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Advancing Health in America

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August 12, 2019

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-6082-NC, Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork; (Vol. 84, No. 112) June 11, 2019.***

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, 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 comment on the Centers for Medicare & Medicaid Services' (CMS) request for information on reducing administrative burden.

As we have expressed to CMS, the regulatory burden faced by hospitals is substantial and unsustainable. In 2017, the AHA released an analysis showing that providers spend nearly $39 billion a year solely on administrative activities related to regulatory compliance. In addition to the sheer volume, the scope of changes required by new regulations is beginning to outstrip the field's ability to absorb them.

We very much appreciate the Administration's continued willingness to tackle this issue. Reducing administrative complexity in health care would save billions of dollars annually and allow providers to spend more time on patients, not paperwork. CMS recently provided some important regulatory relief to hospitals, which we greatly appreciate. For example, the agency has:

- withdrawn the outdated long-term care hospital 25% Rule;
- allowed hospital-based physicians to use their hospital's quality reporting and pay-for-performance measure performance in the Merit-Based Incentive Payment System;
- finalized a 90-day reporting period for the Medicare Promoting Interoperability Program for fiscal year 2021; and

- proposed to eliminate the direct supervision requirement for outpatient therapeutic services for all hospitals, including critical access hospitals and small rural hospitals having 100 or fewer beds.

However, more work remains to be done. In the attached document, we have laid out actions that CMS could take immediately to reduce the regulatory burden on hospitals, health systems and the patients that we serve. They range from suspending and improving the hospital star ratings, to broadening and improving opportunities to participate in alternative payment models, to permanently prohibiting the enforcement of the "96-hour rule."

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

Enclosure

# AMERICAN HOSPITAL ASSOCIATION (AHA) DETAILED COMMENTS ON REGULATORY BURDEN REDUCTION

There are numerous duplicative and excessive rules and requirements on America's hospitals and health systems. The AHA suggests that the Centers for Medicare & Medicaid Services (CMS) takes the following actions to immediately reduce burdens on hospitals and patients.

**Suspend and Improve Hospital Star Ratings.** As longstanding supporters of transparency, America's hospitals and health systems believe that patients, families and communities should have valid and clear quality information to help them make important health care decisions. Unfortunately, one of CMS's laudable goals with its hospital star ratings program – to give a meaningful, simplified view of hospital quality to consumers – is being compromised by a methodology that can lead to inaccurate, misleading comparisons of quality performance. The AHA appreciates that CMS is actively exploring ways to improve star ratings. Nevertheless, unless and until the ratings methodology is improved, it will be difficult for hospitals and the public to have confidence that star ratings portray hospital performance accurately.

***The AHA urges the Administration to suspend the star ratings from the Hospital Compare website while its important work to improve the ratings continues. The agency should work with all stakeholders to develop a more sound approach to giving patients useful information.***

**Use Only Measures that Truly Matter.** Improvements in quality and patient safety are accelerating, but an excessive number of conflicting, overlapping measures in Medicare reporting and pay-for-performance programs can divert time and resources away from what matters the most – improving care. Data collection and reporting activities would be more valuable if federal agencies, private payers and others requiring quality data agreed on a manageable list of high-priority aspects of care. Then, providers could use a small and critically important set of measures to track and report on progress toward improving the care delivered and the outcomes for patients. The AHA applauds CMS's adoption of its "Meaningful Measures" framework, which resulted in the removal of a significant number of measures across its reporting programs in 2018. At the same time, work remains to remove measures that are no longer valuable, and to address high-priority gaps in measurement.

***The AHA encourages CMS to continue the implementation of its Meaningful Measures initiative to remove measures that no longer add value, and to develop and implement other measures that advance quality. As called for in the President's recent Executive Order, CMS also can help drive the alignment of its reporting requirements with other Department of Health and Human Services (HHS) programs. Lastly, CMS and HHS should promote the alignment of measures across public and private payers to ensure all stakeholders are driving***

***progress on quality using as many measures in common as possible. Taken together, these efforts would ensure all providers are spending less time meeting divergent reporting requirements, and more time doing what really matters – improving performance.***

