

June 13, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1677-P, Medicare Program; Hospital Inpatient Prospective Payment Systems (PPS) for Acute Care Hospitals and the Long-Term Care Hospital PPS and Proposed Policy Changes and FY 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices; Proposed Rule (Vol. 82, No. 81) April 28, 2017.

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) request for information on CMS flexibilities and efficiencies. We are submitting separate comments on the agency's proposed changes to the inpatient and long-term care hospital (LTCH) prospective payment systems for fiscal year (FY) 2018.

The regulatory burden faced by hospitals is substantial and unsustainable. As one small example of the volume of recent regulatory activity, in 2016, 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. In addition to the sheer volume, the scope of changes required by the new regulations is beginning to outstrip the field's ability to absorb them. Moreover, this does not include the increasing use of sub-regulatory guidance (FAQs, blogs, etc.) to implement new administrative policies.

We very much appreciate the Trump Administration's willingness to tackle this issue by modifying or eliminating duplicative, excessive, antiquated and contradictory provider



regulations. Reducing administrative complexity in health care would save billions of dollars annually and allow providers to spend more time on patients, not paperwork. CMS already has provided some important regulatory relief to hospitals, which we greatly appreciate. For example, the agency has:

- paused the onerous home health pre-claim review demonstration;
- proposed a 12-month moratorium on the outdated LTCH 25% Rule;
- made the critical access hospital 96-hour rule a low priority for contractor review;
- proposed a 90-day reporting period for the meaningful use program for FY 2018;
- published interpretive guidance for the recently-finalized emergency preparedness rule, well in advance of its implementation date;
- delayed the cardiac and surgical hip and femur fracture treatment mandatory bundled payment models by six months;
- proposed a six-month delay in implementation of the revised home health agency conditions of participation; and
- published interpretive guidance for the recently finalized emergency preparedness rule, well in advance of its implementation date.

Yet, more work remains to be done. To that end, the AHA is currently assembling a report that will catalogue the full sweep of regulatory requirements in a way that provides a holistic view of the combined burden imposed on hospitals and health systems; we anticipate issuing this report later this year. Subsequent to that, we plan to begin “deeper dives” into certain issue areas to further identify specific opportunities and recommendations for burden reduction.

In the attached document, we have laid out actions that CMS could take to immediately reduce the regulatory burden on hospitals, health systems and the patients that we serve. They range from cancelling Stage 3 of the meaningful use program, to postponing and re-evaluating post-acute care quality measurement requirements, to prohibiting the enforcement of direct supervision requirements.

Again, we thank you for your focus on this critical issue and for your consideration of our comments. Please contact me if you have questions or feel free to have a member of your team contact Joanna Hiatt Kim, vice president of payment policy, at jkim@aha.org or (202) 626-2340.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy

Enclosure

REGULATORY RELIEF

There are numerous duplicative and excessive rules and regulations. The AHA suggests that CMS take the following actions to immediately reduce burdens on hospitals and patients.

Suspend hospital star ratings. Despite objections from a majority of the Congress, CMS published a set of deeply flawed hospital star ratings on its website in fall 2016. The ratings were broadly criticized by quality experts and Congress as being inaccurate and misleading to consumers seeking to know which hospitals were more likely to provide safer, higher quality care. While we continue to be concerned that CMS's methodology is flawed, our concern is amplified by the fact that further analysis performed since the star ratings were first released show that substantive errors were made in executing CMS's chosen methodology. As a result, far too many hospitals have been incorrectly classified into star rating categories that are different than those that should have been assigned. *The AHA calls on the Administration to suspend the faulty star ratings from the Hospital Compare website.*

Cancel Stage 3 of the "meaningful use" program. Hospitals face extensive, burdensome and unnecessary "meaningful use" regulations from CMS that require significant reporting on use of electronic health records (EHRs) 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. *The AHA 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, eliminate the all-or-nothing approach, and gather input from stakeholders on ways to further reduce the burden of the meaningful use program from current requirements.*

