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August 27, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS–1633–P, Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals under the Hospital Inpatient Prospective Payment System (Vol. 80, No.130), July 8, 2015.

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) proposed rule for calendar year (CY) 2016.

We support many of CMS's proposals, including the proposed changes to the two-midnight policy. **Specifically, we believe that CMS's proposed changes are a good first step towards resolving some of the problems created by this policy.** We are pleased that CMS's proposal is more reflective of the agency's longstanding policy that recognizes the important role of physician judgment and individual patient needs in the hospital admission decision-making process. In addition, we appreciate that this proposal maintains the certainty that patient stays of two midnights or longer are appropriate as inpatient cases. **We remain concerned, however, that CMS continues to apply its 0.2 percent reduction to the standardized amount that was implemented in FY 2014 and ask that the agency repeal this unlawful reduction.**

In addition, we applaud the agency's Aug. 12 announcement that it will extend the partial enforcement delay of the two-midnight policy through the end of the year. However, we ask CMS to consider extending further the partial enforcement delay until March 31, 2016 to allow hospitals sufficient time to not only implement the policy changes but also to ensure that CMS has the time necessary to issue detailed guidance. This guidance will be essential for proper

implementation of the new policies and revised admissions criteria by hospitals and CMS review contractors.

However, we also have significant concerns, several of which deserve particular attention. **First and foremost, the AHA strongly opposes CMS's proposal to apply a 2 percentage point reduction to the OPPS conversion factor.** The agency's proposed cut is ill-conceived and founded on questionable assumptions, a poorly described methodology and data that are not publically available. **The lack of transparency that the agency provides related to Office of the Actuary (OACT) estimations is becoming a theme of recent rulemaking and is extremely troubling.** Additionally, basing a cut on CY 2014 claims data is inappropriate, as CMS's CY 2014 instructions to hospitals regarding how to bill for laboratory tests were confusing and changed several times. Therefore, any "unexpectedly high" volume of separately payable laboratory tests that CMS observed in CY 2014 claims data does not reflect a permanent change to hospital coding and billing practices, but rather is the direct result of CMS's unclear and frequently shifting billing instructions.

Second, while the AHA generally supports payment reforms that lead to larger units of payment, we are concerned that CMS is moving forward too quickly with expansions and proposing policies that are not adequately explained, difficult to validate and operationally and administratively burdensome for hospitals to implement. For example, CMS proposes two new payment policies that would require the use of modifiers, which would pose significant administrative and operational burden, including requiring the manual review and handling of claims that otherwise would be processed automatically. In our detailed comments, the AHA recommends that CMS slow down and not finalize certain proposals so that it can provide additional details about its methodology, share impact analyses, and consider alternative, less burdensome policies.

Finally, the AHA urges CMS to use the recent recommendations in the Institute of Medicine's *Vital Signs* report to help streamline the measures in the outpatient quality reporting program. OPPS measures should focus on national priority areas for improvement applicable to the entire health care system. We also urge CMS not to adopt its proposed Emergency Department Transfer Communication measure, as we are concerned it would duplicate, and potentially conflict with, other CMS efforts aimed at improving care transitions.

Thank you again for the opportunity to comment. Our detailed comments follow. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President

Attachments

AMERICAN HOSPITAL ASSOCIATION
DETAILED COMMENTS ON THE PROPOSED RULE FOR CY 2016 HOSPITAL OUTPATIENT AND AMBULATORY SURGERY CENTER PPS AND QUALITY REPORTING PROGRAMS; SHORT INPATIENT HOSPITAL STAYS; TRANSITION FOR CERTAIN MEDICARE-DEPENDENT, SMALL RURAL HOSPITAL UNDER THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM

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AMERICAN HOSPITAL ASSOCIATION DETAILED COMMENTS

GENERAL COMMENTS

In the CY 2016 proposed rule, CMS proposes several significant expansions to its payment policies that shift the outpatient prospective payment system (OPPS) more definitively away from a per-service fee schedule to a payment system with larger payment bundles, including changes that could, over time, support movement toward bundled payment. **While the AHA generally supports payment reforms that lead to larger units of payment, such as bundled payment, we are concerned that CMS is moving too quickly with these expansions and proposing policies that are not adequately explained, difficult to validate, and operationally and administratively burdensome for hospitals to implement. For the upcoming final rule and in future rulemaking, we urge CMS to provide additional rationale and explanation as well as separate impact analyses for any significant policy shift.**

Furthermore, our reservations about the complexity of these proposals, the inadequate time to analyze them and the short timeframe until implementation cause us to be wary about the potential for unanticipated sweeping redistributions of funds across hospitals that could result from these fundamental changes to the OPPS. We believe that the hospital field and CMS would benefit from additional time to analyze and validate the technical changes necessary to make these policies possible, as well as to study the impacts they would have on individual hospitals. **The AHA encourages CMS to discuss with the Advisory Committee on Hospital Outpatient Payments (HOP Panel) any and all significant new policies that the agency is considering in order to allow the HOP Panel and the public an opportunity to understand and respond to policies before they are formally proposed.**

We also are concerned about the timing and magnitude of the changes proposed in this rule. Specifically, in addition to the OPPS changes proposed in this rule, by Jan. 1, hospitals also must continue training staff and making systems changes related to the transition to ICD-10, as well as implement potentially significant changes to the two-midnight policy. **In the sections that follow, the AHA recommends that CMS slow down and not finalize certain proposals so that it can provide additional details about its methodology, share impact analyses, and consider alternative, less burdensome policies.**

Finally, we note that in recent years, CMS has repeatedly created new modifiers as a way to operationalize its payment policy changes. For instance, in CY 2016, hospitals are required to begin using the "PO" modifier, which must be reported with every Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology (CPT) code for all outpatient hospital items and services furnished in an off-campus provider-based department of a hospital. CMS also finalized the "L1" modifier to identify laboratory services eligible for separate payment at the Clinical Laboratory Fee Schedule (CLFS) rates. In this rule, CMS proposes to require the reporting of two new modifiers, including a modifier to identify non-primary services that are adjunctive to a "J1" service but reported on a different claim from the J1 service, as well as another modifier to be reported with computed tomography (CT) services that are furnished using equipment that fails to meet each of the attributes of National Electrical Manufacturers Association Standard XR-29-2013. As we discuss below, the use of modifiers poses significant administrative and operational burden, including requiring the manual review and handling of claims that otherwise would be processed automatically. In addition, the Health

Insurance Portability and Accountability Act transaction standard for the 837-I claim allows for only four modifiers per line; these new modifiers, as well as the many existing modifiers, increase the likelihood that claim lines could hit this limit. This limitation could result in hospitals being forced to make a choice about with which Medicare policies they will comply. **The AHA recommends that CMS attempt to find alternative and less burdensome solutions for implementing its payment policies, minimizing the proliferation of new modifiers.**

SHORT INPATIENT HOSPITAL STAYS

In the rule, CMS proposes regulatory modifications to its two-midnight policy and announces changes to its medical review strategy for patient status claims. **The AHA generally supports these proposals, which are a good first step towards resolving some of the problems created by the two-midnight policy. Our specific comments are discussed below.**

Proposed Changes to the Two-midnight Policy. In the FY 2014 inpatient PPS final rule, CMS finalized its "two-midnight" policy under which it generally considers hospital admissions spanning at least two midnights as appropriate for payment under the inpatient PPS. In contrast, hospital stays of less than two midnights generally are considered outpatient cases, regardless of clinical severity or a physician's judgment that an inpatient admission is medically necessary, and therefore appropriate for payment under the outpatient PPS.

This policy has been very problematic for the hospital field. Its time-based threshold overrides the longstanding role of physician judgment by placing emphasis on the expected amount of time – not the level of care – as the driving factor in an admission decision.