**Incorporate Sociodemographic Adjustments.** A body of research demonstrates that performance on a variety of outcome measures used in CMS quality reporting and pay-for- performance programs – including readmissions, mortality efficiency and patient experience – can be influenced by sociodemographic factors beyond providers' control such as being dually eligible for Medicare and Medicaid, and income. As urged by the AHA, Congress and CMS have taken important first steps to incorporate sociodemographic adjustment in programs where necessary and appropriate. For example, the 21st Century Cures Act requires CMS to implement sociodemographic adjustment in the hospital readmissions penalty program starting in fiscal year (FY) 2019. In addition, the physician Merit-Based Incentive Payment System (MIPS) program includes a "complex patient bonus" that recognizes practices caring for large numbers of dual-eligible patients. However, many measures and programs – such as hospital star ratings and value-based purchasing (VBP) – still lack sociodemographic adjustment, and any adjustment approach will need ongoing refinement.

***The AHA continues to urge CMS to incorporate social risk factor adjustment into its quality measurement and pay-for-performance programs where necessary and appropriate. We also urge CMS to use the evolving science around the best ways to adjust for social risk factors to update its approach as needed.***

**Implement the Physician Quality Payment Program (QPP) in a Flexible Manner.** The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 created the two-track physician QPP that ties a portion of physician payment to quality and cost, and includes incentives for participation in advanced alternative payment models (APMs) that lead to more integrated, better coordinated care. As urged by the AHA, CMS adopted a gradual, flexible increase in QPP requirements, and reduced burden by allowing hospital-based clinicians to use their hospital's Medicare value-based purchasing results in the MIPS. Yet, opportunities remain to improve CMS's implementation of MIPS and to expand opportunities to participate in APMs.

***The AHA continues to urge CMS to implement the QPP in a flexible manner that minimizes unnecessary burden on clinicians. This includes expanding MIPS facility-based measurement to include other provider types, such as inpatient rehabilitation facilities (IRF), and increasing quality reporting requirements at a gradual pace. As detailed elsewhere in this letter, successful QPP implementation also entails creating additional voluntary advanced APMs that reward clinicians who partner with hospitals to reduce cost and improve quality.***

CMS also has begun to increase the number and weight of cost measures in the MIPS program. Hospitals and clinicians alike are focused on improving the value of care, and they want well-designed measures of cost and resource use to inform their efforts. However, serious questions remain about the accuracy and reliability of all of the measures in the MIPS cost category. Moreover, clinicians have had insufficient time to review and understand the new episode-based cost measures that CMS added to the MIPS program for calendar year (CY) 2021.

***The AHA urges CMS to take steps to improve the accuracy of the MIPS cost measures, and to delay both the increase of the weight of the cost category to 15%, and the addition of episode-based cost measures, until CY 2022 at the very earliest.***

**Broaden Opportunities for Participation in APMs that Qualify as Advanced APMs under MACRA. The AHA supports accelerating the development and use of alternative payment and delivery models to reward better, more efficient, coordinated and seamless care for patients.** Many hospitals, health systems and payers are adopting such initiatives with the goal of better aligning provider incentives to achieve the Triple Aim of improving the patient experience of care (including quality and satisfaction), improving the health of populations and reducing the per capita cost of health care.

Despite the progress made to date, the field as a whole is still learning how to effectively transform care delivery. There have been a limited number of Medicare APMs introduced thus far, an even smaller number of which qualify as Advanced APMs under MACRA, and existing models have not provided participation opportunities evenly across provider types, such as certain physician specialties and post-acute, behavioral health and rural providers. **As a general principle, the AHA believes the APM provisions of MACRA should be implemented in a broad manner that provides the greatest opportunity for physicians who so choose to become qualifying APM participants.** CMS should take an expansive approach that encourages and rewards physicians who demonstrate movement toward APMs. The agency also should ensure that it designs APMs with a fair balance of risk and reward, standardized and targeted quality measures and risk adjustment methodologies, physician engagement strategies, and readily available data and feedback loops between CMS and participants.

***While we acknowledge and appreciate CMS's development and implementation of more APMs that qualify as advanced APMs, we remain concerned that these existing and announced APMs offer too few opportunities for participation for certain providers that serve more dispersed and vulnerable populations. Therefore, we urge CMS to consider these and other providers when designing APMs and expand opportunities for them to participate in advanced APMs that offer them targeted resources and a manageable amount of risk.***

**Eliminate Regulatory Barriers that Prevent Exploration of Innovative Strategies and Alternative Payment Models.** As providers work to implement new, innovative payment and delivery models that seek to ensure access, increase quality and reduce unnecessary costs, they frequently encounter regulatory barriers to care coordination. Many of these barriers are addressed specifically in this letter, but we urge CMS on an overarching basis to implement policy changes so that hospitals, health systems post-acute care providers, and their communities may successfully coordinate care and ensure that it is provided in the right place at the right time.