Suspend electronic clinical quality measure (eCQM) reporting requirements. Hospitals have spent significant time and resources to revise certified EHRs to meet CMS's eCQM requirements for 2016, with no benefit for patient care. Moreover, CMS acknowledges that the electronic test submissions by hospitals and physicians do not accurately measure the quality of care provided. Despite these facts, CMS proposes to increase the eCQM reporting requirement by 50 percent for 2017 and 2018, creating additional burden without an expectation that the data generated by EHRs will be accurate. *The AHA urges the Administration to suspend all regulatory requirements that mandate submission of electronic clinical quality measures.*

Use only measures that truly matter. Public transparency regarding hospital and other provider quality would be supported by thinking strategically about the information most useful to the public. CMS currently publishes data on nearly 90 measures of hospital quality. In addition, it publishes star ratings, the data on what Medicare pays for services at each hospital, demographic information on hospitals, and has most recently proposed

requiring the accrediting organizations to which it has granted deeming status to publish the lengthy survey reports from the triennial and certain other surveys conducted by those bodies. All of this provides a complex, confusing and sometimes conflicting set of signals to the public about a hospital's quality. Continued expansion of this haphazard set of information is certainly less useful to the public than a strategically chosen, consistently collected set of information on each hospital. ***The AHA urges CMS to step back from this burdensome set of activities that are drowning people in data and not providing real information. Further, we urge the agency to work with a variety of stakeholders, including the AHA, to identify what the critical indicators of quality and safety are that would be useful in giving patients an accurate sense of the quality of different organizations.***

Remove faulty hospital quality measures. Improvements in quality and patient safety are accelerating, but the ever increasing number of conflicting, overlapping measures in CMS programs take time and resources away from what matters the most – improving care. Most recent measure additions to the inpatient quality reporting (IQR) and outpatient quality reporting (OQR) programs provide inaccurate data, and do not focus on the most important opportunities to improve care. ***We urge the Administration to remove all IQR and OQR measures added to the programs on or after Aug. 1, 2014. These measures also should be removed from CMS pay-for-performance programs, such as readmissions and hospital value-based purchasing.***

Eliminate unfair long-term care hospital (LTCH) regulation. With the implementation of site-neutral payments for LTCHs, which began in October 2015 (as mandated by the Bipartisan Budget Act of 2013), the LTCH “25% Rule” has become outdated, excessive and unnecessary. The purpose of the 25% Rule is to reduce overall payments to LTCHs by applying a penalty to selected admissions exceeding a specified threshold, even if the patient meets LTCH medical necessity guidelines. Given the magnitude of the LTCH site-neutral payment cut – a 54 percent reduction, on average, to one out of two current cases – we have called for the 25% Rule to be withdrawn by CMS under its own authority. ***As such, we strongly endorse the agency's recent proposal to implement a 12-month moratorium on the full 25% Rule, beginning October 2017, and again urge the agency to permanently rescind the unnecessary 25% Rule.***

End onerous home health agency pre-claim review. Under CMS's home health pre-claim review demonstration, home health agencies in five states were unfairly 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 1 million home health claims per year. ***The AHA 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.***

Restore compliant codes for inpatient rehabilitation facility (IRF) 60% Rule. During the transition to ICD-10-CM, CMS reduced the number of conditions that qualify toward compliance under the IRF “60% Rule,” which is a criterion that must be met for a hospital or unit to maintain its payment classification as an IRF. Yet certain codes that qualified under ICD-9-CM were inadvertently omitted as a result of the conversion to ICD-10-CM. *We support the Administration’s current proposal to restore some of those codes so they again count toward the 60% Rule presumptive compliance test. However, we urge CMS to also consider adding those codes that were omitted from the proposed restoration.*

Postpone and re-evaluate post-acute care quality measure requirements. Recent laws and regulations are rapidly expanding the quality and patient assessment data reporting requirements for post-acute care providers. The requirements have been implemented aggressively, and without adequate time for stakeholder input. The result is duplicative reporting requirements – such as two different mandated ways of collecting patient functional status data for IRFs – and enormous confusion in the field. *We urge the Administration to suspend any post-acute care quality reporting requirements finalized on or after Aug. 1, 2015, and to work with the post-acute care community to develop requirements that strike a more appropriate balance between value and burden.*

