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June 25, 2018

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-1694-P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims; Proposed Rule (Vol. 83, No. 88), May 7, 2018.

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 comment on the Centers for Medicare & Medicaid Services' (CMS) hospital inpatient prospective payment system (PPS) proposed rule for fiscal year (FY) 2019.

We are submitting separate comments on the agency's proposed changes to the long-term care hospital PPS and CMS's proposals and request for information related to price transparency.

A summary of our key recommendations follows.



MEDICARE DSH PAYMENT:

- Put in place a full audit process for the S-10 data to ensure the data are sufficiently accurate and consistent.
- Implement a stop-loss policy to protect hospitals that lose more than 10 percent in DSH payments in any given year as a result of transitioning to the Worksheet S-10.

CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY:

- Use an alternative method of determining the cost of the CAR T therapy that ensures the agency captures that cost accurately, such as using the therapy's average sales price as a proxy for its cost, or using a cost-to-charge ratio of 1.0 (as mentioned in the rule).
- Approve CAR T for new technology add-on payments (NTAPs) and increase the NTAP marginal reimbursement to 100 percent for CAR T.
- Consider longer-term solutions for these costly new technologies, such as making payment on a pass-through basis.

RURAL HOSPITALS:

- Review and ensure accuracy of the Sole Community Hospital and Medicare-dependent Hospital-specific rate calculations for FY 2019.

WAGE INDEX:

- Extend the "imputed" rural floor policy absent other wage index policies that would address the original need for the imputed rural floor.

HOSPITAL QUALITY REPORTING AND VALUE PROGRAMS:

- Adopt CMS's proposal to remove 18 measures from hospital programs altogether and "de-duplicate" an additional 21 measures. The AHA applauds CMS for beginning to use its "Meaningful Measures" framework to reduce unnecessary data collection burden and to prioritize the measures in hospital programs around the issues that matter the most to improving care.
- Adopt CMS's alternative proposal to weight measure domains of the hospital value-based purchasing (VBP) program equally in calculating the VBP total performance score.
- Require that any measures newly added to the Hospital-Acquired Condition and Hospital Readmissions Reduction Programs be publicly reported without a tie to payment for at least one year to ensure there are no adverse unintended consequences of their use.

RFI ON INTEROPERABILITY:

- Do not create Condition of Participation/Condition for Coverage requirements to promote interoperability.
- Establish a framework for interoperability such that the technology and governance of health information exchange are universally and consistently implemented and demonstrable.

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PROMOTING INTEROPERABILITY PROGRAM:

- Finalize the proposed 90-day reporting period in 2019 and 2020 and removal of requirements that hold hospitals and critical access hospitals (CAHs) responsible for the actions of others.
- Finalize a scoring approach that permits hospitals to get credit for building performance in some areas while earning additional points in areas of strong performance.
- Offer access to at least one application, rather than any application, configured to meet the technical specifications of the application program interface in the hospital's or CAH's electronic health record.

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Erika Rogan, AHA senior associate director for policy, at (202) 626-2963 or erogan@aha.org.

Sincerely,

/s/

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

Enclosure

**American Hospital Association (AHA)
Detailed Comments on the Inpatient Prospective Payment System
(PPS) Proposed Rule for Fiscal Year (FY) 2019**

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DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENT CHANGES

Under the DSH program, hospitals receive 25 percent of the Medicare DSH funds they would have received under the former statutory formula (described as “empirically justified” DSH payments). The remaining 75 percent flows into a separate funding pool for DSH hospitals. This pool is reduced as the percentage of uninsured declines and is distributed based on the proportion of total uncompensated care each Medicare DSH hospital provides.

TRANSITION TO WORKSHEET S-10

In FY 2018, CMS began incorporating the cost report Worksheet S-10 data on hospital charity care and bad debt to determine the amount of uncompensated care each hospital provides. For FY 2019, CMS proposes to continue phasing in the S-10 data and also to continue to use data from a rolling three-year period to estimate uncompensated care payments. Specifically, for FY 2019, CMS would use FY 2014 and 2015 Worksheet S-10 data in combination with FY 2013 Medicaid days and Supplemental Security Income (SSI) ratios to determine the distribution of uncompensated care payments.

Generally speaking, the AHA continues to believe that, if reported in an accurate and consistent manner, the Worksheet S-10 data have the potential to serve as a more exact measure of hospital uncompensated care costs. We appreciate that CMS has made several improvements to the data, such as including discounts provided to uninsured individuals who are unable or unwilling to provide income information to the hospital in its definition of uncompensated care. However, concerns over accuracy and consistency remain. As such, we recommend CMS:

- Further educate hospitals about how to accurately and consistently complete the S-10.
- Put in place a full audit process for the S-10 data to ensure the data are sufficiently accurate and consistent.
- Implement a stop-loss policy to protect hospitals that lose more than 10 percent in DSH payments in any given year as a result of transitioning to the Worksheet S-10. This stop-loss should extend beyond the transition to help hospitals with decreasing uncompensated care payments adjust to their new payment levels.

TECHNICAL COMMENTS RELATED TO THE WORKSHEET S-10

CMS also makes several technical proposals related to the S-10 data. First, as in the past, if a hospital has a cost report that does not equal 12 months of data (in other words, are more or less than 365 days) in any given year, CMS proposes to annualize Medicaid days and uncompensated care data. The agency does not propose to annualize SSI days because those data are not obtained from hospital cost reports. **We support this proposal.**

In addition, CMS would continue to trim data to control for data anomalies. For FY 2019, all hospitals with a Worksheet S-10 cost-to-charge ratio (CCR) that is above a CCR “ceiling,” or that is greater than 3.0 standard deviations above the geometric mean, will receive the statewide average CCR. The agency would continue to exempt all-inclusive rates from this policy. **We support this proposal.**

DSH SUPPLEMENTAL PUBLIC USE FILES

In the prior year DSH supplemental public use files, CMS included: 1) an uncompensated care per claim amount; 2) factor 3, which is each DSH hospital's share of uncompensated care relative to other DSH hospitals; and 3) a claims average. This data was also available for sole community hospitals (SCHs), which CMS projects will be paid at the higher hospital-specific rate. However, in the file titled *FY 2019 Proposed Rule DSH Supplemental File.xlsx*, CMS has included factor 3 but not the claims average or the per claim amount for hospitals that have a SCH flag. **We suggest CMS consider including these values in the FY 2019 final rule DSH supplemental file as well as in future years, as it has done in the past.**

In addition, the AHA tried to recreate the average number of claims variable in the FY 2019 proposed rule DSH supplemental file using the number of claims in the FY 2017 final rule, FY 2018 final rule and FY 2019 proposed rule impact files, but could not replicate CMS's values for most of the providers. For example, for provider 010001, the FY 2015 cases are 8,311, the 2016 cases are 8,538 and the 2017 cases are 7,989. The average for these three years is 8,279, yet the FY 2019 DSH supplemental file has a value of 8,329. Because CMS has calculated a higher claims average, the uncompensated care per claim amount in the DSH supplemental file for this provider is \$601.49, which is too low – this has been calculated as the total uncompensated care payment of \$5,009,786.44 divided by the CMS-calculated claims average of 8,329. The uncompensated care per claim amount should instead be $\$5,009,786.44/8,279 = \605.12 . As stated above, the CMS-calculated amounts for most of the providers do not match with our calculations. **The AHA suggests CMS verify the accuracy of these values, such as in the example above, in the FY 2019 final rule.**

CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY

CAR T-cell therapy is a cell-based gene therapy in which a patient's own T-cells are genetically engineered in a laboratory and administered to the patient by infusion to assist in the patient's treatment to attack certain cancerous cells. For FY 2019, CMS proposes to assign CAR-T therapy procedure codes to MS-DRG 016 (see "Changes to MS-DRG Classifications" below for more information). It also mentions the possibility of using a CCR of 1.0 for charges associated with CAR T in determining payments. In addition, CMS discusses these technologies in the context of potential approval for new technology add-on payments (NTAPs). NTAPs are not subject to budget neutrality and, therefore, do not reduce payments for all other inpatient services. Finally, the agency invites public comments on alternative payment approaches given its concern about potential redistributive effects away from core hospital services toward specialized services.

The AHA shares CMS's concern about redistributive effects away from core hospital services. We also are concerned about beneficiary access to CAR T technologies given their costliness. Specifically, the two CAR T products, YESCARTA™ and KYMRIAH™, have list prices of \$373,000 and \$475,000, respectively. In addition to the cost of the therapy, there also are extremely high patient care costs – both before and after infusion of the therapy – including multiple-week stays in the intensive care unit (ICU). Although costs vary widely, some have estimated that the patient care costs, can average \$150,000 to \$200,000. **To ameliorate concerns**

about redistributive effects and to help ensure beneficiary access to this therapy in the short term, we urge the agency to take the five actions described below for FY 2019, several of which CMS included in the proposed rule.

However, in order to ensure the integrity of the inpatient PPS and beneficiary access in the long-term, additional solutions will be necessary. Specifically, we urge CMS to consider carving these very costly new technologies out of the MS-DRG and paying for them on a pass-through basis. This is especially necessary given that both new and existing therapies are expected to be approved for additional indications. The current payment systems – of any payer, not just Medicare – were not built to sustain access to therapies with costs of these magnitudes. As technology continues to advance, therapies such as these will become more and more prevalent, and it is critical that a precedent is set that ensures beneficiary access to care. This requires not only appropriate payment, but also provider certainty in terms of coverage determinations, as one post-care-provision denial would be devastating to both providers and beneficiaries. We look forward to working with you to develop a long-term solution.

ASSIGNMENT TO MS-DRG 016

We support CMS’s proposal to assign CAR T therapy to MS-DRG 016 (as further described in “Changes to MS-DRG Classifications” below). However, we note that the base standardized operating reimbursement for MS-DRG 016 is proposed to be about \$37,000 in FY 2019. This is entirely inadequate to cover the costs of a treatment for which the therapy alone (not including the actual patient care, which, as noted above, can average \$50,000 to \$100,000) is at least \$373,000. However, when paired with the other policies listed below, it could provide a minimum rate that could help ensure beneficiary access to CAR T.

CMS also set forth a possibility of creating a new MS–DRG for CAR T therapy; we do not oppose this option per se. However, the level of uncertainty as to how this would be accomplished (given the absence of CAR T claims in the data) and the potential redistributive effects it would necessitate are simply too large to recommend for its pursuit for FY 2019. As noted in “Changes to MS-DRG Classifications” below, we do urge CMS to continue exploring this option and potentially re-consider it in the future once data are available, because its eventual implementation could potentially provide much more accurate reimbursement for the therapy. Specifically, the weight of this new MS-DRG would directly reflect the extremely intensive resources involved in the provision of CAR T therapy since it will not be averaged together with much less resource-intensive treatments. In addition, because the weight would directly reflect CAR T resource use, it would avoid the problem of CAR T cases always qualifying for outlier payments as a matter of course, which would essentially drain the entire outlier pool to the exclusion of other services.

USE OF A COST PROXY OR CCR OF 1.0

As noted above, the MS-DRG payment alone would be wholly inadequate to ensure access to the CAR T therapy for Medicare beneficiaries. Other components of the inpatient PPS must be utilized, including outlier payments and NTAPs, in order to ensure access. **We urge CMS to finalize an alternative method of determining the cost of the CAR T therapy that ensures the agency captures that cost accurately, such as using the therapy’s average sales price**

(ASP) as a proxy for its cost, or the option of using a CCR of 1.0. Doing so is critical because the standard method of calculating CAR T costs would vastly underestimate the cost of this therapy. Specifically, if a hospital's overall CCR is 0.25, when applied to the list price for one of the CAR T products, it results in a calculated cost of \$93,250, whereas the actual cost is \$373,000. Even if a hospital with an overall CCR of 0.25 were to adjust the cost of the CAR T product, it would need to set a charge of almost \$1.5 million in order to generate an accurate cost. As such, we agree with CMS that hospitals may be unlikely to set charges significantly different from the cost of CAR T. Therefore, using an alternative method that more accurately identifies the cost is absolutely necessary to make accurate reimbursement – it would allow the full cost of the therapy to be appropriately considered, free from charge compression. In the long-term, CMS should consider additional options such as creating a CAR T-specific cost center and CCR that would apply in weight-setting as well as outlier payment and NTAP calculations. In addition, as described below in “Changes in MS-DRG Classifications,” the National Uniform Billing Committee (NUBC) is recommending a series of new revenue codes associated with cell/gene treatments. We recommend that CMS utilize these codes in addition to the procedure codes not only for processing claims but also for refinements to the Medicare Cost Report.

APPROVAL OF NTAPS

We strongly urge CMS to approve NTAPs for CAR T therapy. Not only does the therapy meet the three NTAP criteria, but these payments also would allow for targeted reimbursement of the therapy while it works its way into the weights. Specifically, these therapies:

- are new – they are not substantially similar to any other therapy currently available because they use novel mechanisms of action and delivery to the patient. They also are the first engineered autologous cellular immunotherapy indicated for the treatment of adult patients with relapsed/refractory aggressive B cell non-Hodgkin lymphoma who are ineligible for autologous stem cell transplant;
- would be assigned to an MS-DRG for which the rate is wholly inadequate to cover the cost, as described above; and
- are clearly a substantial clinical improvement over existing services and technologies. Specifically, the achievement of partial and complete remissions in the relapsed/refractory patients treated with this therapy is not feasible with any other currently available treatment and is, therefore, clinically remarkable.