**For example, we urge CMS to provide those participating in APMs with maximum flexibility to identify and place beneficiaries in the clinical setting that best serves their short- and long-term recovery goals.** Specifically, waiving the following policies would improve care coordination throughout the episode of care:

- The IRF "60% Rule";
- The IRF "3-hour Rule";
- The LTCH minimum average length of stay policy; and
- IRF services being reimbursed only through a PPS bundled payment, rather than allowing per diem rates to enable more flexible use of IRF services.

Further, waivers of these legacy regulations would enable the development of new, patient-centered clinical pathways that produce important insights for policymakers. In addition, outdated fraud and abuse laws are standing in the way of achieving the goals of APMs, specifically, the physician self-referral (Stark) law and anti-kickback statute (AKS). These statutes and their complex regulatory framework are designed to keep hospitals and physicians apart, preventing them from aligning performance objectives and financial incentives across the care continuum. The AHA submitted comments on these laws in response to relevant requests for information from CMS and from the HHS Office of Inspector General, which detailed specific ways to improve the functionality of the Stark law and AKS and reduce or eliminate the impediments they create to the implementation of APMs and value-based care.

***The AHA encourages CMS to revisit these comments and work independently and with Congress to implement the changes detailed therein so that communities may successfully implement new, innovative strategies. Specifically, CMS should reform the Stark law to support the adoption of value-based payment arrangements while removing obstacles to care coordination. Additionally, CMS should work with Congress to create a clear and comprehensive safe harbor under the AKS for arrangements designed to foster collaboration in the delivery of health care and incentivize and reward efficiencies and improvement in care.***

**Increase the Accuracy of LTCH Payments and Compliance Assessments**. LTCH patients fall into two categories: standard rate cases that, in general, have three or more

intensive care unit (ICU) days during the prior hospital stay; and site-neutral cases with 0-2 prior ICU days. The assignment of cases to these subgroups affects not only payment determinations, but also providers' compliance with two Medicare facility requirements. Specifically, LTCHs must satisfy a minimum average length-of-stay requirement and the "50% Rule," which requires that at least 50% of cases per year fall in the standard-rate subgroup.

However, during the admissions process, LTCHs often lack information on a patient's prior ICU use since the timely filing requirements for the referring general acute-care hospital allow 120 days to file a claim. Thus, at admission, LTCHs often are not able to accurately determine a case's payment and impact on compliance with the average length of stay (ALOS) and "50% Rule" requirements. Similarly, the accuracy of Medicare contractors' payment determinations and ALOS and "50% Rule" compliance assessments also are limited due to the 120-day timely filing window.

***We urge CMS to require its contractors to examine other data sources, including additional matching claims, when retrospectively determining whether an LTCH case falls in either the site-neutral or standard-rate subgroups. Doing so would help improve the accuracy of payment determinations and compliance assessments for LTCHs.***

**Replace Home Health Audit Demonstration with Targeted Fraud Interventions.** In 2019, CMS resumed the "Review Choice Demonstration" for all home health providers in Illinois, with four additional states to follow. We strongly oppose this across-the-board approach that results in unwarranted burden and cost for agencies with no history of fraud, as well as for the auditors. This demonstration imposes unnecessary and complex time and paperwork requirements, which reduce resources for patient care. Home health agencies with no payment or fraud issues should not face compliance interventions.

***The AHA urges the Administration to replace this onerous demonstration with proven, data-driven approaches that only target agencies and/or claims with high-payment error rates or other fraud indicators.***

**Revise the Recovery Audit Contractors (RAC) Contracts to Incorporate a Financial Penalty for Poor Performance.** 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. This has led to inappropriately high-denials rates, with many reversals in the hospitals' favor after an exhaustive and costly appeals process.