In the proposed rule, CMS acknowledges as much by stating that certain procedures may have intrinsic risks, recovery impacts or complexities that would cause them to be appropriate for inpatient coverage under Medicare Part A, regardless of the length of hospital time the admitting physician expects a particular patient to require. As a result, CMS now proposes that where the admitting physician expects a patient to require hospital care for a period of time that does not cross two midnights, an inpatient admission of a patient may be appropriate for payment under Medicare Part A based on the clinical judgment of the admitting physician and medical record support for that determination.

We are pleased that CMS's proposal is more reflective of the agency's longstanding policy that recognizes the important role of physician judgment and individual patient needs in the hospital admission decision-making process. In addition, we appreciate that this proposal maintains the certainty that patient stays of two midnights or longer are appropriate as inpatient cases.

CMS, however, must provide hospitals with the tools and time necessary to effectively implement any changes to the two-midnight policy the agency may finalize. For example, CMS must issue clear, detailed and precisely drafted guidance for hospitals, physicians and Medicare review contractors after these changes are finalized. We urge CMS to do so as soon as possible so that providers have ample time to re-evaluate and potentially alter internal policies, educate physicians on these changes, alter work flow processes and update existing electronic medical record systems to ensure compliance with the revised policy.

Enforcement Delays. CMS announced Aug. 13 that the partial enforcement delay of the two-midnight policy will remain in effect through Dec. 31, 2015. Under the partial enforcement

delay, CMS prohibits the Recovery Audit Contractors (RACs) from conducting post-payment patient status reviews for claims with dates of admission from Oct. 1, 2013 through Dec. 31, 2015. **We appreciate CMS's extension of this partial enforcement delay.** However, given that this outpatient PPS rule will be finalized in early November, hospitals will have only two months before the rule's effective date of Jan. 1 to implement the revised policy. **Therefore, we urge CMS to consider extending further the partial enforcement delay until March 31, 2016 to allow hospitals sufficient time to not only implement the policy changes but also to ensure that CMS has the time necessary to issue detailed guidance that will be essential for proper implementation of the new policies and revised admissions criteria by hospitals and CMS review contractors.**

In addition, as discussed in more detail below, CMS announced changes to its medical review strategy that will allow Quality Improvement Organizations (QIOs) to review patient status claims beginning no later than Oct. 1. However, because the proposed changes to the two-midnight policy would not be effective until Jan. 1, 2016, it does not make sense for QIOs to audit claims from Oct. 1 to Dec. 31 under the current two-midnight policy, only to switch three months later to the revised policy. In addition, as explained above, more time is necessary for both hospitals and CMS to properly implement CMS's new policies and revised admissions criteria even after their effective date of Jan. 1, 2016. **Accordingly, we urge CMS to also delay QIO audits until March 31, 2016 to align with our requested extension of the partial enforcement delay, but at minimum, until the Jan. 1, 2016 effective date of the policy.**

Changes to CMS's Medical Review Strategy. In the preamble to this proposed rule, CMS announced changes to its patient status medical review and enforcement strategy that will go into effect regardless of whether the proposed changes to the two-midnight policy are finalized. Under this new medical review strategy, beginning no later than Oct. 1, CMS will use QIOs, rather than Medicare Administrative Contractors (MACs) or RACs, to conduct first-line medical reviews of the majority of patient status claims and to educate hospitals about claims denied under the two-midnight policy.

QIOs will review a sample of post-payment claims and make a determination of the medical appropriateness of the admission as an inpatient. CMS will allow RACs only to conduct patient status audits for those hospitals with consistently high-denial rates. Specifically, those hospitals that are found by the QIO to exhibit a pattern of practices including, but not limited to, having high-denial rates and consistently failing to adhere to the two-midnight policy (including having frequent inpatient hospital admissions for stays that do not span one midnight), or failing to improve their performance after QIO educational intervention, will be referred to the RACs for further payment audit. The number of claims that a RAC will be allowed to review for patient status will be based on the claim volume of the hospital and the denial rate identified by the QIO.