Protect Medicaid disproportionate share hospital (DSH) payments. CMS’s final rule that addresses how third-party payments are treated for purposes of calculating the hospital-specific limitation on Medicaid DSH payments could deny hospitals access to needed Medicaid DSH funds. The Medicaid DSH program provides essential financial assistance to hospitals that care for our nation’s most vulnerable populations. CMS has characterized this rule as interpretive and a clarification of existing policy. But, in reality, the rule is substantive and establishes new policy that could significantly limit or eliminate some hospitals’ access to Medicaid DSH funds. *The AHA urges CMS to withdraw its final rule on Medicaid DSH third-party payments. If the agency does move forward, however, any change in policy with regard to the calculation of the hospital-specific DSH limitation only should apply prospectively, which will give states and hospitals sufficient time to make needed adjustments to ensure compliance. Given the current litigation pending in federal court regarding CMS’s policy in this area, to do otherwise is to create unnecessary confusion for state Medicaid programs and DSH hospitals.*

Preserve Medicaid supplemental payments in managed care. CMS’s final rule on Medicaid supplemental payments in managed care would limit states’ ability to increase or create new pass-through payments for hospitals, physicians or nursing homes under Medicaid managed care contracts. CMS previously provided for a 10-year phase-out of these pass-through payments, from 2017 to 2027, because of the size, number and complexity of hospital pass-through payments programs. However, in the rule, CMS requires that, for state pass-through payment programs to qualify for the 10-year transition period, they had to be in place as of July 5, 2016. This effectively moves up the start of the phase-out period from 2017 to July 5, 2016. We are concerned that this further limitation on pass-through payment programs could adversely affect hospitals dependent on these

supplemental payments. *The AHA urges CMS to withdraw the final rule on Medicaid provider pass-through payments in Medicaid managed care.*

Stop federal agency intrusion in private-sector accreditation standards. HHS has the authority to determine that private sector accrediting bodies standards and survey processes were equivalent to or better than the Conditions of Participation (CoPs) for Medicare and the survey processes that HHS uses to review compliance with the CoPs. When HHS determines that the private sector's accreditation is at least equal to or superior to its own, it can decide that the accrediting body's accreditation determination is sufficient to allow a hospital or other health care facility to participate in Medicare. Recently, HHS has insisted that private sector bodies, such as The Joint Commission, rewrite their standards or alter their survey processes to conform to those used by CMS itself since the Department says it has no other way to determine if the standards and processes are "at least as good" as its own standards. This limits innovation in the private sector that encourages greater attention to safety and quality. *The AHA urges the Administration to find better ways to judge the equivalency of private sector standards and survey methods that do not limit the ability of private sector entities to innovate and to differentiate themselves in the marketplace.*

Promote transparency and timeliness in the development and release of interpretive guidance. Newly finalized rules, such as changes to the CoPs, can become effective before interpretive guidance is released. Thus hospitals may invest time and resources to implement a new regulation without the benefit of clear expectations about how to meet the standards. *We urge CMS to continue the trend of prioritizing the development of guidance after a rule is finalized, which can help avoid the possibility that hospitals will need to modify or revamp their implementation efforts once the guidance is released. In addition, when guidance is updated due to internal CMS policy changes, rather than being issued subsequent to a final rule, we ask CMS to provide stakeholders a reasonable timetable to comply with the new standards. Further, we urge CMS to publicly post draft guidance for a limited period of time on its website, so that providers may ask questions and identify potential unintended consequences of new policies.*

Undo agency over-reach on so-called "information blocking." Hospitals want to share health information to support care and do so when they can. But technology companies and the federal government have so far failed to create the infrastructure to make sharing information electronically easy and efficient. CMS went beyond statutory intent in asking hospitals to attest to three separate statements indicating:

- that they did not "knowingly and willfully take action to limit or restrict the compatibility or interoperability" of their certified EHR;
- that they have implemented the technology to support "secure and trusted bi-directional exchange" of health information; and
- have "responded in good faith and in a timely manner" to requests for exchange information from others.