***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.***

**Reduce Erroneous Denials by Refining OIG Audit Protocols.** IRFs and other providers are being subjected to inaccurate and unreliable audits by OIG. For example, in response to a CMS-commissioned re-review of a 2018 IRF audit by OIG, the OIG acknowledged that 50% of its auditor's findings were wrong – calling into question the efficacy of auditor training and protocols. Further, IRFs' successful appeal rate at the ALJ level also challenges the validity of this and other audit reports, which do not account for these overturned denials in their reported error rates. Collectively, OIG's unreliable accuracy, overstated error rates, and aggressive extrapolation of findings appears to be a great over-reach. They highlight systemic problems and the need to improve auditor education on key payment and coverage policies, as well as a review of auditor protocols. Such improvements would eliminate for both providers and HHS the unnecessary and costly burden associated with adjudicating appeals of erroneous denials.

***The AHA urges stopping OIG audits until the agency's protocols can be reviewed and adapted to lower the occurrence of erroneous denials and the associated, otherwise unnecessary appeals.***

**Re-evaluate Post-acute Care Quality Measure and Patient Assessment Requirements.** Recent laws and regulations are rapidly expanding the quality measure and patient assessment data reporting requirements for post-acute care providers. The requirements have been implemented aggressively, and without adequate time for field testing to demonstrate reliability and validity; in this year's FY 2020 post-acute care final rules, CMS added dozens of tasks to already lengthy patient assessment processes, including several that were shown by CMS's own analysis to lack relevance to post-acute care providers (but would nonetheless be required for completion). In addition, post-acute care providers are required to report data on several quality measures that have not been endorsed by the National Quality Forum (more than half of the required measures across all post-acute care settings will lack endorsement); the endorsement process demonstrates baseline validity and usefulness of quality measures and requires measures to be re-evaluated and updated regularly. Without endorsement, measures may not provide meaningful information to patients and providers. CMS also is developing even more standardized patient assessment data elements and quality measures for adoption in the future.

***We urge the Administration to only adopt quality measures that have received endorsement from the National Quality Forum, and to balance the adoption of new measures by removing less meaningful measures. In addition, we suggest that the administration re-evaluate the finalization of the recently adopted standardized patient assessment data elements that were proven to be relevant to all post-acute providers based on findings from the National Beta Test and any comments on the FY/CY 2020 prospective payment system proposed rules.***

**Medicaid Provider Enrollment Requirement for Care Provided to Out-of-state Patients**. The Affordable Care Act, to combat fraud and abuse, imposed more stringent screening and enrollment requirements on Medicare and Medicaid providers. For hospitals serving out-of-state Medicaid patients, this often means they must enroll in the patient's home state Medicaid program in order to receive reimbursement for services provided. CMS, in 2011, issued implementation guidance encouraging states to collaborate on information regarding the hospitals' enrollment as a way to reduce unnecessary provider screening and inappropriate application fee collection, as federal rules require that only one application fee be collected for a Medicaid enrolling provider. However, many states have not adopted this guidance, leaving the burden on hospitals to submit and pay for provider enrollment applications to the Medicaid programs for their out-of-state patients.

***The AHA recommends that CMS require formal reciprocity arrangements between states regarding Medicaid provider enrollment and screening. Doing so would relieve hospitals and other providers from the administrative burden of enrolling in an out-of-state Medicaid program when providing needed care to out-of-state individuals.***

**Clarify Requirements and Update Surveyor Training and Documentation for EMTALA and Ligature Risk for Psychiatric Facilities.** The Emergency Medical Treatment & Labor Act (EMTALA) requires Medicare-participating health care facilities with a dedicated emergency department to meet certain screening and stabilization requirements for any person with an emergency medical condition, regardless of that person's ability to pay. State survey agencies have applied these requirements to psychiatric facilities inconsistently, sometimes citing the facility for noncompliance if the facility does not admit a person even if inpatient admission is not the best course of action, or if the surveyor determines the staff person performing a medical screening exam is unqualified, despite state scope-of-practice suggesting the staff person is qualified.

In addition, psychiatric facilities have spent millions of dollars on renovations in order to come into compliance with unclear regulations requiring ligature-resistant environments. While recent draft guidance attempted to clarify these requirements, surveyors continue to evaluate facilities inconsistently and subjectively, often citing as non-compliant the use of certain types or brands of fixtures, even though those fixtures meet ligature-resistant criteria.