The AHA is pleased that CMS will be using QIOs as the first line of medical review instead of the RACs, because we believe this will diminish the high volume of inappropriate claim denials by RACs based on patient status determinations. Nevertheless, many details related to this new review process are still unknown, and we request that CMS provide more information as soon as possible to assist hospitals in preparing for these audits. Among other things, such information should include:

- *Additional details related to the QIO review process.* CMS should identify the types of claims that will be subject to QIO review, number of claims that will be audited by the QIO, frequency of QIO reviews and type of education that QIO's will provide as a result of their audit. We request that the QIO review process be designed in a way that is similar to the current MAC probe and education process. As such, it would be useful for CMS to provide the necessary information in documents similar to the "Selecting Hospital Claims for Patient Status Reviews and Reviewing Hospital Claims for Patient Status" documents that the agency issued for the probe and educate audits. In addition, we urge CMS to provide transparency related to the criteria the QIO will use when reviewing patient status claims; and in doing so, CMS should instruct QIOs, as it did with RACs, to consider only the medical documentation available at the time the admission decision was made – and not documentation after that time -- in determining whether an inpatient stay was medically necessary. Finally, we also urge CMS to provide a 30-day "discussion" period - similar to that used in the RAC program - before a QIO may turn a claim denial over to the MAC to issue a demand letter. This will provide hospitals the opportunity to discuss claim denials with the QIO, which could help avoid unnecessary appeals.

- *Further details related to the RAC review process*. Although we generally support CMS's new policy, we are concerned that it will continue to place the ultimate review authority for patient status claims with RACs – contractors that even the agency itself now is acknowledging are ill-suited to review such claims. Regardless, we urge CMS to provide details related to the number of claims that will be subject to RAC review process and how long a provider would be subject to this RAC review penalty before returning to solely the QIO's jurisdiction for patient status audits. We also urge CMS to issue specific guidelines and parameters for the RAC reviews of patient status claims that would provide limits on the number of patient stay audits that RACs may conduct. CMS also should limit RAC reviews to claims that fall after the time period during which the QIO conducted its audit, so that hospitals are not vulnerable to RAC audits for claims that arise while they are working with another contractor to improve performance.

- *Process for determining whether a hospital warrants referral to a RAC.* CMS has not yet provided clear criteria for how a QIO will determine that a hospital warrants referral to a RAC. We believe that this determination should be based on a reasonable sampling of claims and take into consideration more than just the audit denial rate. For example, CMS could factor in the percentage of short stays at a particular hospital or the percentage of inpatient versus outpatient claims for a particular procedure or condition. In addition, the denial rate should be calculated in a manner that excludes those claims that are currently pending in the appeals process. It also is critical that the referrals process consider the financial incentive that RACs have to inappropriately deny patient status claims.

Our members also are concerned about the administrative burden associated with QIOs conducting these patient status audits. Specifically, we have been told that, unlike the RACs, QIOs do not have the ability to accept electronic medical records for review. We urge CMS to ensure that QIOs not only have clear guidance regarding how to perform these audits but also the resources necessary to complete these audits in a fair, impartial and efficient manner, including the capability for accepting electronically medical records for audit review. Finally, we urge

CMS to establish consistent and transparent communications with stakeholders regarding processes and updates related to the QIO reviews.

Changes to the RAC program. In the proposed rule, CMS describes the changes to the RAC program it announced on Dec. 30, 2014 and that it intends to make effective when awarding the new RAC contracts. These include, among other things, revised limits to additional documentation requests (ADRs) that are based on a hospital's compliance with Medicare rules. In addition, in an effort to address hospitals' concerns that they do not have the opportunity to rebill for medical necessary Medicare Part B services by the time the RAC has denied a Medicare Part A claim, CMS will change the RAC lookback period for patient status reviews to six months from the date of service (rather than the current period of three years) in cases where a hospital submits its claim within three months of the date of service.