RAISE MARGINAL NTAP REIMBURSEMENT

NTAPs are made at a rate of 50 percent of the marginal cost of the technology. **However, we are concerned this rate would not ensure beneficiary access to care and urge CMS to make NTAPs for CAR T at a rate of 100 percent of its marginal cost.** When CMS implemented NTAPs, it stated that it set a 50 percent rate “to appropriately balance the incentives.” Specifically, the agency believed that this rate “would provide hospitals an incentive for continued cost-effective behavior in relation to the overall costs of the case. In addition [it believed that] hospitals would face an incentive to balance the desirability of using the new technology versus the old; otherwise there would be a large and perhaps inappropriate incentive

to use the new technology.”¹ However, this rationale does not apply to CAR T. First, for patients eligible for this treatment, there is no balancing “the desirability of using the new technology versus the old.” These patients have typically relapsed or not responded to conventional cancer treatments and are using CAR T as a last measure.

Second, the staggering losses hospitals would face when administering this technology mean that there is no need to provide additional incentives for “continued cost-effective behavior” and, likewise, there is no “inappropriate incentive to use the new technology.” Specifically, in the paragraph preceding the above quotation, CMS provides an example of how the 50 percent rate is calculated. In it, the agency cites three hypothetical cases – in one, the hospital makes \$1,000, in another it loses \$1,000, and in the third it loses \$3,500. However, the amount of losses a hospital would face under a CAR T NTAP rate of 50 percent are not in the thousands, or even tens of thousands of dollars – they are in the *hundreds of thousands* of dollars. As an illustrative example, we considered a hypothetical case in which we assumed the patient care costs were \$0 and the hospital administered the lower-priced CAR T product (YESCARTA™) for which its cost was the list price of \$373,000. In such an example, the costs of the case exceed the MS-DRG payment by \$336,000; therefore Medicare would make an NTAP payment of one half of this, or \$168,000. When combined with the MS-DRG payment, the total payment for this case would be \$205,000 – a shortfall of \$168,000 for the hospital. **This is a stunning amount – particularly considering it more or less represents the absolute lower bound of a hospital’s losses given that we assumed the patient care costs were \$0. This is not sustainable and will threaten beneficiary access to care.**

If CMS were to increase the NTAP marginal rate to 100 percent for CAR T cases, the NTAP payment for the above case would be \$336,000 after the MS-DRG payment, ultimately covering the full cost of the CAR T product. While this does not include the additional patient care costs associated with CAR T treatment, a 100 percent NTAP approach for CAR T would prevent these critical therapies from drastically draining available outlier payment funds and restricting payments for other important high-cost treatments. With the 50 percent marginal NTAP rate, we are concerned that so much funding would be taken from the budget-neutral outlier pool that it would cause huge increases in the threshold in the future. Consequently, this would mean that hospitals with extraordinarily costly cases involving core services may no longer qualify for outlier payments, perhaps jeopardizing access to some of those services. In contrast, with a 100 percent marginal NTAP rate, more funding would come through the NTAP mechanism and less through the outlier pool, lessening the redistribution from core to specialized services.

In addition, an increased payment rate for CAR T would not result in an excessive amount of NTAPs being made as related to the agency’s historical targets. Specifically, when implementing NTAPs, CMS set a target limit for these payments at 1 percent of total operating prospective payments.² Yet, agency spending on NTAPs has never come close to this amount. For example, we analyzed NTAP levels for the past five years, from FY 2013 through 2017 and found that CMS made payments as low as \$14 million in FY 2013 and as high as \$47 million in FY 2016.

¹ 66 *Federal Register* 46918.

² 66 *Federal Register* 46920.

This equates to 0.01 and 0.03 percent of total operating prospective payments, respectively – at least 33 times less than the agency’s target. This indicates that accommodating a 100 percent marginal rate for CAR T NTAPs within CMS’s original target is practicable.

PROVIDE MORE CLARITY FOR PPS-EXEMPT CANCER HOSPITALS

Certain cancer hospitals are exempt from the inpatient PPS; Medicare instead pays them based on their reasonable costs, subject to a ceiling. For these hospitals, the use of a CCR of 1.0 in calculating CAR T costs would best be implemented through standard cost-reporting processes. Specifically, we recommend the following steps:

1. Cancer hospitals report the acquisition costs of CAR T-cell on their cost report. This could be done either on subscribed line 73.01 on Worksheet A or on a new, separate, standard line item on the cost report.
2. Cancer hospitals force the value of line 73.01 (or the new separate line created in step one above) on Worksheet B-1 to zero. Doing so would prevent overhead from accruing and increasing the calculated cost of the CAR T product.
3. Medicare Administrative Contractors (MACs) allow the additional costs from line 73.01 (or the new separate line created in step one above) to be added to the final settlement Worksheet E-3, Part 1. This would prevent any inadvertent recoupment of the interim CAR T-cell therapy payments based on claims. Line 16 or 17 on Worksheet E-3 Part 1 could be used to accomplish this.

Through this mechanism, CAR T-cell therapy drug costs would be added to the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) settlement line at the time of desk audit and treated as allowable costs. This approach would provide fair and timely reimbursement to the PPS-exempt cancer hospitals.

LOW-VOLUME HOSPITAL ADJUSTMENT

For FYs 2019 through 2022, CMS proposes to modify the discharge thresholds for the low-volume adjustment (LVA) as required by the Bipartisan Budget Act of 2018 (BiBA). Specifically, for these years, a low-volume hospital would continue to be defined as one that is more than 15 road miles from another comparable hospital, but may have up to 3,800 *total* discharges. CMS would continue to calculate the adjustment based on a continuous, linear sliding scale formula – qualifying hospitals with 500 or fewer total discharges would receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 total discharges, but more than 500 discharges, CMS proposes that the adjustment be calculated using the following formula:

$$\text{Add-on Percentage} = (95 / 330) - (\text{total discharges} / 13,200)$$

We support the agency’s proposal and its formula included above. However, we note that, while CMS includes this formula as its actual proposed regulation, it includes an erroneous

formula in the preamble to the rule.³ We ask the agency to include the correct formula in both places.

In addition, we would be appreciative if CMS could clarify two issues to avoid confusion with the MACs and provide hospitals with more certainty around these payments. First, **we ask that CMS specify that “total discharges” includes only inpatient PPS discharges** (as reported on cost report Worksheet S-3, Column 15, Line 1) and does not include psychiatric, rehabilitation or skilled-nursing discharges. Also, CMS states that the discharge data are to be taken from “the hospital’s most recently submitted cost report,” but **we ask that it clarify whether this is the most recently submitted as of publication of the final rule, as of Sept. 1 by when low-volume payments must be requested by, or as of Oct. 1 when payments begin.**

MEDICARE-DEPENDENT HOSPITAL (MDH) AND SOLE COMMUNITY HOSPITAL (SCH) EFFECTIVE DATES

Rural reclassification is currently effective as of the filing date, while SCH status is effective 30 days after approval. To minimize the lag between the effective date of any hospitals requiring rural reclassification and the effective date for their SCH status, CMS proposes to make the effective date of SCH status the date that CMS receives the complete SCH application. This would be effective for applications received on or after Oct. 1, 2018. The agency also proposes to make a parallel change for the effective date of MDH status. **We support these proposed changes, but note that CMS is not actually the recipient of SCH and MDH applications – the MACs are the recipients. Therefore, we would appreciate clarity that the effective date is the date that the MAC receives the complete application.**

HOSPITAL-SPECIFIC RATES

We are concerned that the SCH and MDH hospital-specific rates for FY 2019 were not calculated correctly and urge CMS to review them further. Specifically, we believe that the agency may have omitted certain factors when updating the rates and, as a result, they are much lower than they should be.

In analyzing these hospital-specific rates, we found that over the past few years, the annual recalibration of the MS-DRG weights has had a substantially negative impact on rural hospitals. For example, over the past eight years, there has been an impact of negative 2.5 percent on SCHs – a sizeable cut for small, and often vulnerable, rural hospitals. Indeed, it is well documented that many rural communities are facing challenges accessing health care with 83 rural hospitals closing since 2010.⁴ **As such, and in light of CMS’s recently released *Rural Health Strategy* that aims to make health care in rural America accessible, affordable and accountable, we ask the agency to consider ways to ameliorate these cuts. One such possibility is to re-evaluate the agency’s decision to apply documentation and coding cuts totaling 5.4 percent**

³ 83 *Federal Register* 20385: “Add-on Percentage = (95 / 330) x (total discharges / 13,200)”

⁴ <http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/>.

to the SCH and MDH hospital-specific rates in FYs 2011 through 2013, which were not required by law.

PROPOSED REVISIONS OF THE SUPPORTING DOCUMENTATION REQUIRED FOR SUBMISSION OF AN ACCEPTABLE MEDICARE COST REPORT

CMS proposes to update several supporting documentation requirements for cost report submission in order to reflect current practices, improve accuracy and facilitate more efficient cost report review. The AHA supports several of the proposed revisions; however, the requirements for the following two proposed revisions would complicate and increase the cost-reporting burden, without improving the accuracy of the cost-reporting process.

HOME OFFICE ALLOCATIONS

We agree that completing a Home Office Cost Statement (HOCS) is necessary to support the costs a home office allocates to provider cost reports. **However, we do not agree that submitting a HOCS with each provider cost report would facilitate a contractor's review and verification of the cost report without needing to request additional data.** For example, for health systems with a very large number of individual hospitals, and/or many individual hospitals with fiscal years that differ from that of the HOCS, this is an impractical requirement. In the case of individual hospitals that have a different fiscal year end from the HOCS, the HOCS correlating to their year ends may not even be filed yet. For example, in the case of an individual hospital with a fiscal year end of Sept. 30, 2017 and a HOCS fiscal year end of Dec. 31, 2017, the individual hospital cost report would have been filed on Feb. 28, 2018, while the HOCS (which cover nine months (January through September) of the hospital's filed cost report) won't be filed until May 31, 2018. Therefore, home office costs must be estimated for the provider, and contractors still will have to request additional information from the providers to support the home office allocations.

Instead of adopting its proposal, we encourage CMS to continue to utilize the existing system, in which the HOCS is filed with the Home Office MAC, who makes it readily available to provider MACs. The distribution of the filed and accepted HOCS through the Home Office MACs facilitates accurate and consistent reporting of home office allocations across contractors – this would be more difficult to achieve if all the many individual hospitals provided them separately.

INTERN AND RESIDENT INFORMATION SYSTEM (IRIS) DATA

The AHA also has concerns with the proposed requirement that the count of total full-time equivalents (FTEs) in the IRIS data must equal the count of total FTEs in the cost report, for cost-reporting periods filed on or after Oct. 1, 2018. Specifically, there are various situations in which the IRIS FTE total count will not agree with the total FTEs in the cost report, by definition, such as if the number of residents trained exceeds the number of accredited FTE slots. These inconsistencies may be resolved by adding a line to the cost report or by incorporating changes into the Extensible Markup Language (XML)-based IRIS file format, which should

consider that different categories of residents are placed on different cost report lines, e.g., residents from new programs and residents from existing programs. **As such, we urge CMS to delay implementation of this requirement until the necessary changes are made to the IRIS data and/or cost report form, and the changes are incorporated and tested.** We also recommend that CMS release a draft of the IRIS instructions and proposed file format for comment prior to implementation.

MEDICARE BAD DEBT REIMBURSEMENT AND DSH PAYMENT ADJUSTMENT

CMS also makes several proposals related to supporting documentation for bad debt, charity care and Medicaid days. We note that revisions often need to be made to these numbers after a hospital submits its cost report and request that CMS clarify that these amendments will continue to be made as they are now. We also ask that CMS clarify that SCHs and MDHs paid their hospital-specific rates are not required to include supporting documentation for Medicaid days or for Worksheet S-10 amounts related to DSH payments. While these hospitals may technically be “DSH eligible,” they do not actually receive DSH or uncompensated care payments – submitting this documentation is unnecessary.

POST-ACUTE CARE TRANSFER POLICY

Certain Medicare patients discharged to a post-acute care setting – including rehabilitation hospitals and units, long-term care hospitals and units, cancer hospitals, psychiatric hospitals, children’s hospitals and skilled-nursing facilities – or discharged within three days to home health services, are defined as transfer cases and are paid a daily (per-diem) rate, rather than a fixed DRG amount, up to the full PPS rate. The BiBA required that, beginning in FY 2019, this inpatient PPS post-acute care transfer policy also apply to discharges to hospice care. Accordingly, CMS proposes that, if a discharge is assigned to one of the MS-DRGs subject to the post-acute care transfer policy and the individual is transferred to hospice care by a hospice program, the discharge would be subject to payment as a transfer case. The agency proposes that patients with a discharge of either “50” or “51” would qualify as being discharged to hospice. **While the AHA continues to oppose this misguided policy, CMS is implementing this provision in line with the BiBA requirements.**

AREA WAGE INDEX

In the proposed rule, CMS states that there have been numerous studies, analyses, and reports on disparities across individual hospitals and different geographic areas. The agency invites comment on suggestions and recommendations for regulatory and policy changes to address these issues. The area wage index is intended to recognize differences in resource use across types and location of hospitals. If these resource differences are not adequately accounted for by Medicare payment adjustments, hospitals are either inappropriately rewarded or put under fiscal pressure. Taking this into account, hospitals have repeatedly expressed concern that the wage index is greatly flawed in many respects, including its accuracy, volatility, circularity, and substantial reclassifications and exceptions. Members of Congress and Medicare officials also have voiced concerns with the present system. While a consensus solution to the wage index’s

shortcomings has not yet been developed, further analysis of alternatives is needed to identify approaches that promote payment adjustments that are accurate, fair, and effective.