***We ask the Administration to issue updated, clarifying interpretive guidance specifying requirements for psychiatric facilities regarding admissions and medical screening exams under EMTALA, and to require surveyors to undergo training on these requirements. In addition, we request that surveyors be required to provide standardized documentation of any cited ligature risks to facilities***

***before the end of the onsite surveys, similar to the documentation required in recent guidance for immediate jeopardy citations.***

**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 is 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 electronic health record (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.***

**Make Future Bundled Payment Programs Voluntary.** Through the Center for Medicare and Medicaid Innovation (CMMI), CMS established a new mandatory bundled payment model for cardiac care and also expanded a mandatory bundled payment model for comprehensive joint replacements. Recently, CMS proposed to cancel implementation of these new models.

***The AHA supports bundled payment programs as tools to potentially improve care coordination and efficiency. However, we urge the Administration to ensure that any new bundled payment programs are voluntary. Hospitals should not be forced to bear the expense of participation in these complicated programs if they do not believe they will benefit patients.***

**Expand Medicare Coverage of Telehealth Services.** Hospitals are embracing the use of telehealth technologies because they connect patients to vital health care services through videoconferencing, remote monitoring, electronic consults and wireless communications. By increasing access to physicians and specialists, telehealth helps ensure patients receive the right care, at the right place, at the right time.

However, coverage and payment for telehealth services remain major obstacles for providers seeking to improve patient care. Medicare generally still limits coverage and payment for many telehealth services, lagging behind other payers. While we appreciate Medicare's recent expansion of coverage for telehealth services for stroke patients, substance use treatment and for virtual check-ins, more can be done to address outstanding policy and operational challenges to the use of telehealth. Specific issues include credentialing and privileging, online prescribing, privacy and security, and fraud and abuse. Limited access to adequate broadband services also hampers the ability of some rural facilities to deploy telehealth. And, the challenge of cross-state licensure continues to be a major issue.

***The AHA appreciates that CMS has focused on expanding and improving access to telehealth services for patients. We urge 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. We further urge CMS to eliminate geographic and setting locations' requirements so patients outside of rural areas can benefit from telehealth, resolve legal and regulatory challenges to the use of telehealth, increase federal research on the cost-benefits of telehealth, and improve the Federal Communications Commission's Rural Health Care Program.***

**Reduce Burden of Program that Encourages Appropriate Use Criteria (AUC).** The Protecting Access to Medicare Act (PAMA) of 2014 required CMS to establish a program to promote the use of AUC for advanced diagnostic imaging that integrates AUC into the clinical workflow. The statute requires that, beginning Jan. 1, 2017, payment may be made to the furnishing professional for an applicable advanced diagnostic imaging service provided in specific settings 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 delayed the implementation of AUC requirements. However, we remain deeply concerned about the policy CMS finalized in the CY 2019 Physician Fee Schedule final rule that requires furnishing facilities – in addition to furnishing professionals – to report AUC consultation information on their claims.** This requirement is in direct contradiction to this Administration's goal of reducing regulatory burden – it actually increases the regulatory burden for furnishing facilities by introducing new data-reporting variables to the flow of information needed for hospital billing. Under the AUC program, this information will have already been captured on furnishing professionals' claims, rendering any repetition of the information on the claims of furnishing facilities as just that – duplicative. Moreover, hospitals and health systems have no way to report complete AUC consultation information, as the electronic claim standard for the institutional provider (837i) does not capture or have a placeholder for reporting the ordering physician's national provider identifier (NPI). Even

if the 837i is modified, hospitals and health systems still would need to make sweeping and costly system changes to interface with a modified 837i.

The AUC program was intended to evaluate physicians who order advanced diagnostic imaging services, not hospitals and health systems. By shifting the burden of compliance to furnishing providers, this requirement could force hospitals and health systems to take dollars away from patient care, driving up patient costs. This is especially true given that while CMS utilized 2014 data to analyze the impact of the AUC program, today many fewer institutional claims receive separate reimbursement for advanced diagnostic imaging services. As Medicare moves away from fee-for-service payment and hospitals and health systems increasingly enter payment arrangements with other payers and other Medicare programs, requiring facilities to report AUC information imposes additional costs that could otherwise be directed toward patient care services.