However, it is unclear when CMS will award the next round of RAC contracts. Given that in June CMS withdrew the Requests for Quotes for the next round of RAC contracts and has yet to update the Statement of Work and release new Requests for Proposals, it could be many months, if not years, before these important changes would be effective. **Therefore, the AHA urges CMS to adopt and make these changes fully effective as soon as possible, rather than waiting until the next round of RAC contracts is awarded. Further, we urge the agency to provide clear and transparent communications to the provider community on the progress of these changes as they are incorporated into the RAC program.**

In addition, we continue to urge CMS to consider and support the following additional changes that would address the systemic problems with the RAC program:

- Prohibit any RAC payment structure that encourages RACs to deny claims.
- Impose a financial penalty on RACs when a denial is overturned on appeal.
- Codify in regulation the requirement that RACs consider only the medical documentation available at the time the admission decision was made in determining whether an inpatient stay was medically necessary.
- Eliminate application of the one-year filing limit to rebilled Part B claims.
- Limit RAC auditing of approved issues to a defined time period, instead of approving them indefinitely, as is now the practice.

Payment Reduction. As part of the FY 2014 inpatient PPS final rule, CMS unlawfully imposed a *permanent* prospective 0.2 percent reduction to the operating PPS standardized amount, the Puerto Rico-specific standardized amount, the hospital-specific payment rates and the capital federal rate to offset what the agency claimed would be an increase of $220 million in inpatient PPS expenditures resulting from implementation of the two-midnight policy. This reduction was based, CMS claimed without further explanation and analysis, on the Office of the Actuary's (OACT) estimate of an anticipated net increase in hospital inpatient encounters that would result from the implementation of the two-midnight policy. Specifically, without setting forth its actuaries' assumptions, reasoning, calculations or the data on which the actuaries relied, CMS asserted that approximately 400,000 encounters would shift from outpatient to inpatient and

approximately 360,000 encounters would shift from inpatient to outpatient, causing a net *increase* of 40,000 inpatient encounters. The agency stated that this shift would increase inpatient PPS expenditures by approximately $220 million, and necessitated the 0.2 percent reduction.

In this proposed rule, CMS provides limited information to support its initial projections and its decision to impose the 0.2 percent reduction. However, the information CMS sets forth cannot be used to support or justify that the 0.2 percent reduction is warranted. Specifically, the agency offers only tangentially related information that does not align directly with its initial projections. For example, CMS reports the absolute proportions of short- and long-stay claims and encounters in FY 2014. Yet, these numbers are irrelevant, since they do not address the assumptions and behaviors that CMS made in its initial model by, for example, comparing the relative number of short- and long-stay claims and encounters. To provide an effective comparison with its projections, CMS should have, at minimum, analyzed the following for the FY 2014 data:

- The number of cases that shifted from inpatient to outpatient and outpatient to inpatient;
- The number of surgical and medical cases that shifted; and
- The ratio of outpatient costs to inpatient costs.

If CMS had calculated these figures, it would then be able to directly compare this information to its initial projections and determine whether there was actually a net increase in inpatient encounters as the actuaries predicted. Although it is unlawful under the exceptions and adjustments authority and is otherwise inconsistent with the statutory scheme, CMS has failed to prove that the 0.2 percent reduction is supported by the data. CMS also fails to provide any justification for considering only surgical (and not medical) cases that shift from inpatient to outpatient in its analysis. **This continued absence of a full and transparent explanation of the data, methods and assumptions behind the actuaries' calculations renders it impossible for hospitals to offer a thorough and informed critique of the actuaries' estimate, which we believe to be unfounded. It further calls into question the agency's rationale for its decision to impose the offset. In Appendix 1, we outline the information we need in order to analyze fully these estimates. We request, if the agency intends to keep the 0.2 percent payment reduction in place, it make available this information as soon as possible and allow hospitals a reasonable amount of time to review and comment on this new information.**