IMPUTED RURAL FLOOR

In FY 2005, CMS temporarily adopted an “imputed” rural floor policy by establishing a wage index floor for those states that did not have rural hospitals. CMS subsequently has extended this policy through FY 2018. However, CMS does not propose to extend the policy again, expressing concern that the methodology creates a disadvantage in the application of the wage index to hospitals in states where rural hospitals but no urban hospitals receive the rural floor. **Absent any new wage index policies that address the original need for the imputed rural floor, the AHA asks CMS to extend the current policy on the imputed rural floor.**

PROPOSED REVISION REGARDING PHYSICIAN CERTIFICATION AND RECERTIFICATION OF CLAIMS

CMS proposes to remove the requirement that Part A certification statements detail *where* in the medical record the required information can be found. **We support this change.**

PROPOSED REVISION OF HOSPITAL INPATIENT ADMISSION ORDERS DOCUMENTATION REQUIREMENTS UNDER MEDICARE PART A

CMS proposes to remove the requirement that a written inpatient admission order be present in the medical record as a specific condition of Medicare Part A payment. The intent of this proposal seems to be to prevent Part A inpatient admission denials solely for technicalities with the inpatient admission order, which we support. However, under the revised regulation, an order for inpatient admission is still required, it just does not need to be documented in the medical record. **We therefore request CMS to provide clarity around where the documentation must be maintained. Finally, to provide commensurate regulatory relief, we urge CMS to consider modifying 42 CFR §413.3(c) so that the order must be furnished at or before the time of discharge, rather than the time of admission.**

PROPOSED CHANGES TO MEDICARE GRADUATE MEDICAL EDUCATION (GME) AFFILIATED GROUPS FOR NEW URBAN TEACHING HOSPITALS

CMS proposes to provide more flexibility for new urban teaching hospitals to enter into Medicare GME affiliation agreements, which allow hospitals to share FTE cap slots to accommodate the cross training of residents. **We support this change.**

OUTLIER PAYMENTS

In order to estimate the proposed FY 2019 outlier fixed loss threshold, CMS inflated the charges in the FY 2017 MedPAR file by two years, from FYs 2017 to 2019. To estimate the one-year average annualized rate-of-change in charges per case for FY 2019, CMS proposes to compare the average covered charge per case from the second quarter of FY 2016 through the first quarter of FY 2017 (Jan. 1, 2016 – Dec. 31, 2016) to the average covered charge per case from the second quarter of FY 2017 through the first quarter of FY 2018 (Jan. 1, 2017 – Dec. 31, 2017). CMS finds a one-year rate-of-change of 4.2 percent (1.04205) or 8.6 percent (1.085868) over two years.

However, the publicly available FY 2017 MedPAR dataset contains claims only through Sept. 30, 2017. Therefore, we do not have access to claims in the first quarter of FY 2018 (Oct. 1 – Dec. 31, 2018) and, hence, cannot replicate the rate-of-change computed by CMS. **The AHA urges CMS to add the claims data for the first quarter of FY 2018 (and any other quarters that it may use in the future for such calculations) to its list of limited data set (LDS) files that can be ordered through the usual LDS data request process. This will enable the field to obtain the data necessary to replicate CMS’s calculation of the charge inflation factor. Not having access to these data severely limits our ability to sufficiently comment on this issue.**

COST-TO-CHARGE RATIOS

We believe the proposed CCRs for FY 2019 were miscalculated and are incorrect, as are, by extension, some of the calculations they feed into, such as the outlier threshold. While we recognize that CMS will be recalculating them for the final rule with more up-to-date data, **we urge it to review its data sources and methodology to ensure they are correct.**

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM

Hospitals are required to report measures and meet the administrative requirements of the IQR program to avoid having their annual market basket update reduced by one quarter. The IQR program is “pay-for-reporting” only, while CMS’s other hospital programs – Hospital Value-based purchasing (VBP), the Hospital Readmissions Reduction Program (HRRP) and Hospital-Acquired Condition (HAC) Reduction Program – all tie payment incentives or penalties to measure performance. The IQR also includes requirements to report electronic clinical quality measures (eCQMs) that align with the eCQM reporting requirements in the Promoting Interoperability Program.

MOVING CMS QUALITY MEASUREMENT TOWARDS MEANINGFUL MEASURES

The AHA applauds CMS for beginning to use its “Meaningful Measures” framework to streamline the measures used in its hospital quality reporting and value programs. The AHA has long urged the agency to reduce and prioritize the measures used in its quality programs so that they focus on the issues that matter the most to improving care and outcomes.

CMS's Meaningful Measures framework identifies six overarching quality priorities and 19 specific measurement areas aligned with those priorities. The priorities CMS identified are intended to cut across the full continuum of its quality measurement programs – hospitals, physicians, post-acute care and health plans. **The AHA is pleased that most of the “meaningful measure” priority areas are ones that the AHA has consistently recommended to the agency.**

The AHA strongly supports CMS's proposal to add a measure removal factor to the IQR and VBP programs, allowing the agency to consider whether the costs of a measure outweigh the benefits of its continued use. Appropriately, the agency would consider the costs to hospitals and the agency itself in implementing this criterion. The AHA believes this criterion is a long overdue addition to its programs, and would give the agency more flexibility to remove measures that are inappropriately burdensome.

While we recognize CMS's proposals in the rule are just a first step, “Meaningful Measures” is a promising framework that holds the potential to reduce unnecessary administrative burden and unify provider efforts across the continuum around a common quality agenda. We look forward to continuing to work with CMS in the coming months and years to implement and update the framework.

PROPOSED MEASURE REMOVALS

The AHA supports CMS's proposed removal of 39 measures from the IQR program for FYs 2020 through 2023. Of the 39 measures proposed for removal, 18 measures would be removed from hospital quality programs altogether because they are “topped out” in performance, do not lead to better care, or have a costs that outweigh their value. The remaining 21 measures would be “de-duplicated.” That is, the measures would be removed from the IQR program, but retained in one of the other hospital measurement programs (i.e., VBP, HAC or HRRP). We agree with CMS's assessment of the 18 measures that would be removed altogether. We also agree that de-duplication can reduce administrative burden because hospitals would no longer receive multiple preview reports on the same measures that might contain slightly different performance data.

As the removal and de-duplication of such a significant number of measures will have a significant impact on CMS's public reporting of data on *Hospital Compare*, we urge the agency to clarify some of these impacts in the final rule. Specifically, we would ask that CMS provide greater detail on the following issues:

- The timing of the removal of the 18 measures from *Hospital Compare*. The website is updated quarterly, so CMS should clarify what the final quarter of publicly-reported data would be for each measure
- How the 21 de-duplicated measures will be displayed on *Hospital Compare*. In the proposed rule, CMS indicates that all of the de-duplicated measures will continue to be publicly reported on *Hospital Compare*. However, the website currently has two different ways of reporting information. IQR measures are displayed on *Hospital Compare* itself with graphics that show how individual hospital performance compares to others. However, performance results for VBP, HAC, and HRRP are displayed by linking to

interactive spreadsheets on data.cms.gov. Those spreadsheets are not nearly as user-friendly as the *Hospital Compare* website itself. Thus, we encourage CMS to explore whether it can retain measure data reporting in the more user-friendly format used for IQR measures.

- How the measure removals would impact Hospital Overall Star Ratings. Lastly, we note that many of the measures proposed for removal from the IQR are used in CMS's Overall Hospital Star Rating. The current methodology for star ratings suggests that CMS draws measures from only the IQR and outpatient quality reporting (OQR) programs. As a result, it is not clear whether the measures would remain in the star ratings methodology, or whether the methodology would be altered to include measures that are in one of the value payment programs.

The AHA appreciates CMS's decision to postpone the July update of star ratings, allowing more time for a fuller analysis of its methodology and measures as well as to hear from stakeholders, including hospitals and health systems. **At the same time, we continue to have significant concerns about the methodology used to report star ratings. If CMS is intent on continuing to publish star ratings, or something similar in the future, the AHA urges CMS to use notice-and-comment rulemaking (such as the inpatient or outpatient PPS proposed rules) to adopt significant changes to the measures or methodology in star ratings.** We believe this approach would lend greater predictability and transparency to the rating approach.

POTENTIAL FUTURE IQR MEASURES

CMS solicits comment on two measures it is considering for future years of the IQR program:

All-Cause Hospital-Wide Mortality Measure. **The AHA has significant concerns about the design of this measure, and does not support its inclusion of the measure in future years of the IQR.** Hospitals already report and are evaluated on mortality data for high-priority conditions (e.g., heart attack, heart failure, pneumonia). These measures would include this data, making them redundant, but mask any condition-specific outcomes when publicly reported. This would significantly limit their usefulness to consumers and providers.

Furthermore, we are concerned that this measure's design will lead to inaccurate, misleading, and unfair performance comparisons. Each hospital's mix of available services and patient acuity – which greatly influence mortality rates – is different. For example, a 100-bed community hospital is unlikely to offer the specialized tertiary and quaternary services of an academic medical center. And, the patients treated in an academic medical center or other large referral center will likely have greater clinical complexity. Yet, by including all conditions, this measure assumes one can perform an “apples to apples” comparison of these types of hospitals and render a generalized judgment of which ones provide better care.

While risk adjustment can help, we know of no risk-adjustment methodology that is up to the task of adjusting for the many varied clinical and sociodemographic differences that may put a patient at a higher risk of death. Thus, this measure might actually serve to obscure any meaningful differences in performance. In fact, a technical report on the measures released in November 2017 showed that, of the 4,793 hospitals included in the analysis, only 102 (2.1

percent) show up in the better than average category, and only 6 hospitals in the worse than average category (0.1 percent), leaving over 97 percent of hospitals as not statistically different from one another.

Lastly, these measures were developed using ICD-9 codes; thus, the predictive model is not indicative of the current and future care environment (which uses ICD-10 codes). The measure developer suggested that, if implemented, the measure would use ICD-10 codes; however, because the measure was not developed and specified using these codes, it would in effect be a different measure. For this reason, the AHA believes this measure must be re-specified and re-tested using the ICD-10 codes before it is deemed worthy of either National Quality Forum (NQF) endorsement, or use in the IQR program.

Opioid-Related Adverse Event eCQM. While the AHA and our members have been active in addressing the opioid crisis, we believe that this measure provides potential value to the IQR. But because it has not been fully tested, let alone evaluated and endorsed by the NQF, it is not ready for inclusion in the IQR at this time. The measure assesses the percentage of patients who received naloxone (an opioid reversal agent) outside of the operating room either: (1) After 24 hours from hospital arrival; or (2) during the first 24 hours after hospital arrival with evidence of hospital opioid administration prior to the naloxone administration.

The AHA is interested to see whether it is truly feasible to collect the information necessary to calculate this measure, as well as whether there is true performance variation in care across hospitals. In addition, we encourage the measure developers to be watchful of any unintended consequences the measure may carry, including encouraging more invasive efforts to combat respiratory events (like intubation) over the necessary use of naloxone. We also suggest that the developers consider multiple risk-adjustment approaches, including stratification rather than overall risk adjustment and testing for the appropriate population exclusions.

ECQMS IN THE IQR PROGRAM

For the FY 2021 payment determination, CMS proposes to continue the FY 2020 IQR program requirement, specifically that hospitals will report on a minimum four self-selected eCQMs from the 15 eCQMs available for reporting to the IQR program. CMS proposes hospitals submit one self-selected quarter of eCQM data from calendar year (CY) 2019. CMS does not propose any changes to the submission deadlines. CMS also does not propose changes to sampling or case threshold policies. CMS proposes to continue the alignment of eCQM reporting requirements in the Hospital IQR Program and the Promoting Interoperability Programs. **The AHA supports continuation of current eCQM reporting policies for the CY 2019 reporting period. We also recommend that CMS monitor the transition to the 2015 edition EHR and the shift to the Clinical Quality Language (CQL).**

For the FY 2022 payment determination, CMS proposes to require hospitals to report on a minimum of four self-selected eCQMs from eight eCQMs proposed to be available for reporting to the IQR program. **The AHA supports the proposal to remove seven eCQMs as the reduction aligns with the Meaningful Measures framework. We also support the proposal as it reiterates our view that two years is required between an eCQM included in a final**

rule and the start of hospital eCQM reporting. We recommend that CMS continue to evaluate eCQM data submitted and findings from the eCQM validation process to inform future program requirements and to inform hospitals about successful practices in eCQM reporting. The AHA also supports the continued alignment of eCQM reporting requirements in Hospital IQR and the Promoting Interoperability Programs.

REQUEST FOR COMMENT ON ECQM IMPLEMENTATION

In the proposed rule, CMS requests stakeholder comment on several aspects on eCQM implementation, maintenance, and reporting. CMS also requests comments on hospital participation in improving existing eCQMs and testing new eCQMs. Hospitals strongly support the long-term goal of using EHRs to streamline and reduce the burden of quality reporting while using the data to support their own quality improvement initiatives. After two years of experience with required electronic submission of eCQM data, the entire eCQM process – from measure specifications updates through data file submission – present opportunities for improvement. The ultimate metric of success should confirm that eCQMs are feasible and valid measures of the quality of care. The AHA has several recommendations to address the diverse eCQM challenges, increase hospital trust in eCQM data and to support improvements in the eCQMs process.