***We urge CMS to exempt furnishing facilities (hospitals and health systems) from reporting AUC requirements, as this policy does not appropriately target the AUC program to the ordering professionals to whom it is designed to apply. In fact, these costly regulatory routines that CMS introduced inappropriately penalize hospitals and health systems, putting their payment, and thus patient care, at risk if AUC information does not appear on orders they receive from individual physicians. We continue to recommend that CMS consider alternative methods of implementing this proposal that do not require reporting by furnishing professionals or facilities.***

**Do Not Activate Edits for Hospital Outpatient Prospective Payment System (OPPS) Providers with Multiple Service Locations.** CMS has announced that it soon will enact changes for OPPS providers that have multiple off-campus provider-based department (PBD) locations. Specifically, the agency will put in a system edit to check whether the address on a provider's claim exactly matches their address in the Medicare Provider, Enrollment, Chain and Ownership System (PECOS). When CMS fully activates the edit, the Medicare Administrative Contractors (MACs) will "Return-to-Provider" (RTP) claims where the addresses do not *exactly* match. For instance, if a provider's enrollment information includes a service location with the word "Road" but the provider entered "Rd" on the claim, the claim would be RTP. The provider then will have to resubmit such claims to their MAC. This will be unnecessarily time-consuming and disruptive for both providers and MACs. We understand the need to ensure that Medicare pays the correct rate for excepted and non-excepted off-campus PBDs by ensuring that all off-campus locations are properly enrolled in Medicare and that claims contain the correct address where such services were furnished. However, minor differences in address, like "Road" versus "Rd," or "Suite" versus "Ste," should not generate a RTP for claims. We believe that if the United States Postal Service is able to deliver mail to the correct location regardless of whether common acronyms are used, CMS should be able to accommodate these small differences as well.

***The AHA urges CMS not to RTP claims where the only mis-match identified involves the use of common acronyms. Rather, the agency should update its claims processing systems to allow such claims to be processed normally.***

**Rescind the Requirement that Hospital "Outreach" Laboratories Collect and Report Private Payer Rates.** CMS recently revised the Clinical Laboratory Fee Schedule (CLFS) regulations to define an "applicable laboratory" to include hospital laboratories that bill Medicare for their non-patient laboratory services on the CMS 1450 14X Type of Bill (TOB). This bill type is only used by hospital outreach laboratories. This policy change means that all hospital outreach laboratories, except for those that receive less than $12,500 in CLFS revenues on the 14X TOB during the most recent data collection period, will be required to report their private payer rate and volume data to CMS in the upcoming data reporting period of Jan. 1 through March 31, 2020.

The AHA remains strongly opposed to this requirement due to the significant operational burden this private payer data collection and reporting imposes on hospitals, the concern that this burden is not justified by what CMS itself has repeatedly acknowledged will be a minimal impact on the CLFS rates, as well as our belief that Congress did not intend hospital outreach laboratories to qualify as applicable laboratories.

***We urge CMS to immediately rescind this burdensome change in the definition of applicable laboratory. If the agency is unable to rescind this policy in advance of the upcoming reporting period, at the very least it should:***

1. ***Simplify reporting for hospitals by clarifying in subregulatory guidance that outreach laboratories that meet the requirements to be applicable laboratories must report only private payer data that is billed on a 14x Type of Bill (TOB);***
2. ***Apply the same enforcement discretion for hospital outreach laboratories that the agency applied for applicable laboratories during the 2017 data reporting period,[1]; and***
3. ***Rescind for the next reporting period the policy that defines an "applicable laboratory" to include hospital laboratories that bill Medicare for their non-patient laboratory services on the CMS 1450 14X TOB.***

**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 solutions. In addition, it

[1] In the last reporting cycle, CMS announced that it would exercise enforcement discretion until May 30, 2017, with respect to the data reporting period for reporting private payer data and the application of the Secretary's potential assessment of civil monetary penalties for failure to report the data.

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.***

**Ensure Consistent Coding and Documentation Requirements.** Hospitals billing for outpatient services are required to report Current Procedural Terminology (CPT) codes or Healthcare Procedure Coding System (HCPCS) level II codes. Both CPT and HCPCS are considered HIPAA code set standards used by all payers. However, within HCPCS level II codes, there is a subset of "temporary codes" called Q codes and G codes. According to CMS, temporary codes are for the purpose of meeting, within a short time frame, the national program operational needs of a particular insurance sector that are not addressed by an already existing national code. However, some "temporary" codes have remained in place for years. This disconnect results in confusion and additional work requiring different code assignments for the same service provided to Medicare patients vs. patients covered by commercial insurance. For example, for screening colonoscopies, Medicare uses HCPCS G codes, while commercial payers require CPT codes.