In the absence of a full explanation of the actuaries' data and methods, we attempted to analyze CMS's data using our own assumptions. While this analysis does not alleviate CMS's obligation to provide a full explanation of its own actuaries' data and methods, our analysis clearly demonstrates that, in its first full year of implementation, the two-midnight policy *did not* result in a net increase in inpatient encounters, as OACT estimated. As a result, we believe strongly that the agency should reverse its 0.2 percent reduction in full and urge that the payment rates (the standardized amount, hospital-specific rate, Puerto Rico-specific standardized amount and capital federal rate) for FY 2014 and subsequent years be revised accordingly, and that hospitals be reimbursed for the shortfall in Medicare payments they received for hospital discharges on or after Oct. 1, 2013 that have resulted from CMS's unlawful imposition of the 0.2 percent payment reductions.

We provided the data below in our comment letter on the inpatient PPS proposed rule. We have now updated those numbers with the most recent data, and a straightforward comparison of FY 2014 and FY 2013 cases continues to show a decrease, not an increase, in the number of inpatient encounters (see Table 1). Specifically, total inpatient encounters declined by 4 percent and total inpatient encounters of less than two-midnights declined by 10 percent.

Table 1: Percent Change in Inpatient Encounters, FY 2013 to FY 2014

Length of Stay	FY 2013	FY 2014	% Change
Less than 2 days	1,173,783	1,059,254	-10%
2-3 days	3,376,510	3,356,805	-1%
4 or more days	5,016,479	4,773,975	-5%
All Cases	9,566,772	9,190,034	-4%

Source: FY 2009-2014 MedPAR (March (final rule) updates).

In addition, our analysis continues to take into account and recognizes that even prior to implementation of the two-midnight policy, inpatient encounters were decreasing. Specifically, our analysis examined case counts for those stays that were less than two midnights and those that were greater than two midnights from FY 2009 through FY 2013, using final rule Medicare Provider Analysis and Review (MedPAR) data sets for each year. We looked at different compound annual growth rates (CAGRs) and created one for each of the following time periods:

1. FY 2009-2013;
2. FY 2009-2011 (the time period used by OACT in the FY 2014 final rule); and
3. FY 2011-2013 (a more recent time period for comparison purposes).

We then used these numbers to calculate projected inpatient encounters for FY 2014 absent the two-midnight policy, and compared these to the actual inpatient encounters for FY 2014, which, include the effect of the two-midnight policy. The difference in encounters can be deemed as the two-midnight effect. **Under no scenario do the numbers support OACT's estimation that the two-midnight policy would cause a net increase of 40,000 inpatient encounters. In fact, as shown in Table 2, using the longer term FY 2009-2013 CAGR, the two-midnight policy caused a net decrease of almost 200,000 inpatient encounters.**[3]

Table 2: Inpatient Encounters by Length of Stay and Difference between Actual and Expected Cases Using 2009-2013 CAGR

Length of Stay	Actual FY 2013 Case Counts	Actual FY 2014 Case Counts (With 2 MN Policy in Effect)	2009-2013 CAGR	Projected FY 2014 Case Counts Absent 2 Midnight Policy Using	Difference between Actual and Projected FY 2014

[3] It was unclear whether CMS used 2-3 and 4 or more days (as opposed to 2-4 and 5 or more days) when breaking down its analysis. For purposes of this letter, we are breaking down the data using 2-3 and 4 or more days. Regardless, however, the result would be similar if we had chosen 2-4 and 5 or more days for the breakdown.

				2009-2013 CAGR	
Less than 2 days	1,173,783	1,059,254	-4.2%	1,124,831	-65,577
2-3 days	3,376,510	3,356,805	-0.5%	3,359,537	-2,732
4 or more days	5,016,479	4,773,975	-2.4%	4,895,893	-121,918
All Cases	9,566,772	9,190,034	-2.0%	9,380,261	-190,227
Source: FY 2009-2014 MedPAR (March (final rule) updates).					