Address the Mismatch Between Hospital Reporting Requirements and Vendor Support For Their Customers. In the request for comment, CMS inquires about actions that could reduce costs and maximize the benefits of eCQMs. Hospitals recognize that EHR and eCQM vendors require time to build, test, and provide updates as eCQM specifications change annually. However, EHRs are not required to be certified to support every available eCQM. The specific eCQMs presented for certification are determined at the developer’s discretion. The certified EHRs also are not required to be recertified following annual updates. The result is that some hospitals are forced to select eCQMs based on what the EHR vendor makes available rather than selecting the eCQMs that reflect their patient population and quality improvement initiatives. **The AHA recommends that certified EHRs support all of the eCQMs available for reporting in Hospital IQR and the Promoting Interoperability Programs.**

Expand Meaningful Engagement Opportunities With Hospitals. Hospitals continue to demonstrate their willingness to participate in initiatives aimed at improving existing eCQMs. However, the participation will be enriched when hospitals are able to discuss eCQM improvement in the context of data from prior eCQM data submissions and an opportunity to inform future eCQM priorities that reduce reporting burden and advance improvements in the quality of care. **The AHA recommends that CMS develop a long-term strategy for eCQMs that applies the Meaningful Measures framework to eCQMs, the development of metrics to inform the readiness of eCQM data for public reporting, and an ongoing role for hospital engagement.**

Increase Opportunities for Hospitals to Participate in eCQM Testing and Innovative Uses of Health Information Technology (IT). In the request for comment, CMS asks how to encourage hospitals to engage in testing new eCQMs and what could incentivize or reward innovative uses of health IT. **The AHA recommends that hospitals participating in eCQM testing or**

engaging in innovative use of health IT receive credit for meeting the eCQM reporting requirement in the Promoting Interoperability Programs. We recommend that CMS work with hospitals to identify areas of innovative use of health IT that align with the Meaningful Measures framework. We also recommend that CMS work with their federal partners to encourage health IT vendors to support hospitals in their efforts to use eCQMs and health IT to address the highest priority areas for quality measurement and improvement.

Improve the Reporting Portal to Support the Needs of Data Submitters. In the request for comment, CMS asks about hospitals' experience with data submission. Hospitals and health systems experienced several issues with the QualityNet Portal that challenged eCQM data submissions for the CY 2017 reporting period. The inability to receive immediate feedback on errors in test file submissions and the nearly month-long delay in the availability of the portal for eCQM data submissions were two notable issues. **The AHA recommends CMS improve the capacity of the QualityNet portal to receive test and production QRDA-I files and send submission summary and performance reports. If CMS finds that updates to the QualityNet are not feasible, we recommend that CMS work with hospitals and other stakeholders to identify alternatives for future reporting: a new QualityNet portal, use of an existing eCQM reporting portal or an alternative to electronic submission of eCQM data files.**

HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM

As required by the Affordable Care Act (ACA), CMS proposes to fund the FY 2019 VBP program by reducing base operating DRG payment amounts to participating hospitals by 2.0 percent. The VBP program is budget neutral; all funds withheld must be paid out to hospitals. CMS proposes to remove a total of 10 measures from the VBP, including all seven measures used in the "safety of care" measure domain. Those seven measures would be retained in the HAC Reduction Program. CMS also proposes to re-weight VBP's measure domains.

PROPOSED MEASURE REMOVALS

The AHA supports CMS's proposals to remove the seven measures in the safety of care measure domain. We have long been concerned by the overlap of measures between the VBP and HAC Reduction programs given the different constructions and goals of each program. The VBP program uses all of the current HAC measures but employs a different methodology to delineate performance. The measure overlap has created "double penalties" for some hospitals, while assessing disparate scores on the same measures for other hospitals. We believe using the safety of care measures solely in the HAC Reduction Program will reduce the possibility of double penalties, and reduce the potential for conflicting signals on performance.

The AHA also supports the proposed removal of the three condition-specific episode-based payment measures related to heart attack, heart failure, and pneumonia from the VBP.

While we continue to agree that well-designed measures of cost and resource use can assist with assessing the value of care, we have long been concerned that the overlap between these

condition-specific measures and Medicare's spending per beneficiary (MSPB) measure may lead to unnecessary confusion among hospitals and patients.

PROPOSED VBP MEASURE DOMAIN REWEIGHTING

The VBP program currently includes four measure domains that are each weighted as 25 percent of the VBP total performance score – clinical outcomes, safety, patient experience, and efficiency/cost reduction. However, because CMS has proposed to eliminate all seven of the safety of care measures in the VBP, the agency proposes to adopt one of two potential approaches to reweighting the measure domains.

CMS's preferred approach is to increase the weight of the clinical outcomes domain to 50 percent, while leaving the weights of the patient experience and efficiency domains unchanged. CMS believes this approach places an appropriate emphasis on outcomes. The agency also suggests this approach is responsive to a 2017 Government Accountability Office (GAO) report suggesting that many hospitals were able to get positive VBP adjustments by doing well on the efficiency domain while scoring more poorly on the domains with quality measures. However, the agency also offers an alternative scoring approach in which the three remaining measure domains would be equally weighted (i.e., 33 percent each).

The AHA urges CMS to adopt its alternative approach of weighting all three measure domains equally. It appears that CMS's preferred approach of increasing the clinical domain to 50 percent would result in significantly more hospitals experiencing a loss under the VBP program. With this methodology, we estimate that only 44 percent of hospitals would experience a gain under VBP, while 56 percent would incur a loss. In contrast, the equal domain weighting approach would result in a roughly 50/50 distribution of VBP gains and losses. It would give hospitals an opportunity to be rewarded for good performance on any of the domains. Furthermore, equal domain weighting would be consistent with the prior approach to weighting VBP domains, and provides a more balanced assessment of hospital performance.

MODERNIZING THE HOSPITAL CONSUMER ASSESSMENT OF PROVIDERS AND SYSTEMS (HCAHPS) SURVEY

CMS does not propose changes to the HCAHPS survey and would retain it in both the IQR and VBP programs. **While the AHA continues to support the use of the HCAHPS, we believe the agency should undertake a review of how it uses all surveys in the CAHPS family, and consider approaches to modernizing how the survey is administered. This assessment should begin with an examination of CAHPS survey requirements across all of its reporting programs to minimize the number of surveys that patients must respond to in a given time.**

A patient's course of care often crosses multiple care settings and providers within a given time period, and the CAHPS program has surveys for nearly every setting. Indeed, CAHPS includes surveys for physicians, hospitals, dialysis facilities and home health agencies. Patients who receive care in two or more of these settings could receive multiple surveys. Typically, surveys are not distributed until days or weeks after a patient has received their care. This may create

confusion about which provider or facility is actually being assessed. A patient may inadvertently attribute a positive or negative experience to the wrong provider.

In addition, we strongly urge CMS to explore the development of more modern and economical survey administration approaches for the HCAHPS and all other CAHPS surveys, such as emailed or web-based surveys. While we appreciate the value of assessing the patient experience across the care continuum, the use of multiple surveys means more time spent by patients to answer surveys, and more resources expended by providers to administer them. Moreover, for the purposes of CMS reporting programs using CAHPS tools, providers are permitted to use only two survey administration modes – mailed surveys and telephone surveys. Mailed surveys are relatively inexpensive to administer, but often suffer from low response rates and a significant time lag. Telephonic surveys typically yield a higher response rate and provide more timely results, but are much more expensive to administer.

We strongly encourage CMS to work with the CAHPS Consortium to develop guidelines for emailed and web-based surveys for the entire CAHPS family. Once this guidance is developed, CMS should permit the use of emailed and web-based surveys in CMS reporting programs. To date, the Agency for Healthcare Research and Quality (AHRQ) has provided very limited guidance on appropriate procedures for using electronic survey methodologies. Yet, electronic survey administration modes, such as email and web-based portals, make survey data collection and aggregation timelier and less expensive, and may allow hospitals to increase sample size without greatly increasing cost. In developing guidance for emailed and web-based surveys, AHRQ also should engage with hospitals and other providers that have been using emailed and web-based surveys to collect data on patient experience.

HOSPITAL-ACQUIRED CONDITION (HAC) REDUCTION PROGRAM

The HAC Reduction Program imposes a 1 percent reduction on all Medicare inpatient payments for hospitals in the top (lowest-performing) quartile of certain risk-adjusted national HAC rates. CMS does not propose to add or remove any measures from the HAC Reduction Program. However, CMS proposes two important changes to the program – the elimination of measure domains in determining the Total HAC score, and the adoption of data collection and validation requirements for the healthcare-acquired infection (HAI) measures in the program.

GENERAL CONSIDERATIONS

America’s hospitals remain deeply committed to eliminating avoidable harm, and data show that we are making care safer. A recent report from AHRQ showed that certain HACs declined by 8 percent between 2014 and 2016, preventing an estimated 8,000 deaths and \$2.9 billion in health care costs. HACs decreased by an estimated 350,000 over the period, including a 15 percent decline in infections and adverse drug events. Though more work remains, hospitals are making progress and their efforts are proving successful.

The AHA continues to support quality measurement and pay-for-performance programs that effectively promote improvement, especially value-based approaches that measure both a hospital's actual performance, as well as how much it has improved over a baseline period. **For this reason, we have long opposed the arbitrary statutory design of the HAC Reduction Program, which imposes penalties on 25 percent of hospitals each year, regardless of whether hospitals have improved performance, and regardless of whether performance across the field is consistently good.** In addition, we are concerned that CMS's implementation of the program has unfairly placed teaching hospitals, large hospitals, small hospitals and hospitals caring for larger number of poor patients at greater risk of a penalty as a result of faulty measurement, not bad performance.

The AHA appreciates that CMS has proposed to eliminate the overlap between the HAC Reduction Program and the VBP program. Furthermore, CMS will now use the HAC program's measures only in the HAC program, eliminating overlap with the IQR program. However, the elimination of overlap with the IQR introduces the possibility that a measure could be added to the HAC Reduction Program – and tied to payment – without it being first publicly reported. **The AHA recommends that CMS adopt a requirement in the HAC Reduction Program that any newly added measure be public reported and not tied to payment for at least a year. This could be accomplished through putting the measure into the IQR program first, or adopting a HAC Reduction Program category of “reporting only.”** Public reporting is an essential step before tying a measure to payment that allows for all stakeholders to ensure there are no adverse unintended consequences of reporting a measure. Indeed, this is why Congress requires CMS to put a measure into the IQR program for at least a year before adding it to the VBP program.

ELIMINATION OF MEASURE DOMAINS

The AHA generally supports CMS's proposal to eliminate HAC measure domains, and agrees the approach should help improve the fairness of HAC penalty assessments for smaller hospitals. Under the proposal, CMS would assign a weight to all six performance measures in the program. This approach would address the concerns of smaller hospitals whose HAI domain scores could often rest on only one or two measures.

However, we would urge CMS to consider additional changes to the HAC program beyond the measure domain weightings. For example, the agency could work with the Centers for Disease Control and Prevention (CDC) to examine whether it can lower the number of expected infections hospitals must have to receive a score on the HAI measures without compromising measure reliability and accuracy. Part of the reason that many small hospitals do not have scores on the HAI measures is because their volumes are not sufficient to meet the threshold of one expected infection. Yet, their performance often is exemplary on these measures. By lowering the threshold, CMS may be able to score smaller hospitals on a wider variety of HAI measures. However, we urge that if CMS moves in this direction, it works with a wide range of stakeholders and makes any and all analyses of the impact of changing the threshold available for public review and comment.

Furthermore, the AHA continues to urge CMS to remove the deeply flawed patient safety indicator (PSI) composite measure from the HAC program and any hospital reporting or pay-for-performance program. The AHA has long been concerned by the significant limitations of PSI 90 as a quality measure. PSIs use hospital claims data to identify patients that have potentially experienced a safety event. However, claims data cannot and do not fully reflect the details of a patient's history, course of care and clinical risk factors. As a result, the rates derived from the measures are highly inexact. PSI data may assist hospitals in identifying patients whose particular cases merit deeper investigation with the benefit of the full medical record. But, the measures are poorly suited to drawing meaningful conclusions about hospital performance on safety issues. In other words, PSI 90 may help hospitals determine what "haystack" to look in for potential safety issues. But the ability of the measure to consistently and accurately identify the "needle" (i.e., the safety event) is far too limited for use in public reporting and pay-for-performance applications.

Examples of the inconsistency of the results of PSI component measures with clinical reality abound.⁵ One recent study that validated the results generated by PSI 3 (pressure ulcer rates) using direct patient surveillance found that PSI 3 frequently misclassified hospital performance.⁶ And another recent study showed that performance on the PSI measures is more a function of bed size than of underlying quality performance.⁷ It is not surprising, then, that a CMS-commissioned study showed that many of the individual components of PSI-90 have low levels of reliability when applied to Medicare claims data.⁸

MEASURE VALIDATION REQUIREMENTS FOR HAI MEASURES

The AHA supports CMS's proposal to adopt the IQR's HAI measure validation process in the HAC Reduction Program. The validation requirements and process for the IQR are well established, so we appreciate CMS maintaining continuity as it removes the measures from the IQR but retains them in the HAC program.

⁵ See for example:

Ramanathan R et al. Validity of Agency for Healthcare Research and Quality Patient Safety Indicators at an academic medical center. *The American Surgeon*. 2013 Jun; 79(6):578-82.

Cevasco M et al. Validity of the AHRQ Patient Safety Indicator "central venous catheter-related bloodstream infections. *Journal of the American College of Surgeons*. 2011 Jun;212(6):984-90;

Kaafarani H et al. Validity of Selected Patient Safety Indicators: Opportunities and Concerns. *Journal of the American College of Surgeons*. 2011 Jun; 212(6):924-34.

Utter GH, Zrelak PA, Baron R, et al. Positive predictive value of the AHRQ accidental puncture or laceration patient safety indicator. *Ann Surg*. 2009;250(6):1041-1045

Rajaram R et al. Concerns About Using the Patient Safety Indicator-90 Composite in Pay-for-Performance Programs. *Journal of the American Medical Association*. 2015; 313(9):897-898.

⁶ Meddings JA et al. Hospital Report Cards for Hospital-Acquired Pressure Ulcers: How Good are the Grades. *Annals of Internal Medicine*. 519(8):505-13. October 2013.

⁷ Koenig L et al. Complication Rates, Hospital Size and Bias in the CMS Hospital-Acquired Condition Reduction Program. *American Journal of Healthcare Quality*. Dec. 19, 2016.