***CMS should work to eliminate or minimize the use of "temporary" HCPCS level II codes and align billing requirements with CPT codes to ensure that the exact same national CPT code is billed for the same service regardless of the payer.***

**Proactively Identify Codes for Complex New Technologies.** Complex new technologies that are delivered in different settings pose challenges for providers and CMS alike in terms of claims coding and processing. For example, chimeric antigen receptor (CAR) T-cell therapies have required a patchwork of codes utilizing different coding systems (i.e. CPT category III codes, revenue codes, HCPCS level II Q or J codes) to report different components of the clinical services required to provide the therapy. This resulted in an overlap between the different codes until CMS issued guidance nearly a year after the therapy was approved. Rather than revising or deleting overlapping Q codes, CMS guidance instructed how the CAR-T service was to be coded and billed with the existing codes. While the CMS guidance was appreciated, it has resulted in providers having to determine how CAR-T should be billed for other payers as they each have different requirements.

***CMS should actively work with stakeholders to proactively identify new technologies requiring complex processes delivered in different settings and update or create any necessary codes to report those new services.***

**Issue a Permanent Enforcement Moratorium on Direct Supervision Requirements.** In the 2009 OPPS 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 many years there has been an enforcement moratorium on this policy. However, CMS in its recently issued CY 2020 OPPS proposed rule seeks to change the minimum required level of supervision from direct supervision to general supervision for all hospital outpatient therapeutic services provided by all hospitals and CAHs. General supervision means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. The Hospital Outpatient Payment Panel would continue to provide advice on the appropriate supervision levels for individual hospital outpatient services, and CMS would retain its authority to make changes to the level of supervision required for individual services through notice-and-comment rulemaking. The AHA supports this proposal, as we have repeatedly pushed CMS for a solution to this critical issue for rural hospitals.

***We urge the Administration to finalize its proposal to change the minimum required level of supervision from direct supervision to general supervision for all hospital outpatient therapeutic services and thus provide a solution to this critical issue for rural hospitals.***

**Issue a Permanent Enforcement Moratorium on the "96-hour" Rule.** In 2013, CMS 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, reducing local access in rural areas and forcing patients to travel longer distances for care. Taking this into account, in the inpatient PPS final rule for FY 2018, CMS indicated that its contractors would make reviews of this issue a "low priority." The AHA appreciates CMS's recognition that this condition of payment could stand in the way of promoting essential, and often lifesaving, health care services to rural America. However, while this directive 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.

***We continue to recommend that CMS issue a permanent enforcement moratorium on the 96-hour Rule. In addition, 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.***

**Eliminate the Observation Hours Carve-out Policy.** Currently, CMS requires that hospitals "carve out" from their count of observation hours the time involved in furnishing other diagnostic or therapeutic services that also require active monitoring. Doing so is burdensome for hospitals, as it requires manual estimation and recording of the time required to complete each separate service. It also is unnecessary given that payment for observation services is now packaged and, in most cases, diagnostic or therapeutic services furnished in conjunction with observation no longer separately paid. Further, CMS itself has decided to disregard this "carving out" of time from observation services in its final policy for implementing the Notice of Observation Treatment and Implication for Care Eligibility Act. That is, in determining whether a hospital has furnished more than 24 hours of observation services to a Medicare beneficiary (thus, triggering the MOON notification), CMS instructed hospitals to disregard this notion of "billable hours" and instead directed hospitals to count the time directly as clock hours from the initiation of observation services.

***The AHA recommends that CMS eliminate the current requirement that hospitals "carve out" from the count of observation hours the time involved in furnishing other diagnostic or therapeutic services that also require active monitoring.***

**Eliminate Second Important Message from Medicare.** Currently, hospitals are required to provide a written explanation of a beneficiary's appeal rights and obtain a signature at the time of admission (known as the "Important Message"). In addition, the hospital must provide this message a second time (known as the "Second Important Message") to the beneficiary if the initial message was provided more than two days prior to discharge. Presenting the beneficiary with the same information twice in one stay leads to confusion and feelings of being overwhelmed with paperwork. It also is burdensome and redundant for the hospital and staff.