The last two of the three attestations go beyond both statutory intent and the current capability of the technology hospitals have available to them. That unfairly places hospitals

at risk of payment penalties for technical issues outside of their control. ***The AHA urges the Administration to remove the second two attestations, keeping only the statutory requirement that hospitals did not knowingly or willfully take action to limit or restrict the compatibility or interoperability of their EHRs.***

Hold Medicare Recovery Audit Contractors (RACs) accountable. Medicare RACs are paid a contingency fee that financially rewards them for denying payments to hospitals, even when their denials are found to be in error. ***The AHA urges the Administration to revise the RAC contracts to incorporate a financial penalty for poor performance by RACs, as measured by Administrative Law Judge appeal overturn rates.***

Adjust readmission measure to reflect differences in socio-demographic factors. A body of research demonstrates that readmissions are higher in communities that are economically disadvantaged. This is because 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. For this reason, the 21st Century Cures Act requires CMS to implement sociodemographic adjustment in the hospital readmissions penalty program starting in fiscal year (FY) 2019. At the same time, a recent series of reports from the National Academy of Medicine show that other outcome measures, such as 30-day mortality rates and measures of efficiency and patient experience, are similarly impacted by sociodemographic factors. Moreover, a report from ASPE shows that providers caring for large numbers of poorer patients are more likely to perform worse on a wide range of hospital, physician and post-acute care pay-for-performance programs. ***The AHA urges CMS to ensure its implementation of a sociodemographic adjustment in the hospital readmissions penalty program is done in a transparent and fair manner. We also urge CMS use the evolving science around the best ways to adjust for sociodemographic factors to update its approach as needed. Lastly, we urge CMS to incorporate sociodemographic adjustment into its other quality measurement and pay-for-performance programs where necessary and appropriate.***

Make future bundled payment programs voluntary. Through the Center for Medicare and Medicaid Innovation (CMMI), CMS has established a new mandatory bundled payment model for cardiac care and also expanded a mandatory bundled payment model for comprehensive joint replacements. While it is important to offer opportunities to explore new payment models, CMMI has 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. ***The AHA urges the Administration to ensure that any new bundled payment programs are voluntary.***

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. For example, CMS approves new telehealth services on a case-by-case basis, with the result that Medicare pays for only a small percentage of services when they are delivered via telehealth. *The AHA urges 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.*

Delay payment impact of program that encourages appropriate use criteria. The Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to establish a program that promotes appropriate use criteria (AUC) for advanced diagnostic imaging. The statute requires that payment be made to the furnishing professional for an applicable advanced diagnostic imaging service only if the claim indicates that the ordering professional consulted with a qualified clinical decision support mechanism (CDSM) as to whether the ordered service adheres to applicable AUC. We appreciate that CMS has taken a thoughtful and deliberate approach to this program by implementing different components in the Physician Fee Schedule (PFS) for calendar years 2016 and 2017. However, under CMS's current timeline, the first qualified CDSMs will not be specified until June 30, 2017. This leaves providers very little time – a mere six months after specification of the first qualified CDSMs – to acquire access to and deploy qualified CDSMs before payment depends on their use starting Jan. 1, 2018. *We urge CMS to delay the payment reduction associated with a lack of consultation of, and compliance with, AUC until at least 12 months from the date that approved CDSMs are announced.*

Rescind “JW modifier” requirement for certain drug claims. Currently, providers are required to report the “JW modifier” on certain Part B drug claims for discarded drugs/biologicals in single-dose or single-use packaging, as well as document the amount of discarded drugs/biologicals. Compliance with this requirement requires complex coordination and specialized information technology (IT) solutions. In addition, it poses a patient safety concern because it requires both the amount of medication administered and the amount of medication discarded to be recorded on the patient's bill as well as in the patient's chart. Including two amounts for a single administration of medication increases the possibility of human error in entering and reviewing the record during the course of treatment. *The AHA urges CMS to withdraw this requirement.*

Prohibit enforcement of direct supervision requirements. In the 2009 outpatient PPS final rule, CMS mandated a new policy for “direct supervision” of outpatient therapeutic services that hospitals and physicians recognized as a burdensome and unnecessary policy change that could harm access to care in rural and underserved communities. Because CMS characterized the change as a “restatement and clarification” of existing policy in place since 2001, hospitals, particularly small and rural hospitals and critical access hospitals (CAHs), found themselves at increased risk of unwarranted enforcement actions. For CYs 2010-2013, in response to hospital concerns, the agency prohibited its contractors from enforcing the direct supervision policy. While Congress has extended this

enforcement moratorium annually since 2014, this annual reconsideration of the misguided direct supervision policy places these hospitals in an uncertain and untenable position. *The AHA urges the Administration to permanently prohibit its contractors from enforcing the direct supervision regulations in CAHs and small and rural hospitals.*