PROPOSED CONVERSION FACTOR REDUCTION DUE TO LABORATORY TEST PACKAGING OVERESTIMATION

In the proposed rule, CMS applies a 2 percentage point reduction to the conversion factor to correct for the OACT's previous overestimation of the amount of packaged laboratory payments in the OPPS for laboratory tests. CMS alleges that these laboratory tests were, instead, separately paid under the CLFS. Specifically, OACT estimates it included about $1 billion in the OPPS payment rates for laboratory tests that were instead paid under the CLFS. It is this reduction in the conversion factor that is largely responsible for the proposed net negative OPPS payment update for CY 2016.

The AHA strongly urges CMS to withdraw this proposed conversion factor cut, which is ill-conceived and raises concerns about the accuracy and transparency of OACT's estimations. It is founded on questionable assumptions and an unclear methodology and is based on data that are not publicly available. Furthermore, CY 2014 is not a valid base year to use in determining whether a $1 billion "coding and classification" reduction to the conversion factor is justified; hospital billing practices were too unstable due to evolving CMS instructions about how to bill for unrelated laboratory tests. Finally, it is inappropriate for CMS to propose a cut based on the CY 2014 clinical laboratory packaging policy when it proposes to again significantly change this policy in CY 2016.

The AHA attempted to replicate the laboratory analysis conducted by OACT that resulted in the estimate of $1 billion in over-packaged laboratory test costs. We identified a number of troubling issues with OACT's analysis, as detailed below.

Initial laboratory packaging issues and assumptions. In this proposed rule, CMS reveals, for the first time, that the aggregate dollar amount that it moved from the CLFS to the OPPS in CY 2014 to account for laboratory services that were newly packaged into the OPPS was $2.4 billion. However, because the CY 2014 proposed and final rules neither included details about CMS's calculations regarding laboratory packaging nor provided an amount, the AHA was not able to verify or validate that CMS incorporated laboratory services correctly.

In this CY 2016 proposed rule, CMS also does not provide complete information about its methodology. This is critical because if the agency's initial estimate was incorrect, some of the

other analyses and the basis for estimating the impacts that CMS describes in this rule also would be incorrect.

As a specific example, we do not know whether the $2.4 billion estimate excluded laboratory tests that, under the agency's policy, should have remained separately payable under the CLFS. That is, we do not know if CMS excluded laboratory tests that were unrelated to other OPPS payable services furnished to a beneficiary on the same date of service (i.e., ordered for a different purpose by a different practitioner than the practitioner who ordered the other OPPS service) or laboratory tests that were the only services furnished to the beneficiary on a particular date of service. In fact, the AHA raised this issue in its CY 2014 comment letter to CMS, stating:

> "We request that CMS clarify how it was able to determine from the CY 2012 claims data when a lab test was ordered 'for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service.' Hospitals bill using the UB-04 Form 1450, and there are four distinct fields to report the involvement of the physician on a hospital claim. However, all of these physician identifications apply to the hospital claim as a whole; there is no way to associate individual physicians with individual service lines. **Therefore, AHA is concerned that in the proposed rule CMS may have over-packaged lab costs by assuming that all of the lab tests that occur on the same date of services as the primary service are related, even though they may, in fact, be entirely unrelated to the primary procedure.** [*Emphasis added*] For instance, necessary lab services will often be scheduled on the same day as an unrelated primary procedure for patients who live in underserved rural areas in order to avoid these beneficiaries having to make multiple trips to the hospital."

Given that CMS explicitly provided for such exceptions to its laboratory packaging policy, it seems logical that the agency would have excluded some laboratory services. Yet, CMS never stated in the final rule whether this was the case, despite explicit requests for clarification.

