient incentive arrangements and programs. However, we believe that more needs to be done in this area. For example, the new Anti-Kickback safe harbor protects transportation assistance for patients to obtain medically necessary items or services under certain conditions. However, it does not cover transportation assistance for a patient to access nonmedical care or meet other needs related to health (e.g., access to social services, counseling, food bank). OIG's protection for assistance other than transportation is similarly too narrow. CMS should explore providing a safe harbor for services that encourage, support or help improve access to care. Arrangements protected under the safe harbor should also be protected from financial penalties under the Civil Monetary Penalties (CMPs) for providing an inducement to a patient.

Group Reporting Under MACRA

In 2015, Congress passed the *Medicare Access and CHIP Reauthorization Act of 2015 (*MACRA) to change the way physicians are reimbursed and repeal the Sustainable Growth Rate (SGR) formula. MACRA ties physician payments to quality by creating two paths for reimbursement: The Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs).

Under MIPS, payments for physicians and other clinicians will be adjusted up or down based on how they perform with respect to four performance categories. To report their performance, MACRA grants physicians the option to report quality data as a group or as an individual. Under group reporting, physicians will get a payment adjustment based on the group's performance. A group is defined as a set of clinicians sharing a common Tax Identification Number (TIN), no matter the specialty. Essentially, group scoring treats all physicians in the group as if they were one individual. Under individual reporting, a physician's payment adjustment is based solely on the performance of one individual instead of a group.

AHPA recommends that CMS revise MACRA's reporting requirements to facilitate the seamless reporting of data by physician groups. We believe that this is necessary to address two unique situations where providers within a TIN:

- Do not use the same Electronic Health Record (EHR).
- Are part of a unique specialty (transplant surgeons, neuropsychiatrists, etc.)

Physicians with Different Electronic Health Records

Currently, physicians reporting as a group are required by CMS to submit their quality performance data via the same EHR. Because large groups often have providers on different EHRs, the inability to submit data as a group using multiple EHRs is causing undue administrative burden to both providers and EHR vendors. CMS is placing the burden on vendors to identify a way to incorporate data from other EHR's or from providers on paper into the reporting EHR.

We recommend that CMS allow groups to report data using multiple EHRs and aggregate the data to provide a final score. Even if the aggregation tool was manual, the group reporting could perform this and identify a composite score for their TIN. Currently, there is no way to do this.

Physician Specialists Within a Group

When reporting as a group, Eligible Clinicians (ECs) are currently prohibited by CMS from reporting as an individual for some measures and as a group for others. This means that all members of the TIN, regardless of their specialty, must report the same measures to CMS.

AHPA believes that physicians should have the option to select individual measures or specialty specific measure sets when reporting as a group. We believe that accounting for these measures would offer a more appropriate evaluation of physician performance within a group.

Guiding Patients to the Best Provider

The Medicare statute states that any individual who is entitled to benefits under Medicare Part A or Part B may obtain health services from any institution, agency, or person that is qualified to provide services under Medicare. The Medicare CoPs require providers to inform patients of their right to choose any PAC provider. They also prohibit providers from limiting the providers that are available to a patient. Hospitals must provide the patient with a list from which the patient may openly choose a PAC provider.

AHPA believes that there must be a reasonable constraint upon patient choice when that choice can result in a beneficiary receiving care from a low-quality provider, such as one who has higher rates of readmission, higher infection rates or higher rates of referral back to physician for the treatment of the patient. **We recommend that CMS make a policy determination of what balance the Agency wishes to achieve between open choice and quality of care.** If there is a desire to institute a program that will lead to efficiency and improved quality of care, then there also must be increased guidance to beneficiaries on their choice of PAC providers.

As hospitals develop preferred-provider PAC networks, CMS should provide further guidance on patient steering regulations so that hospitals can direct patients to high-quality performers. For example, hospitals should be allowed to share a list of their preferred-provider network as opposed to an entire list of PAC providers, some which may have very low quality ratings. A preferred provider list would consist of facilities that are high performers on CMS' quality metrics, such as star ratings, readmission rates and unscheduled returns to the Emergency Department (ED). In rural areas or other areas with limited PAC providers, hospitals could share a list beyond their preferred-provider network.

Immediate Jeopardy

To participate in the Medicare program, acute, critical access or psychiatric hospitals are required to be in "substantial" compliance with each CoP. There are two different types of citations that CMS can issue when a hospital is in non-compliance with a CoP: A Standard-Level Deficiency and a Condition-level Deficiency.

Within the Condition-level deficiency, there is a more severe citation available called Immediate Jeopardy (IJ). Providers that receive an IJ are placed on a 23-day termination track from the Medicare and Medicaid programs if they fail to correct the deficiencies.

AHPA believes that IJ guidelines need to be revised because the definition of IJ is too subjective, which leads to inconsistency among surveyors seeking to implement the guidelines.

The Definition of Immediate Jeopardy

An IJ arises in a situation in "which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." We believe that the ambiguity behind what is considered serious harm or potential harm can often lead surveyors to use the IJ citation more often than appropriate.

In health care settings, there exists a continuum of harm from mild to severe. As health care providers, we must work to effectively improve the delivery of care while reducing harm. However, it is important to

match process improvement resources to the level of harm identified in each case. **We believe that the current IJ process does not capture this continuum of harm. AHPA recommends that CMS expand the types of findings available to state survey teams.** This would allow surveyors to more accurately capture the different levels of harm that can be found in health care. Consequently, IJ citations would be used more appropriately to reflect their original intent. An IJ citation would only be used in cases when an identified process must be immediately stopped and redesigned to ensure that no further serious or potential harm occurs. To receive an IJ, there would have to be a clear indication that any delay to change the care environment of the patient will result in serious harm or death.

Although the Medicare State Operations Manual specifies 10 different triggers to alert surveyors of a potential IJ, these triggers are very broad and can be subject to various interpretations. For example, if a nurse wrongfully engages in a dispute with a patient, the patient may claim psychological harm, causing the hospital to receive an IJ citation. What is considered psychological harm is subject to the surveyor's interpretation and because there are no tools to capture the level of psychological harm, the surveyor may likely provide an IJ to the facility.

AHPA believes that CMS has the statutory authority to revise the current IJ guidelines. Sections 1861(e)(1) through (8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary of the Department of Health and Human Services (HHS) finds necessary in the interest of the health and safety of individuals furnished services in the institution. Under this authority, the Secretary can establish *and* change regulatory requirements that a hospital must meet to participate in Medicare.

Furthermore, Executive Order 13563, entitled ''Improving Regulation and Regulatory Review,'' gave all executive agencies the authority to review existing regulations to identify those rules that can be eliminated or modified to be more effective, flexible and streamlined. Under this authority, CMS has released several rules to change the Medicare CoPs and other outdated rules. Examples of these rules include, CMS–3244–F, CMS–9070–F and CMS–3267–F. **Therefore, AHPA urges the Agency to explore revising the current IJ regulations so that they more appropriately reflect their original intent.**

Conclusion

AHPA welcomes the opportunity to further discuss any of the recommendations provided above. If you have any questions or would like further information, please do not hesitate to contact Julie Zaiback-Aldinger, Director of AHPA, at Julie.Zaiback@ahss.org.

Sincerely,

Jeff Bromme
President
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