⁸ See http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf

HOSPITAL READMISSIONS REDUCTION PROGRAM (HRRP)

The HRRP imposes penalties of up to 3.0 percent of base inpatient PPS payments for having “excess” readmissions rates for selected conditions when compared to expected rates. CMS proposes only minor updates to the program for FY 2019. Additionally, CMS will continue to implement the socioeconomic adjustment approach mandated by the 21st Century Cures Act of 2016 that it adopted in the FY 2018 inpatient PPS final rule.

PROPOSED FY 2019 PERFORMANCE PERIOD

The AHA is concerned that the proposed FY 2019 HRRP performance period – July 1, 2014 through June 30, 2017 – continues to combine data collected under both ICD-9 and ICD-10. We continue to urge CMS to provide further empirical analysis demonstrating that measure reliability and validity are not compromised by using these two different coding systems. We also urge CMS to ensure that the ICD-10-only versions of the measures in the HRRP are endorsed by the NQF as soon as practicable.

ICD codes are integral to collecting and calculating quality measures in CMS’s programs, especially those measures like readmissions that are based solely on Medicare claims data. The codes define the patient population included in the measure, identify the outcome being measured (e.g., a readmission), and are used to perform risk adjustment. There are significant differences between ICD-9 and ICD-10 codes, and as a result, the agency is in the process of re-specifying measures previously collected in ICD-9 so the specifications work in an ICD-10 environment. However, as CMS revises the measures, it is imperative for the agency to examine how coding changes may affect measure performance, and to consider whether it is appropriate to combine or compare data collected using the two different coding systems.

REFINING SOCIOECONOMIC ADJUSTMENT

The AHA continues to support the socioeconomic adjustment approach that CMS adopted in the FY 2018 inpatient PPS final rule and believe it will provide relief to hospitals caring for communities with socioeconomic challenges. However, we also strongly encourage CMS to continually evaluate its adjustment approach, and to engage with the field on ensuring its adjustment approach keeps up with the evolving measurement science around accounting for social risk factors.

The AHA has long urged CMS to implement socioeconomic adjustment in the HRRP because of the significant body of research showing that readmissions performance is impacted by poverty, availability of resources and other social risk factors beyond hospitals’ control. To meet the mandate of the 21st Century Cures Act, CMS will place each HRRP-eligible hospital into five peer groups (or quintiles) based on the proportion of Medicare fee-for-service (FFS) and Medicare Advantage dual-eligible patients it treats. The agency will then calculate each hospital’s readmissions performance relative to the median of its quintile, applying a budget-neutrality modifier to ensure aggregate penalties across all hospitals are equivalent to the current approach.

However, it is clear that Congress intended for the dual-eligible peer grouping approach to be a starting point in a longer term effort to account for socioeconomic factors in the readmissions penalty program. Indeed, the 21st Century Cures Act affords CMS the opportunity to alter the adjustment approach after FY 2020. Going forward, CMS should consider both whether it should continue to use dual-eligibility as the adjustment variable, and whether to move from the current peer grouping approach to one in which it incorporates one or more socioeconomic variables into the risk-adjustment models of the HRRP measures (i.e., direct risk adjustment).

The ideal data for use in either peer groupings or direct risk adjustment should: 1) have a conceptual and statistical relationship to readmission rates; 2) use a readily available data source; and 3) be collected in a consistent way using standardized definitions. Dual-eligible status has all three of these characteristics, which is why we remain supportive of its use in adjusting readmission penalties.

Nevertheless, dual-eligible status also has important limitations as a risk adjustor. Most notably, there is variation in the generosity of state Medicaid program benefits, and, in the long run, the adjustor may be sensitive to differences in state-level decisions to expand Medicaid. Dual-eligible status also may not fully reflect the poverty in communities. For example, it would not fully reflect the proportion of homeless in communities.

The use of peer groups – in this case, quintiles based on the proportion of dual-eligible patients – obviates the need to change the risk adjustment models for underlying quality measures. However, the use of peer groupings involves somewhat subjective choices about where to set the cut points of a particular group. Those hospitals at the upper end of one quintile and those at the lower end of the next quintile would have similar proportions of dual-eligible patients, but would be placed into different quintiles for performance comparison purposes. This is true regardless of the number of peer groups chosen to use to evaluate performance.

The science of quality measurement is dynamic, and there are a number of options that we encourage CMS to evaluate for improving the risk adjustment approach. The NQF and National Academy of Medicine both have reports identifying the types of socioeconomic and social risk factors that may influence performance on readmissions. One particularly promising set of data are census-tract data on poverty rates and income. Census variables like poverty rate and income are readily available, and could be mapped to a hospital's patient population using zip codes. Moreover, census data could be a more direct measurement of poverty than dual-eligible status, and would not be sensitive to differences in state Medicaid programs.

CHANGES TO MS-DRG CLASSIFICATIONS

In general, the AHA supports CMS's proposed changes to the MS-DRG classifications, which seem reasonable given the data, the ICD-10-CM/PCS codes, and information provided, with the exceptions noted below.

PRE-MAJOR DIAGNOSTIC CATEGORY (MDC)

As noted in the “CAR T-cell Therapy” section above, we recommend CMS assign ICD-10-PCS procedure codes XW033CS (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3), and XW043C3, (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3) to the Pre-MDC MS-DRG 16 Autologous Bone Marrow Transplant with CC/MCC.

Once sufficient data becomes available for this unique therapy, consideration should be given to create a unique MS-DRG for CAR T-cell therapy, as noted in the “CAR T-cell Therapy” section above.

Cell/gene therapy is likely to grow in the near future; this new approach provides life-saving results, but comes at high cost. The NUBC has been working with a number of hospitals and health plans looking at these new treatments. To date they are recommending a series of new revenue codes associated with cell/gene treatments. As noted in the in the “CAR T-cell Therapy” section above, we recommend that CMS utilize these codes in addition to the procedure codes not only for processing claims but also for refinements to the Medicare Cost Report.

MDC 6 (DISEASES AND DISORDERS OF THE DIGESTIVE SYSTEM): BOWEL PROCEDURES

CMS’s proposal included two distinct sections of ICD-10 PCS procedure codes for bowel procedures in MDC 6.

CMS proposes that eight ICD-10-PCS procedure codes that describe repositioning of the colon and takedown of end colostomy be maintained in the current assignment of MS-DRGs 344, 345 and 346 (Minor Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively). Resources required for large bowel repositioning procedures are clinically aligned with resources required for cases assigned to MS-DRGs 344, 345, and 346.

In addition, CMS proposes to reassign 12 ICD-10-PCS procedure codes for repair of ascending colon, transverse colon, descending colon and sigmoid colon (open and percutaneous endoscopic approach) and reposition of ileum and large intestine (open and percutaneous endoscopic approach). The procedures would be reassigned from MS-DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 344, 345, and 346 (Minor Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) when reporting a bowel procedure as the only operating room procedure. These are minor procedures relative to the major bowel procedures assigned to MS-DRGs 329, 330, and 331.

We recommend that CMS delay implementing its proposal until a more thorough analysis is done, including the principal diagnosis, length of stay and charges as there may be different resources utilized for the seemingly similar procedure codes. We urge CMS to reevaluate the proposed ICD-10-PCS codes to determine the appropriate assignment of these procedures in either Major or Minor Small Bowel and Large Bowel Procedures. Given the complexity of ICD-10-PCS coding for these procedures, several questions and

answers were published in three different issues of *Coding Clinic* between the third quarter of 2016 and the fourth quarter of 2017. As such, there is less than two years' worth of reliable coded data.

We note that there is a potential for incorrect interpretation of the data associated with the ICD-10-PCS codes without also examining the corresponding ICD-10-CM diagnosis codes for the indication for the procedure. For example, our analysis of FY 2017 MedPAR data (used in FY 2019 NPRM), revealed that ICD-10-PCS code 0DSN4ZZ, Reposition sigmoid colon, percutaneous endoscopic approach, used as the only procedure on the claim with a principal diagnosis of ICD-10-CM code K56.2, Volvulus, resulted in average charges of \$29,362 with an average length of stay of 3.0 days. Conversely, the same ICD-10-PCS procedure code as the only procedure on the claim with a principal diagnosis of Z43.3, Encounter for attention to colostomy, resulted in average charges of \$62,913 and average length of stay of 4.2 days.

We also note that ICD-10-PCS is still a relatively new coding system, and hospital coding professionals have required extensive training and education to sort out the correct coding for a variety of procedures that were more easily coded in ICD-9-CM. Specifically, *Coding Clinic for ICD-10-CM and ICD-10-PCS* published the following examples which would have affected the data:

- Closure of Hartmann stoma (Third Quarter 2016, pages 5-6) using root operation Reposition.
- Reduction of ileocolic intussuception (Third Quarter 2017, page 9) using root operation Reposition.
- Repair of malrotation of intestine with small bowel obstruction (Fourth Quarter 2017, page 49), using root operation Reposition.
- Stoma closure where the divided portions of the colon are sutured together without any removal (Third Quarter 2016), using root operation Repair.
- Coders were warned that although the ICD-10-PCS Index entry under "Takedown, stoma" lead to "Repair," there were various types of procedures with different root operations for stoma takedown (Third Quarter 2016, page 4). In fact, the Index entry for "Takedown, stoma" wasn't revised until FY 2018 to "see Excision" and "see Reposition."

In addition, Repair is considered the ICD-10-PCS root operation of "last resort" for when no other root operation applies. The root operation Repair may be assigned for a simple suture, or it may be assigned for a more complex procedure that doesn't easily fit into any other root operation.

It appears clinically inconsistent to consider a simple ileostomy closure (e.g. ICD-10-PCS code 0DBB0ZZ, Excision of ileum, open approach), a Major Bowel Procedure while a more complex procedure such as closure of a Hartmann end stoma (e.g. ICD-10-PCS code 0DSM4ZZ, Reposition descending colon, percutaneous endoscopic approach), would be grouped to a Minor Bowel Procedure. During reversal surgery of a transverse or other loop colostomy, an incision is made around the stoma to access the abdomen and the distal colon is identified. After

mobilization, both ends of the intestine are excised and end-to-end anastomosis is done. On the other hand, closure of a Hartmann (end stoma) is more complex, and requires a more invasive approach to access the bowel, since the two divided ends are not in proximity. The stoma end and the distal end of the bowel must first be mobilized sufficiently to reach each other, and then re-anastomosed. After reconnecting the two ends of the intestine, the bowel is returned to its proper anatomical location within the abdominal cavity.

MDC 8 (DISEASES AND DISORDERS OF THE MUSCULOSKELETAL SYSTEM AND CONNECTIVE TISSUE): SPINAL FUSION

CMS does not propose to make any changes to the spinal fusion MS-DRGs for FY 2019. However, a total of 213 ICD-10-PCS procedure codes with “Z” for “no device” are being deleted, effective Oct. 1, 2018, because a spinal fusion procedure always requires some type of device to facilitate the fusion of vertebral bones. The results of the data analysis demonstrates the reporting of an invalid spinal fusion procedure with device value “Z” represents approximately 12 percent of all discharges across the spinal fusion MS-DRGs.

We agree with CMS’s proposal not to make any changes to the MS-DRGs involving spinal fusion procedures for FY 2019. With regard to CMS’s comment that claims data shows inaccuracies in the coding of spinal fusions, we note that there has been confusion as to whether a spinal fusion code could be assigned when no bone graft or bone graft substitute is used (e.g., instrumentation only), but the medical record documentation refers to the procedure as a spinal fusion. Recent questions published in *Coding Clinic for ICD-10-CM/PCS* Second Quarter 2017 and First Quarter 2018, have attempted to clarify the correct application of the root operation “Fusion.” Deletion of ICD-10-PCS procedure codes with “no device” should help remedy the confusion.

MDC 14 (PREGNANCY, CHILDBIRTH AND THE PUERPERIUM)

The FY 2018 inpatient PPS proposed and final rule noted that the MS-DRG logic involving a vaginal delivery under MDC 14 is technically complex due to the requirements to satisfy assignment to the affected MS-DRGs. CMS solicited public comments on which diagnosis or procedure codes, or both, should be considered in the logic to identify a vaginal delivery. CMS also solicited public comments on which diagnosis codes should be considered in the logic to identify a complicating diagnosis.

The AHA agreed with CMS that the MS-DRG logic involving a vaginal delivery under MDC 14 is technically complex. We convened a workgroup of member hospitals and recommended that CMS convene a stakeholder group, including hospitals and physicians, to systematically review MDC 14 to consider which conditions should appropriately be considered complicating diagnoses. In the interim, the AHA had suggested that CMS consider recommendations to remove a select number of ICD-10-CM diagnosis codes from MS-DRG 767 (Vaginal Delivery with Sterilization and/or Dilation and Curettage) and MS-DRGs 774 and 775 (Vaginal Delivery with and without Complicating Diagnoses, respectively).

For FY 2019, CMS is proposing to delete 10 MS-DRGs and create 18 new MS-DRGs with a three-way severity level split in MDC 14 (Pregnancy, Childbirth and the Puerperium). **We**

commend CMS on the proposed new structure and believe it to be clearer, clinically appropriate and likely to provide more clarity on similar cases than the current structure.

CHANGES TO THE MEDICARE CODE EDITOR (MCE)

In general we agree with all proposed MCE changes. However, we recommend that CMS reconsider its proposal to add diagnosis code Z49.01 (Encounter for fitting and adjustment of extracorporeal dialysis catheter) to the Unacceptable Principal Diagnosis edit code list. Although we agree with CMS that this code is more likely to be assigned in an outpatient setting, it appears to be in conflict with what is outlined in section II.F.9 for MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) of this proposed rule. In this section, CMS proposes to reassign admission for renal dialysis as 3 of 4 ICD-9-CM equivalent codes of V56.0, which are unacceptable principal diagnoses (Z49.02, Z49.31, and Z49.32). CMS notes only to use ICD-10-CM diagnosis code of Z49.01 as principal diagnosis as part of the proposal to delete MS DRG 685 and reassign this principal diagnosis code to MS-DRGs 698, 699, 700.