Issue a permanent enforcement moratorium on the 96-hour Rule. CMS previously indicated it would begin enforcing a condition of payment for CAHs that requires a physician to certify that a beneficiary may reasonably be expected to be discharged or transferred to another hospital within 96 hours of admission. While CAHs must maintain an annual average length of stay of 96 hours, they may offer some critical medical services that have standard lengths of stay greater than 96 hours. Enforcing the condition of payment will force CAHs to eliminate these “96-hour-plus” services. However, in the inpatient PPS rule for fiscal year 2018, CMS indicates its contractors will make reviews of this issue a “low priority.” The AHA appreciates CMS’s recognition that this CoP could stand in the way of promoting essential, and often lifesaving, health care services to rural America. *We urge CMS to finalize this proposal on a permanent basis to provide CAHs with certainty that the agency will not begin to audit the 96-hour hour certification requirement in the future.* In addition, while this moratorium offers some comfort, it does not remove the 96-hour certification requirement from the statute, and the AHA remains concerned that CAHs may still be at risk for penalties. *As a result, the AHA will continue to advocate for a legislative solution that permanently removes the 96-hour physician certification requirement as a condition of payment for CAHs and we urge CMS to work with us to support that effort.*

Remove the mandatory free-text field from the Medicare Outpatient Observation Notice (MOON). The MOON’s mandatory free-text field requires that hospital staff describe the patient-specific clinical considerations made by their physician when ordering outpatient observation services rather than inpatient admission. This requirement is burdensome to hospitals and of no benefit to patients. For example, it negatively impacts the hospital’s workflow by precluding hospital registration or access staff from preparing the MOON. This is because the medical record does not contain information about why a patient is not an inpatient; rather, it contains information about the patient’s evolving clinical situation during his or her outpatient observation encounter. In addition, these clinical specifics would be difficult and confusing for most beneficiaries to understand. In contrast, beneficiaries who do wish to understand such clinical specifics would have ample opportunity to ask questions during the required oral explanation of the MOON. *The AHA recommends that this field be removed from the MOON. It should be replaced with CMS-prepared standard language that describes the established reason that physicians order observation services for patients. Indeed, CMS itself acknowledged the standard explanation for why a patient is placed in outpatient observation status and included it in the preamble to the FY 2017 inpatient PPS final rule.*

Allow flexibility for providers who want to share treatment space to address gaps in patient access to care. Many hospitals share treatment space with other providers in order to offer a broader range of medical services and better meet patient needs. In rural areas,

hospitals may lease space to visiting specialists from out of town several days per month. Recently, CMS issued several very restrictive interpretations of the shared space rules, such as disallowing visiting specialist arrangements because the spaces for the specialists are not completely separate from the hospital and do not provide independent entrance and waiting areas. 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. ***CMS should stop categorically disallowing visiting specialist leased space arrangements simply because they do not have separate spaces, entrances and/or waiting areas.***

Clarify Medicaid payment policies regarding justice-involved individuals receiving inpatient care. For patients in the custody of law enforcement, some hospitals provide general acute care beds in special units that are guarded and have appropriate security features, such as metal detectors and controlled entrances. Secure units enable hospitals to maintain a safe environment for patients, visitors and staff while providing prisoners and jail inmates access to needed care. Last year, the CMS Survey and Certification Group confirmed that these units are allowed in Medicare-certified hospitals. However, page 13 of an April 28, 2016 [memo](#) from the Center for Medicaid and CHIP Services contains language that appears to prohibit federal financial participation for care provided in secure units. ***We ask CMS to remove that language so that the certification and payment policies are clearly aligned.***

Create Stark regulatory exception for clinical integration arrangements. Hospitals cannot succeed in their efforts to coordinate care and participate in new payment models because of outdated regulations, such as the Anti-Kickback Statute and the “Stark” law. ***We urge the Administration to create an exception under Stark for any arrangement that meets a newly created Anti-Kickback safe harbor for clinical integration arrangements.*** (See also next two actions on creating Anti-Kickback safe harbors for clinical integration arrangements and patient assistance.)