***We urge CMS to eliminate the requirement for a second notice if the initial message was provided more than two days prior to discharge. Any benefit to presenting a second message is outweighed by the added confusion to the patient and burden borne by the hospital.***

**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. For example, in rural areas, hospitals may lease space to visiting specialists from out of town several days per month. In urban and suburban areas, two hospitals, such as an adult general acute care hospital and a children's hospital or a psychiatric hospital may be co-located to improve efficiency and access for patients. Recently, CMS issued draft guidance on allowing hospitals to co-locate with other hospitals and health care entities and sought public comment on that draft guidance. We submitted a letter in response to the draft guidance and encouraged the agency to make several revisions so that co-located hospitals are able to serve their patients in a more efficient and effective manner.

***We urge CMS to review our comment letter and consider making the recommended revisions in order to provide necessary clarity and flexibility for those hospitals that co-locate with other hospitals or health care entities. Specifically, we raise attention to our comments requesting changes to the distinct and share space requirements, the removal of staffing contract non-float provisions in certain instances and our proposed revised language concerning emergency services.***

**Modify Conditions of Participation (CoPs) to Allow Hospitals to Recommend Post-acute Care Providers.** CMS's discharge planning regulations have been interpreted to prevent a hospital from offering advice to a patient on the selection of a provider for post-hospital care. However, efforts to prevent unnecessary readmissions and improve the health of individuals with chronic medical conditions have shown that coordination of care makes a difference in patient outcomes. This kind of coordinated care is essential to meeting the goals of the new payment models and would benefit all patients.

***The AHA urges CMS to amend the CoPs to establish that, while the choice must always be up to the patient, a hospital may make recommendations about post-acute care providers.***

**Standardize and Facilitate Electronic Submission of Prior Authorization Requests within Medicare Advantage.** Certain health plan utilization management practices can, when poorly structured or implemented, create unnecessary and excessive burdens on providers and, worse, delays in patient care that can negatively impact patients. Prior authorization is a tool that, when used appropriately, can help ensure a patients' care is consistent with their health plan benefit structure and facilitate alignment with clinical best practices. However, prior authorization processes vary among health plans (even among different plans offered by the same issuer) and can be confusing and burdensome for providers. Delays in health plan responses to prior authorization requests frequently delay patient access to care. The AHA has worked with both provider and health plan representatives to identify ways to streamline and improve prior authorization processes. One particular area of agreement is the advancement of electronic tools and standards to ease transmission of prior authorization requests and responses.

***The AHA urges CMS to pursue a standardized approach for providers to submit and receive prior authorization requests and, correspondingly, require that Medicare Advantage plans adhere to these standards.***

**Create Incentives for Medicare Advantage Plans to Eliminate Inappropriate Claims Denials.** Hospitals spend a considerable amount of resources appealing inappropriate claims denials by Medicare Advantage plans. Our members' experience is consistent with the findings of OIG in its September 2018 report on prior authorization and payment denials in the Medicare Advantage program. OIG found that the plans they examined denied approximately 1 million prior authorization requests (4%) and 36 million payment requests (8%). They also found that when beneficiaries or providers appealed, plans overturned 75% of their own rulings at the first stage of appeal, suggesting that many of these denials were inappropriate in the first place. However, providers and beneficiaries only appealed 1% of denials. The low rate of appeal is frequently a result of the burden associated with the appeals process.

***The AHA urges CMS to increase its oversight of health plan performance in these areas and take action against plans found to have high rates of inappropriate payment and prior authorization delays and denials to discourage this practice and reduce providers' burden of tracking down reimbursement for which they are fairly due.***

**Amend 42 CFR Part 2 to Align with HIPAA.** The section of the Code of Federal Regulations that dictates requirements and restrictions around information sharing for patients with substance use disorder (SUD) has not been updated in more than 40

years, and is misaligned with other health information sharing laws, including HIPAA. The outdated regulations limit the use by and disclosure of patients' SUD records for certain clinicians, which puts patients at risk: If clinicians are not aware of a patient's history with opioids, alcohol, or other addictive substances, they cannot provide the appropriate care.

***We urge the Administration to align 42 CFR Part 2 with HIPAA for the purposes of treatment, payment, and health care operations (TPO) to allow appropriate access to patient information, which is essential for providing whole-person care while protecting patient privacy. Specifically, the regulations should be amended to allow for the transmission of SUD records without separate written consent for TPO.***