CHANGES TO SEVERITY LEVELS

Human Immunodeficiency Virus [HIV] Disease. CMS proposes to change the severity level of ICD-10-CM diagnosis code B20 (Human immunodeficiency virus [HIV] disease) from an MCC to a CC. **We oppose the downgrading of HIV disease to a CC as CMS has acknowledged that its own analysis of the data did not strongly suggest that the categorization of HIV as an MCC was inaccurate. We recommend that until further data analysis can more comprehensively and clinically support the severity level change, ICD-10-CM diagnosis code B20 remain an MCC.**

MCC/CC Acting as its Own MCC/CC When Assigned as a Principal Diagnosis. CMS proposes to remove the special GROUPER logic for processing claims containing two lists of ICD-10-CM diagnosis codes. These lists represent conditions normally coded using two or more diagnosis codes in ICD-9-CM, but required a single ICD-10-CM that combined the conditions. If one of these ICD-9-CM codes is a CC or MCC, then the single ICD-10-CM combination code used as a principal diagnosis would be grouped to the MS-DRG with CC/MCC. The lists were initially developed in the absence of ICD-10 coded data by mapping the ICD-9-CM diagnosis codes to the new ICD-10-CM combination codes. The lists were created to allow replication of the ICD-9-CM MS-DRG version. **We oppose CMS's global deletion of the list without the usual in-depth analysis that is more consistent with the approach that CMS conducts when proposing severity level changes (MCC/CC) for conditions, i.e., in this proposed rule, reference section II.F.1.a - Overview of Comprehensive CC/MCC Analysis. While we understand that CMS is no longer attempting to replicate the ICD-9-CM MS-DRG grouper logic, the conditions represented by the ICD-10-CM combination codes are *clinically* the same conditions that were CCs or MCCs before under ICD-9-CM.** By omitting the typical analysis afforded to downgrade the severity level of conditions, this global deletion of CC/MCCs appears arbitrary.

REDUCTIONS IN MS-DRG PAYMENTS

In the proposed rule, CMS proposes a number of significant reductions to the relative weights of certain MS-DRGs, which could potentially limit access to these necessary services for Medicare beneficiaries. For example, CMS's calculations of the relative weight for MS-DRG 215 ("Other Heart Assist Implant") would lead to a 25 percent reduction in FY 2019, which comes on the heels of a 20 percent reduction in FY 2018 and would result in a cumulative decline of more than 40 percent over two years. The impact of a decrease of this magnitude over two years would have a significant negative impact on hospitals that care for critically ill cardiovascular patients who require the implantation of a heart pump in the operating room or cardiac catheterization laboratory after heart attacks or decompensating heart failure. **The AHA has previously urged the agency to phase in substantial fluctuations in payment rates in order to promote predictability and reliability for the hospital field.** We appreciated that the agency limited the payment decrease for MS-DRG 215 for FY 2018, and **we urge CMS to again consider such an approach in this situation or when the relative weight for any MS-DRG is drastically reduced in a given year, particularly when it follows a significant decline in the previous year.**

REQUEST FOR INFORMATION ON INTEROPERABILITY

In this proposed rule, CMS asks for input regarding the opportunity to further advance interoperability of health information through the creation of Conditions of Participation (CoPs) for hospitals and critical access hospitals (CAHs) and conditions for coverage (CfCs) for other providers. CMS invites comments, noting a number of other related initiatives it has undertaken to promote broader adoption of electronic health records systems, and the use of these systems to facilitate communication among the providers caring for individual patients as well as between providers and patients. CMS observes that some of its previous initiatives have resulted in significant advances in the use of electronic health records systems while others have not yet been finalized, such as the proposed discharge rule of 2015, or have only recently been finalized by CMS and have not yet realized their full impact in terms of changing the delivery of health care. **The AHA strongly opposes creating additional CoPs/CfCs to promote interoperability of health information as described further below.**

BACKGROUND

The AHA strongly supports the creation of an efficient and effective infrastructure for health information exchange. This is central to the efforts of hospitals and health systems to provide high-quality coordinated care, support new models of care and engage patients in their health. However, we do not believe a new mandate tied to CoPs is the right mechanism to advance health information exchange. We are making progress on information exchange, due to the investment and concerted efforts of hospitals and health systems. According to AHA survey data⁹, 93 percent of hospitals and health systems provide patients with the ability

⁹ Sharing Health Information for Treatment. <https://www.aha.org/guidesreports/2018-03-01-sharing-health-information-treatment>

to access their electronic health records online, up from only 27 percent in 2012. Consumers also can download their information and choose to send it to a third party. Hospitals and health systems increasingly offer other online services, such as prescription refills, appointment scheduling, and secure messaging that make care more convenient. AHA data¹⁰ also show that hospitals and health systems have deployed systems to share health records with other providers of care to better support care coordination and transitions across settings of care. Seventy-one percent of hospitals and health systems share clinical or summary of care records with ambulatory care providers outside their system, up from 37 percent in 2012.

However, the commitment of health care providers is not sufficient by itself to create interoperability. The technical and organizational infrastructure must be available and allow for efficient exchange and all parties to exchange must be using compatible technology in consistent ways. All of this must be achieved in a way that simultaneously allows the free flow of information to others who have a legitimate reason to have the information while protecting the information from hackers and others with nefarious intent. **We urge CMS to recognize the impediments to information sharing described below and address them directly. We do not believe that creating a CoP or CfC that would apply to only one set of actors is an appropriate strategy. Further, it is not clear that such requirements would have any greater impact on interoperability than the existing federal requirements to share information, but could have unfortunate consequences for some hospitals and communities.**

THE IMPOSITION OF CoPs AND CfCs HAS PRACTICAL IMPLICATIONS

CMS's CoPs/CfCs are taken seriously by health care providers because failure to comply carries a heavy penalty. Declaring a hospital to be out of compliance with the CoPs can be extremely disruptive for patients, providers, and communities, as it means that a hospital could be removed from these programs and would no longer be able to care for Medicare or Medicaid patients. The penalty of not meeting an interoperability CoP is too stringent, especially given that the journey towards interoperability is still underway. Moreover, use of the CoPs/CfCs to promote interoperability are misguided for the following reasons:

1. **CoPs/CfCs are requirements to ensure safe health care delivery, and care can be delivered safely without the interoperability of electronic health records.** The Social Security Act (Title 18, Section 1861) authorizes the Secretary to establish requirements that are necessary for the health and safety of those being cared for in hospitals and other organizations. Clearly, the timely exchange of information among providers caring for an individual is an important step forward in ensuring that the relevant clinical information about the patient's diagnoses and treatment plan are in the hands of those providing care. This can help prevent errors in care as well as ensure the continued provision of the right care at the right time to patients. Because patients and their designated family members

¹⁰ Expanding Electronic Patient Engagement. <https://www.aha.org/guidesreports/2018-03-01-expanding-electronic-patient-engagement>

are a critical part of the care team, it is important that they, too have access to the patient's information in an accurate, complete and timely manner to ensure high-quality, safe care.

We agree that interoperable electronic health records should be capable of achieving information exchange. No other form of communication has the potential to enable such a complete set of information in a manner that can easily be searched by the recipient so that vital facts can quickly be identified and used. To the extent EHRs are capable of this type of information exchange, hospitals are already using them, and there already are substantial incentives in place for hospitals and some other providers through the now Promoting Interoperability Program (formerly known as Meaningful Use), as noted below. It is not clear that a CoP or CfC would increase the feasibility of information sharing by these health care organizations. Since neither the CoPs nor the CfCs apply to government agencies, patients, or others with whom hospitals and other providers would be trying to exchange information, we believe such requirements would have limited effect in promoting interoperability. **Instead, the AHA urges CMS to focus its attention on resolving problems created by the lack of a fully implemented exchange framework, adoption of common standards and incentives for EHR and other IT vendors to adhere to standards.**

- 2. It is premature for CMS to consider imposing COPs/CfCs until the barriers to exchange have been addressed and all of those affected by the requirements can, in fact, achieve compliance.** Compliance is impossible when there is no commonly accepted operational definition of interoperability and no commonly accepted metrics for interoperability. The implementation of EHR in general acute care hospitals is widespread. Our latest survey data from 2016 show that 96 percent of hospital have a certified EHR. Similarly, many physician practices have implemented EHRs that are compliant with the requirements imposed on physician practices for achieving meaningful use. However, the uptake of EHR systems in other parts of health care is less robust because other care providers did not have the same incentives provided under the meaningful use program.

Other barriers to interoperability exist as hospitals and health systems try to electronically send, receive, or query patient health information to and from other care settings or organizations. In responding to the AHA Survey, hospitals identified the following challenges:

- the information sent is not useful to recipients;
- the workflow required to enter and send information from their EHR is cumbersome;
- identifying the correct patient between systems is difficult because there is no single patient identifier; and
- exchanging information across different vendor platforms is difficult.

Almost half of respondents noted they experience greater challenges exchanging information across different vendor platforms and more than one-third report difficulty matching or identifying the correct patient between systems.¹¹ Some provider organizations, particularly those that are small or that serve a large number of patients with limited insurance coverage, simply do not have the resources to invest in expensive EHR systems. Regardless of why some providers do not have EHR systems, it is extremely difficult to achieve interoperability with those who are not using a system.

Further, although the Office of the National Coordinator (ONC) was charged with developing standards for collecting information in EHRs so that it could be readily exchanged with other providers, those standards have yet to be consistently implemented across systems in ways that make exchange efficient and effective. This is largely the reason why it is challenging to exchange information between providers on two different types of EHRs and, in some cases, between providers using EHRs manufactured by the same company, but with different versions and different installations. Considerable efforts are underway, and progress is being made. However, exchange across settings, such as between two hospitals or a hospital and a post-acute care setting or clinician office, is very challenging. And, without the exchange infrastructure discussed below, can require expensive point-to-point interfaces.

- 3. Modification of the CoPs/CfCs require clear and unambiguous evidence that compliance could be readily seen by a survey team charged with assessing the facility's compliance.** Health care organizations want to be in compliance with the CoPs/CfCs at all times. They view this as their obligation to the patients they serve. Yet, to be in compliance, they must have a clear and unambiguous understanding of what is expected and how they are to be judged as being in compliance. Since there are no clear, common metrics of interoperability, and since the survey team only visits the facility they are assessing, what evidence would they be looking for to assess the ability of the hospital or other provider to transmit/receive patient information to/from other providers, state or federal agencies, or others with whom they are to achieve interoperable exchange of information? Further, what would surveyors rate as full compliance with the requirement? If the hospital or other provider can transmit the information, but the intended recipient cannot receive it, has interoperability been achieved? If not, is it right or fair to hold the hospital or other provider accountable for the other organization's failure to be able to receive the data, especially since failure to comply with a CoP/CfC on interoperability can put a hospital or other organization in jeopardy of losing its ability to participate in Medicare and Medicaid. This seems to be too steep a penalty for not being able to communicate with another entity, especially if that failure is not within the hospital's ability to correct.

We also are concerned about the costs of compliance. Based on our survey to understand the regulatory costs associated with health IT, on average, surveyed hospitals spend

¹¹ Sharing Health Information for Treatment. <https://www.aha.org/guidesreports/2018-03-01-sharing-health-information-treatment> p 3- 4.

\$760,000 annually meeting regulatory requirements, most of which is being used to hire and maintain additional staff. Hospitals made additional IT investments averaging \$411,000 during the year for the Promoting Interoperability Program, an investment more than 2.9 times larger than that made in any other area.¹² Small provider organizations or those serving communities with few resources may simply be unable to afford the necessary investment in EHR technology, personnel and support systems to sustain this kind of interoperability

The AHA urges CMS not to move forward with a plan to require interoperability as a CoP/CfC until such time as it is reasonably feasible to efficiently and effectively achieve such communication across the majority of providers delivering health care in a region. Instead, CMS should coordinate with ONC on implementation of the Trusted Exchange Framework and Common Agreement (TEFCA) and other steps needed to create the infrastructure that would support interoperability.

OTHER OPPORTUNITIES EXIST TO FURTHER INTEROPERABILITY

CMS already holds hospitals accountable for supporting interoperability under the Promoting Interoperability Program. The agency requires hospitals to attest to three separate statements indicating it:

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

Those failing to attest face significant financial penalties under the inpatient PPS and CAH programs. Further, the specific requirements of the Promoting Interoperability Program promote information sharing across providers and with patients.

GREATER AVAILABILITY OF HEALTH INFORMATION TECHNOLOGY IS NEEDED IN THE POST-ACUTE CARE SETTINGS TO SUPPORT WIDESPREAD HEALTH INFORMATION EXCHANGE

Sharing information across the continuum of care is a clear priority. Post-acute care hospitals were not included in the EHR Incentive Program yet have worked diligently to identify and deploy technology to support their care delivery and care coordination goals. However, challenges to attainment of this goal persist as post-acute providers vary in size and resources and have more limited options than acute care providers when choosing an EHR related to their size, locations and technology, and implementation costs. **The AHA recommends that CMS not implement a CoP/CfC to increase interoperability across the continuum of care because post-acute care providers were not provided the resources or incentives to adopt health IT**

¹²Regulatory Overload. Assessing the Regulatory Burden on Health Systems, Hospitals and Post-Acute Providers. <https://www.aha.org/system/files/2018-02/regulatory-overload-report.pdf>

and creating this requirement would put another unfunded mandate on these organizations. Such a requirement would only be workable if all facilities were afforded the same opportunity to acquire certified EHRs that actually conformed to standards that enable the kind of interoperability CMS envisions.