Create Anti-Kickback safe harbor and stark exception for clinical integration arrangements. Hospitals and other providers are now more accountable than ever for financial and patient outcomes, across the entire spectrum of care. This collective accountability requires hospitals, physicians, and other providers to work together in new ways. They must be able to financially align themselves with shared incentives, shared resources, seamless technology and pooled information. However, current laws impede innovation. The principal obstacle to innovation is an overly complex legal framework grounded in the increasingly outdated fee-for-service payment structure. Hospitals and physicians cannot partner on innovative programs unless the arrangement meets highly technical requirements of both an exception under Stark Law and safe harbor under Anti-Kickback Law. However, the core requirements of existing laws are not in sync with collaborative models that reward value and outcomes. ***CMS should work with the Office of the Inspector General (OIG) to 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:

- **Transparency:** Documentation of the use of incentives or other assistance is required and must be available to HHS on request.
- **Recognizable improvement processes:** Any performance standards that providers use to govern their collaboration (e.g., required care protocols, metrics used to award performance bonuses) must be consistent with accepted medical standards and reasonably fit for the purpose of improving patient care.
- **Monitoring:** Performance under integration arrangements must be internally reviewed to guard against adverse effects and documentation disclosed to HHS upon request.

The safe harbor should not try to supplant, duplicate or recreate existing quality improvement processes or the mechanisms for monitoring quality of care in hospitals. Currently, there is both internal and external oversight. State licensing agencies and accrediting organizations have an ongoing role. The Medicare Quality Improvement Organizations continuously review the quality of care for beneficiaries. Other Medicare program oversight includes the hospital inpatient and outpatient quality reporting programs, readmissions program and value-based purchasing program.

The safe harbor would cover arrangements established for one or more of these purposes:

- Promoting accountability for the quality, cost and overall care for patients;
- Managing and coordinating care for patients; or
- Encouraging investment in infrastructure and redesigned care processes for high-quality and efficient care delivery for patients.

The safe harbor would protect remuneration, including any program start-up or support contribution, in cash or in-kind.

In addition, CMS should create a new Stark Law exception that protects any arrangement that meets the terms of the newly created Anti-Kickback safe harbor for clinical integration arrangements.

Create Anti-Kickback safe harbor for patient assistance. Hospital responsibility for patient care no longer begins and ends in the hospital setting or any other site of care provided by the hospital. Maintaining a person in the community requires more than direct patient care. It includes encouraging, supporting or helping patients access care, or making it more convenient. It would include removing barriers or hurdles for patients as well as filling gaps in needed support. However, current laws impede hospitals from providing such assistance. 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.

CMS should work with the OIG to create an Anti-Kickback safe harbor that permits hospitals to help patients achieve and maintain health. Arrangements protected under the safe harbor also would be protected from financial penalties under the Civil Monetary Penalties (CMPs) for providing an inducement to a patient.

The safe harbor should:

- Protect encouraging, supporting or helping patients to access care or make access more convenient;
- Permit support that is financial (such as transportation vouchers) or in-kind (such as scales or meal preparation); and
- Recognize that access to care goes beyond medical or clinical care, and include the range of support important to maintaining health such as social services, counseling or meal preparation.

Halt use of encounter data to formulate MA risk scores. CMS uses a blended risk score to calculate Medicare Advantage payments. Specifically, the agency uses both Risk Adjustment Processing System data and encounter data. Collection of encounter data is significantly burdensome on both providers and plans. Provider data collection systems and processes were not designed for such a task, and collecting the necessary information often requires significant back-and-forth between both parties. Despite these efforts, the accuracy of such data has been challenged by the Government Accountability Office (GAO). The GAO, in updating an earlier report on the use of encounter data, found that “CMS has yet to undertake activities that fully address encounter data accuracy... Given the agency’s limited progress, GAO continues to believe that CMS should implement GAO’s July 2014 recommendation that CMS fully assess data quality before use.” ***We encourage CMS to halt use of encounter data until the issues related to data quality and provider and plan burden are addressed.***