AN INFORMATION EXCHANGE FRAMEWORK IS NECESSARY TO ASSESS INTEROPERABILITY ACROSS SETTINGS

We recognize that today's health information exchange landscape is comprised of a complex set of existing networks that include large national networks, regional and state networks and networks maintained by individual electronic health record vendors. There are initiatives to connect across networks but the work is nascent at this time. **The AHA supports the advancement of and adherence to a framework for interoperability so that the technology and the rules governing the exchange of health information are universally and consistently implemented and the implementation can be clearly demonstrated. We strongly urge CMS and ONC to focus on creating the infrastructure for exchange and continuing to build toward consistent use of standards across vendor platforms.**

Any framework and common agreement must specify minimum standards and essential elements needed to facilitate exchange so that end-users have assurance that all health information exchange networks are following the same rules of the road to ensure that exchange is trustworthy, reliable and efficient. The framework and common agreement should address, among other things:

- The minimum standards and implementation requirements that must be met to ensure efficient exchange, including standards to secure information;
- The permitted purposes for exchange;
- A clear understanding of the means to identify and authenticate participants of an individual exchange;
- A clear understanding of how the identity of individuals will be matched and managed across networks; and
- Assurance that each network will be transparent in the terms and conditions of exchange, including any technical prerequisites and costs of participating in exchange.

On Jan. 5, 2018, ONC released the draft TEFCA, which describes a set of legal relationships, governance approaches and types of information exchange that would allow for more efficient and effective sharing of health information across the country. The draft TEFCA puts forward six principles and more than 100 minimum required terms and conditions that would apply to those entities that voluntarily choose to share information under the trusted exchange framework. It also creates a structure for trusted information exchange and sets forward six "permitted purposes" for information exchange – treatment, payment, health care operations, public health, individual access to health information, and benefits determination (specific to determining eligibility for disability benefits under the Department of Veterans Affairs and Social Security Administration). It describes three "use cases," representing the ways in which exchange may happen and include:

- A broadcast query to all participants in the exchange asking for information about a specific individual(s);
- A directed query to a specific organization(s); and
- Population level data requesting information about multiple individuals in a single query (with no upper bound provided).

At this time, we understand that work is underway to revise the draft TEFCA in response to stakeholder feedback. **The AHA recommends that CMS postpone initiatives to advance requirements for interoperability prior to the finalization of TEFCA.**

PROMOTING INTEROPERABILITY PROGRAM

CMS proposes several changes to the Promoting Interoperability Program, formerly the EHR Incentive Program, to focus on relieving regulatory burden and to emphasize the role of electronic exchange of health information among providers and with patients. **The AHA supports and greatly appreciates the various proposals that introduce flexibility in the program's requirements on providers. Specifically, the AHA supports the following proposals:**

- **Removing objectives and measures that hold hospitals and CAHs responsible for the actions of others;**
- **Shifting the program to a performance-based scoring methodology that eliminates required thresholds and permits hospitals to get credit for building performance in some areas while earning additional points in areas of strong performance;**
- **Establishing a threshold of 50 points to meet the measure scoring requirements and avoid payment penalties; and**
- **Setting the reporting period to be of a minimum of any continuous 90-day period in CYs 2019 and 2020.**

The AHA opposes the use of Stage 3 requirements in FY 2019. We continue to believe the level of difficulty associated with meeting all of the Stage 3 current measures is overly burdensome. Some of the measure thresholds require the use of certified EHRs in a manner that is not supported by mature standards, technology functionality, or an available infrastructure. For example, the Stage 3 Coordination of Care Through Patient Engagement objective includes a measure requiring the incorporation into the EHR of patient-generated health data or data from a nonclinical setting for more than five percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23). However, the types of data to be integrated are not specified, the data sources range from social service organizations to consumer fitness devices, and the manner by which to incorporate the data into the EHR is not specified.

AHA RECOMMENDATIONS SUPPORTING THE TRANSITION TO THE PROMOTING INTEROPERABILITY PROGRAM

The AHA shares CMS's view that eligible hospitals (EHs), CAHs and eligible professionals will benefit from additional time to implement and optimize the 2015 edition certified EHR

technology. Experience to date indicates that the transition to a new edition of certified EHR technology is challenging due to lack of vendor readiness, the necessity to update other systems to support the new data requirements, the time required to review and modify workflows and build performance. We are concerned that the 2019 transition will present additional challenges due to new reporting requirements and requirements to use EHR functionality that were not included in the 2015 edition certification criteria. To address these challenges and to provide additional relief to providers, the AHA offers several recommendations intended to facilitate an effective transition to the Promoting Interoperability Program and the safe use of 2015 edition certified EHRs.

New Performance-Based Scoring Methodology. CMS proposes a new scoring methodology for EHs and CAHs applied to four objectives derived from objectives found in Stage 3: Electronic Prescribing (e-Prescribing), Patient Electronic Access to Health Information, Health Information Exchange and Public Health and Clinical Data Registry Reporting. The Protect Patient Health Information objective would be the fifth objective in the Promoting Interoperability Program and would continue as a required yes/no attestation. CMS proposes to eliminate the Coordination of Care through Patient Engagement objectives and associated measures included in Stage 3.

Objective	Measures	Maximum Points
e-Prescribing	e-Prescribing Query of PDMP Verify Opioid Treatment Agreement	20 points in 2019 (includes 10 bonus points for new opioid measures) 15 points in 2020
Health information exchange	Create and Send Summary of Care Receive Summary of Care and Conduct Clinical Information Reconciliation	40 points
Provider to patient exchange	Provide Patients Electronic Access to Their Health Information	40 points in 2019, 35 points in 2020
Public health and clinical data exchange	Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Registry Reporting Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Results Reporting	10 points
<p><i>CAHs and EHs must report on all required objectives and measures. An overall score of 50 or more points would be sufficient to meet meaningful use and avoid a Medicare payment penalty.</i></p> <p><i>The Protecting Patient Health Information objective does not have a performance-based measure but EHs and CAHs are required to attest to meeting the Security Risk Analysis measure requirements.</i></p>		

MAKE THE NEW ELECTRONIC PRESCRIBING MEASURES AVAILABLE FOR BONUS POINTS BEYOND CY 2019

Query of Prescription Drug Monitoring Program (PDMP). The AHA strongly supports the intent to use the health IT infrastructure to provide insight on Schedule II opioid prescribing practices. The first measure would require the EH or CAH to use data from certified EHRs to conduct a query of a PDMP for prescription drug history for Schedule II opioids electronically prescribed using a certified EHR and report on the percent of patients prescribed an opioid for whom this occurred.

In the rule's preamble, CMS acknowledges that PDMP integration with certified EHRs is not widespread and states that many EHs and CAHs will likely need to enter data manually into the certified EHR to document the completion of the query and conduct manual calculation of the measure. We understand that laws in several states do not permit PDMP data to be brought into and stored within a certified EHR, thereby extending the need for manual data entry and manual calculation of the measure indefinitely. The development of interfaces to connect EHRs and a gateway to the PDMP vendor solution is underway. However, our members communicate that the cost to access electronically the PDMP technology gateway is as high as \$200 per prescribing clinician per year. To access this gateway, clinicians are generally required to leave their workflow and log into a separate PDMP website where they can query the PDMP and view a patient's PDMP report. In some instances, an option for a single sign-on in the EHR enables access to the PDMP gateway. Also, in some locations, a state may have its own PDMP database, supported by a Health Information Exchange and use an open application programming interface (API) to allow vendors to connect EHRs to the PDMP without additional charge.

In order to ensure that the new opioid measure is meaningful, reduces burden, and reflects the diversity of approaches currently used to access PDMPs, the AHA has a number of recommendations.

First, given the significant burden that will be associated with calculating a percentage measure, **the AHA recommends that the measure be reported as either Yes, the hospital has enabled the capability for prescribers to check the PDMP, or No, they have not. We also recommend that this measure be eligible for five bonus points in both CY 2019 and 2020.**

Second, **we recommend that CMS clarify that EHs and CAHs are permitted to continue use of the health information exchange to gain access to Schedule II opioid prescription drug history and thereby earn points for this measure.**

Third, we urge CMS to monitor the development of electronic means within the provider workflow to query, retain and use prescribing histories retained in PDMPs and the ability of a PDMP to share information with another state. **We also urge CMS to consider the use of an open API by PDMPs to enable a provider's EHR to access the Schedule II opioid prescription drug history of a patient.**

Finally, CMS states that in order to meet this measure, EHs and CAHs must use the capabilities and standards as defined for certified EHRs, specifically the certification criteria supporting e-

prescribing and drug formulary query and preferred drug list. However, certification criteria specific to support PDMP query are not included in the 2015 edition EHRs, and it is unclear whether ONC will promulgate updated certification requirements to support this functionality. **In the absence of technology and infrastructure specifically supporting a direct electronic query of a PDMP, retention of the prescribing history identified and use of the information for measure calculation, the AHA recommends that CMS remove the requirement that EHs and CAHs use capabilities and standards of certified EHR technology for querying the PDMP.**

Verify Opioid Treatment Agreement. CMS proposes that EHs and CAHs seek to identify the existence of a signed opioid treatment agreement and incorporate it into the EHR if a Schedule II opioid was electronically prescribed by the EH or CAH using certified EHR and the total duration of the patient's Schedule II opioid prescription is at least 30 cumulative days within a six month look-back period. The AHA commends the intent that EHs and CAHs identify an opioid treatment agreement in support of care coordination and care planning by the patient and the provider. However, we are concerned that this measure lacks a standard that specifies the data to be included in the agreement. Without such standards, and accompanying certification requirements, it is unclear how a provider's certified EHR technology could support this activity. We also are concerned that requiring EHs and CAHs to report this measure could inadvertently disrupt the primary care provider's relationship with the patient for ongoing care, particularly the six-month look-back requirement. We believe the measure is more appropriate for ambulatory providers. **The AHA recommends CMS not include this measure in the ePrescribing objective for EHs and CAHs in the Promoting Interoperability Program. If CMS finalizes this measure for EHs and CAHs, the AHA recommends that the measure remain available for bonus points until such time that standards and certification criteria are developed to identify the data necessary to support the measure intent.**

PROVIDE ADDITIONAL FLEXIBILITY TO SUPPORT HEALTH INFORMATION EXCHANGE

CMS proposes two measures for health information exchange in support of transitions of care or referrals to another care setting. The first measure requires the creation and sending of a summary of care record using certified EHR. The second measure requires the receipt and clinical information reconciliation of the information received in the electronic summary of care record. The 2015 edition EHR certification criteria that support the creation, sending, and receipt of a summary of care record is limited to the consolidated continuity of care document (C-CDA), referral summary and discharge summary document. Other document templates are available, but EHRs are not required to be certified to support them. ONC's TEFCA may create opportunities for EHs and CAHs to utilize other formats or mechanisms to enable health information exchange. As an interim step in this journey, **the AHA recommends that CMS allow EHs, CAHs and EPs to use certified EHR technology or other options supported by health information technology to meet CY 2019 reporting requirements. Specifically, we urge CMS to permit the choice to use any of the HL7 formats available to meet the health information create and electronically send a summary of care in support of transitions of care.**

The AHA also recommends that CMS continue to work with federal partners to support the widespread availability of patient identifiers. Providers continue to experience challenges in identifying patients and matching them to their medical records. Safe and effective interoperability of health information that originates in disparate sources depends on the accurate link of a patient with the correct record. The nation lacks a single mechanism for identifying individuals such as a unique patient identifier. A single solution that would match individuals across IT systems would allow providers to know with confidence that a patient being treated in an emergency department is the same patient that a physician in another location diagnosed with an acute or chronic health condition that requires ongoing management. Patient safety concerns arise when data are incorrectly matched, such as a patient's current medication not being listed in the medical record or the wrong medications are included in the record. The 2015 edition EHRs are required to certify the ability to create a transition of care/referral summary document that contains the data elements in accordance with the specified standards/constraints. The health IT is not required to demonstrate how it performs patient matching with these data. For example, the C-CDA template can accommodate more than one address but cannot distinguish between the historical and current address. Successful attainment of a level of performance in CY 2019 would be easier to achieve with advancement of a patient matching solution that is widely followed and available.

INCREASE CONFIDENCE IN THE SECURITY OF PROVIDER TO PATIENT EXCHANGE

CMS proposes to create an objective titled Provider to Patient Exchange that is worth up to 40 points. The single measure for this objective states that hospitals would be required to provide patients (or their representatives) electronic access to their health information through two mechanisms:

- (i) "The patient (or patient-authorized representative) is provided timely access to view online, download and transmit his or her health information; and"
- (ii) "The eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API [application programming interface] in the eligible hospital or CAH's CEHRT."

Hospitals and health systems believe that securely sharing health information is central to providing high-quality coordinated care, supporting new models of care and engaging patients in their health. New tools and technologies, including APIs and apps, will allow for more convenient and flexible access to health information and new ways for individuals to engage in their health.

America's hospitals and health systems are committed to moving forward with new forms of sharing health information with individuals. However, we believe that CMS must balance the pace for moving in this positive direction with the real and developing risks that this approach raises for systems security and the confidentiality of health information. To ensure a successful transition, stakeholders must work together to develop a secure app ecosystem and health care providers must move forward deliberately to gain experience in using these tools. And the federal government must make clear how necessary measures providers

must take to secure systems will be evaluated when the rules against information blocking are enforced in the emerging API environment.

Recommended Changes to the Measure. The requirement to connect “*any application*” of the patient’s choice, without allowing hospitals to evaluate the app for security or test that it functions as expected, poses particular challenges for systems security. This risk is particularly acute given the lack of a secure app ecosystem. This requirement also assumes a level of experience with the use of APIs that providers and consumers have yet to achieve.

To ensure an appropriately measured transition that allows the development of a secure app ecosystem and allows sufficient time for providers to develop competence in using and securing APIs, we recommend that CMS revise the second part of the measure to read:

- (ii) “The eligible hospital or CAH ensures the patient’s health information is available for the patient (or patient-authorized representative) to access using **at least one** application that is configured to meet the technical specifications of the API in the eligible hospital or CAH’s CEHRT.”

We also recommend that CMS provide an exclusion for this measure in FY 2019 for hospitals and CAHs that cannot successfully identify an app that meets the security needs of their system.

Systems Security. In recent years the health care sector has been under attack by cyber criminals and nation states looking to infiltrate systems and steal patient data. Connecting a wide-range of unfamiliar, and frequently untested, apps that are presented by patients creates a significant and real risk that can serve as a possible point of entry for malware into systems. According to Symantec, mobile devices, which are the primary platform for apps, are now a key target for cyber attacks, with the “number of new mobile malware variants increased by 54 percent in 2017, as compared to 2016. And last year, an average of 24,000 malicious mobile applications were blocked each day.”¹³

Furthermore, the apps presented by patients will be running on devices that are not under the control of hospitals and health systems. Updating operating systems is a key tool in preventing cyber attacks. However, Symantec further notes that, “While threats are on the increase, the problem is exacerbated by the continued use of older operating systems. In particular, on Android™, only 20 percent of devices are running the newest major version and only 2.3 percent are on the latest minor release.”

Finally, as the global WannaCry cyber attack experience showed, the impact of malware can move far beyond information systems to affect health care operations and even patient safety. The risk landscape is constantly changing, as cyber criminals identify previously unknown vulnerabilities and new forms of attack. For these reasons, the federal government has declared

¹³ Symantec Internet Security Report. March 2018. Available at: <https://www.symantec.com/content/dam/symantec/docs/reports/istr-23-executive-summary-en.pdf>.

health care and public health to be a part of the nation's critical infrastructure that must be diligent in protecting against cyber attack.

Given the alarming trend in cyber attacks in health care, providers must be granted the right to control the technology that is connected to their systems in order to keep them secure. While we acknowledge that there are encryption and patient authentication specifications within the technical specifications of the API, connecting an app still poses risks for injection of malware into a hospital's information system. In addition, hospitals must monitor for and guard against malware that could attempt to access data for patients other than the individual that has provided authorization for access. If a malicious app were to successfully inject malware or access data for multiple patients, the hospital could face catastrophic effects on its information systems and clinical operations. It also could be in violation of the Health Insurance Portability and Accountability Act (HIPAA) and could face significant penalties for noncompliance, despite the cause of the problem stemming from a patient's app. Therefore, hospitals and health systems must have the ability to deploy and maintain strong security safeguards.

Patient Confidentiality. Since the passage of HIPAA in 1996, patients have understood that their sensitive health information will be kept confidential, and hospitals and health systems have operated under the HIPAA privacy rules. However, commercial app companies generally are not HIPAA-covered entities. Therefore, when information flows from a hospital's information system to an app, it likely no longer will be protected by HIPAA. Most individuals will not be aware of this change and may be surprised when commercial app companies share their sensitive health information obtained from a hospital, such as diagnoses, medications or test results, in ways that are not allowed by HIPAA. Furthermore, individuals may consider the hospital to be responsible if their data hold – and that may be indistinguishable from that held by the hospital – is sold to a third party or used for marketing or other purposes.

While ONC has released a voluntary model privacy notice for app companies, use of this notice is not required. Recent studies have shown that the majority of health apps on the market today do not have adequate privacy policies and routinely share sensitive health information with third parties. In one study of diabetes apps, almost 80 percent did not even have privacy policies, and about half of those with a privacy policy indicated that they would share data with third parties. Only a handful indicated that they would ask for permission from the individual before sharing personal health information.¹⁴ Research also shows that individuals generally do not fully understand the privacy policies presented by commercial app companies, and from a practical point of view have no option but to agree to them if they want to use a product.¹⁵ And, recent headlines indicate that even large technologies companies, such as Facebook, have shared people's data without their consent, while the Federal Trade Commission (FTC) is reportedly

¹⁴ Blenner, Sarah R., et al. Privacy Policies of Android Diabetes Apps and Sharing of Health Information, JAMA, March 8, 2016, available at <http://jama.jamanetwork.com/article.aspx?articleid=2499265>).

¹⁵ See, for example, Obar, Jonathan A. and Oeldorf-Hirsch, Anne, Clickwrap Impact: Quick-Join Options and Ignoring Privacy and Terms of Service Policies of Social Networking Services (June 1, 2017). In Proceedings of the 8th International Conference on Social Media & Society (p. 50). ACM.. Available at SSRN: <https://ssrn.com/abstract=3017277>.

investigating the privacy practices of companies that collect and analyze genetic information from consumers.

While we understand that patients have the right to share their data as they see fit, and may be willing to take the risk of less privacy when using commercial apps, we believe that significant consumer education efforts are needed to help individuals understand the vastly different, and less stringent, federal privacy requirements for entities not covered by HIPAA. **Therefore, to address concerns about patient privacy, we recommend that CMS work with the FTC, which provides consumer protection, and the Office for Civil Rights (OCR) to provide model language that health care providers can present to their patients that choose to access their data via an app.** This language should clearly explain that data shared with and held by the commercial app is no longer protected by HIPAA, but is governed by the privacy policy and terms of service of the commercial app company. The language also should make clear that the health care provider bears no responsibility for the use of patient data by the commercial app company and that any concerns about how data are used once shared with an app should be directed to the FTC.

We also strongly recommend that CMS work with the OCR and the FTC to develop an extensive education program so that all consumers can become aware of how app companies can and may use their data, and the importance of reviewing and keeping updated about the privacy practices of any app that they choose to use to access their sensitive health information.

Building Expertise. Very few hospitals and health systems have experience in offering API access to patient-facing apps. This functionality is part of the 2015 Edition CEHRT, which has yet to be fully implemented across the country. In addition, AHA members seeking to gain experience have reported that there are very few apps currently available for them to test out. For example, many of the products in EHR vendor “app stores” are still in testing versions.

Once hospitals have the technology and apps available to them, deploying an API approach for patient-facing applications requires significant work and collaboration from EHR vendors to build connections, understand how the API works within their health information system, and ensure that these new connections do not inadvertently damage other parts of the network. IT staff must be trained and the hospital must build out capabilities for monitoring use of the API and identifying both possible malware and attempts to access more data than is authorized by the individual. They also must evaluate how this new connection point affects their risk management and compliance strategies. Hospitals also will need to develop a communications plan for their patients and train front-line staff on how to answer patient questions. One large health system has already devoted considerable staff and time to understanding and building out a strategy for deploying their API. Smaller hospitals and systems with fewer resources will likely need more time to develop expertise in deploying APIs, and may face significant financial and human capital constraints.

Secure App Ecosystem. To ensure a robust, secure set of tools for individuals to engage with hospitals and health systems via apps, stakeholders will need to work together to build an app

ecosystem that is based on a rigorous and continuous vetting process that takes into account evolving risks. This could be done in the public sector, through certification, or through a public-private partnership. There are examples of this type of approach in other sectors, such as the Payment Card Industry Data Security Standard for processing bank cards. Any entity that wants to process bank card payments must attest to following these standards.

In the health sector, Medicare has developed a vetting process for apps that connect to Medicare claims data via the Blue Button 2.0 API. CMS will not connect any app that meets the technical specifications to its API. Rather, it has developed a process to evaluate apps before they are connected, and applies a number of security and privacy requirements. The full guidelines for Blue Button developers are available at <https://bludbutton.cms.gov/developers/>. However, as an overview, Medicare requires the following:

- Developers must request access to the Blue Button production API by email.
- Approval will take one to two weeks and involve a phone call and demo to the CMS Blue Button API team.
- Developers must be U.S.-based companies.
- Developers must articulate to CMS both their business model and the value the app will provide to beneficiaries.
- Developers must demonstrate to CMS how data will be protected within the app.
- Developers must agree to future audits by CMS as part of a Production API access renewal process.
- Developers must provide a URL to their privacy policies and terms and conditions when registering their app with CMS.
- The agency also requires agreement to additional terms of service that include, among other things, a statement that “CMS reserves the right (though not the obligation) to: (1) refuse to provide the API to you, if it is CMS’s opinion that use violates any CMS policy; or (2) terminate or deny you access to and use of all or part of the API at any time for any other reason which in its sole discretion it deems necessary to in order to prevent abuse.” The full terms of service are available at: <https://bluebutton.cms.gov/terms/>.

Taken together, these protections established by CMS could serve as a starting point for a sector-wide approach to developing a trusted app ecosystem.

Implications for Information Blocking. Hospitals and health systems need clarity in understanding how steps they might need to take to secure their systems will be treated as CMS and the Office of the Inspector General (OIG) enforce the provisions against information blocking promulgated in the 21st Century Cures Act. They are concerned that denying access to a suspect commercial app will be considered information blocking and subject a hospital to a meaningful use payment penalty. **To ensure that reasonable actions to secure systems are not considered noncompliant, we recommend that CMS work with ONC and OIG to ensure that these protective measures are included in the forthcoming guidance on actions that do not constitute information blocking.**

In addition, we note that information sharing about security risks is a best practice that is encouraged under the Cybersecurity Information Sharing Act of 2015. **To advance information sharing about risks posed by health apps, we recommend that CMS work with ONC and FTC to develop a place for hospital and health systems to report suspect apps so that others can be aware and take needed steps.**

OFFER ADDITIONAL SCORING OPPORTUNITIES FOR PUBLIC HEALTH AND CLINICAL DATA REPORTING

The final Stage 3 requirements, adopted in the FY 2018 rule, state that hospitals and CAHs must report any three measures for the Public Health and Clinical Data Exchange Reporting objective. CMS now proposes to require EHs and CAHs to report the Syndromic Surveillance measure and select one additional measure, eliminating the flexibility for EHs and CAH to select from all available measures. Hospitals and health systems devoted time to determine the measures to report and resources for technology and interfaces to be able to report the selected measures. The availability of exclusions for the measures in this objective is an acknowledgement of the lack of uniform readiness for acceptance of the specific standards required to meet the certified EHR definition or the lack of readiness to receive reported data six months prior to the start of the reporting period.

The AHA recommends that CMS permit EHs and CAHs to report any two measures to meet the Public Health and Clinical Data Exchange requirements for CYs 2019 and 2020. Additionally, we recommend that CMS permit the option for EHs and CAHs to report additional measures and receive bonus points for CYs 2019 and 2020. This recommendation will leverage the work undertaken to prepare for Public Health and Clinical Data Exchange reporting and will spur the continued preparation on the part of public health to receive electronic data from EHRs.

Given the continued engagement by hospitals and public health departments to improve the infrastructure that supports this aspect of health information exchange, **the AHA recommends that CMS not pursue a proposal in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022.** The willingness of hospitals to share data with public health entities is, in part, dependent on the willingness of health IT vendors and the infrastructure for health information exchange to support health information exchange that contributes to the health of the nation. We recommend that CMS continue to analyze the attestation data from EHs and CAHs for the Public Health and Clinical Data Exchange reporting and continue working with federal partners and state governments to build public health department capacity to receive automated reporting.

REVISE THE PROPOSAL FOR CY 2020 REPORTING REQUIREMENTS

CMS proposes Promoting Interoperability Program requirements for the CY 2020 reporting period. At this time, EHs and CAHs lack widespread experience with the 2015 edition certified EHR and do not have experience with the new performance-based scoring methodology. **The AHA recommends that CMS examine the experience from the CY 2019 reporting period to inform proposed program requirements for the CY 2020 reporting period.** For example, the TEFCA under development by ONC may be deployed during CY 2019. As drafted, the TEFCA

provides an opportunity to reconsider interoperability and health information exchange beyond point-to-point exchange of documents. This development could initiate a re-evaluation of the characteristics of successful health information interoperability.

RETAIN AND MODIFY THE EXCEPTION FOR LIMITED ACCESS TO BROADBAND

CMS proposes to remove the exclusion criterion related to broadband availability, which was set at 4 Mbps of broadband availability within the county in which the facility is located (as opposed to availability for the provider). **We recommend that CMS retain the exception and examine whether it will need to be modified over time, as the use of telehealth and other modalities dependent on Internet access increases.** According to the Federal Communication Commission's most recent "Broadband Progress Report", the existing community speed benchmark is 25 Mbps download/3 Mbps upload (25 Mbps/3 Mbps) for what it considers as fixed broadband. Over 24 million Americans still lack fixed terrestrial broadband at speeds of 25 Mbps/3 Mbps, with deployment in rural areas and Tribal lands lagging behind that of urban areas (see https://apps.fcc.gov/edocs_public/attachmatch/FCC-18-10A1.pdf). With respect to health care providers specifically, the FCC's 2012 *Healthcare Connect Fund* included a needs assessment of "health care provider (HCP) needs for broadband capability in light of the current and future state of telemedicine, telehealth, and health care information technology (Health IT)." The assessment found that the optimal bandwidth needs for the transmission of HD video consultation averages 22 Mbps. The report also notes that a minimum speed of 10 Mbps symmetrical is necessary to support the majority of telehealth applications, but emphasizes that larger facilities utilizing multiple concurrent technologies and connections may require upwards of 100 Mbps (see https://apps.fcc.gov/edocs_public/attachmatch/FCC-12-150A1.pdf at §§ 6-12). Thus, in the future, CMS may need to deploy an exception based on the bandwidth available to the health care provider, at higher speeds. In the interim, we recommend maintaining the existing exception.