Lack of public availability of data. CMS conducted several different analyses on the lab packaging issue. **For some of these analyses, the agency uses data that are not publicly available, making it impossible for stakeholders to replicate or offer any meaningful critique of these analyses.** For example, in the CMS report "Summary Analysis Supporting Adjustment for Excess Laboratory Packaging," released with the rule, CMS notes that it used claims processed through May 31, 2015. In contrast, the CY 2014 data released with the proposed rule only contains claims processed through Dec. 31, 2014, which the agency believes are only 90 percent complete. The CY 2014 claims processed from Jan. 1 through May 31, 2015 will not be publically available until the final rule is issued. In addition, CMS's analysis of the data was conducted by month, which is a greater level of detail than is available to the public. Finally, the data used by CMS contains other information not present in the publicly released data, such as certain types of claims. That is, CMS acknowledges in the proposed rule that "the 'OPPS limited data set' that we make available to accompany each proposed and final rule is not a complete set of institutional Part B claims, containing only the 12X, 13X, and 14X bill type claims that we use to model the OPPS rates and excluding claims weeded or trimmed as discussed in our claims accounting document..." This lack of transparency is troubling, makes it impossible for stakeholders to replicate the CMS analysis and leaves us without adequate and complete information to provide meaningful comments.

Lack of transparency in methodology. **CMS provides incomplete information about its modeling methodology.** In the proposed rule, CMS acknowledges that that it made certain assumptions, but does not describe what those assumptions are. For example, CMS states, "This assessment required some assumptions about what payment would have been at the CY 2014 CLFS payment amounts using the CLFS national limitation amount (NLA) price or the mode price among jurisdictions where an NLA did not exist for all laboratory services in 12X, 13X, and 14X bill type claims less actual payments for those same services and the $2.4 billion in packaged payments." However, CMS does not provide any further detail about these assumptions.

Additionally, CMS states, "We adjusted our total estimates for incomplete claims data because the data that we use to model the proposed rule are data from CY 2014 claims processed as of December 31, 2014, estimated at 90 percent based on historical claims data." However, CMS does not describe exactly how it made these adjustments. Therefore, it is unclear whether the agency assumed an across-the-board 10 percent mark-up was necessary, or recognizing that there were changes in billing instructions and claim composition during the year, CMS weighted their gross-up factor more heavily towards the revised billing information and guidance. This information is critical for the stakeholders to have in order to validate and offer meaningful comments on CMS's estimates.

Use of an inappropriate base year. **CY 2014 is not a valid base year to use in determining whether a $1 billion "coding and classification" reduction to the CY 2016 conversion factor is justified.** The agency's instructions to hospitals on how to properly bill for both related and unrelated laboratory tests were confusing and changed several times that year. Specifically, CMS's final rule policy on how to bill for non-referred laboratory tests eligible for separate payment under the CLFS was to report these services on the 14X bill type. However, beginning July 1, 2014, the agency then instructed hospitals to report these on a 13X bill type with a new L1 modifier appended. This left many hospitals unsure about how to bill for laboratory services that were unrelated to other OPPS services furnished on the same date of service. In this proposed rule, CMS acknowledges this confusion. We believe that this proves that hospitals needed more time to implement these significant changes in their operations and billing practices. Therefore, any "unexpectedly high" volume of separately payable laboratory tests that CMS observed in CY 2014 claims data does not reflect a permanent change to hospital coding and billing practices, but results directly from CMS's confusing and changing billing instructions. As a result, the CY 2014 claims data should not be used to justify a conversion factor cut.

Lack of transparency around accounting for the effect of proposed CY 2016 laboratory packaging policy changes on the packaged amount. CMS is proposing additional changes to its laboratory packaging policy for CY 2016 that will impact the amount of laboratory costs that are packaged into the OPPS and, consequently, the amount that will be separately payable under the CLFS in CY 2016. Among these proposed changes is a more complete exclusion of molecular pathology tests, as well as an exclusion of all preventive laboratory tests and claims level packaging. It is unclear whether CMS's proposed 2 percentage point reduction to the conversion factor takes into account the impact of these proposed changes in the laboratory packaging policy. While we strongly oppose CMS moving forward with this payment reduction, in the interest of accuracy, we would expect that any adjustment to the conversion factor due to alleged laboratory "over-packaging" take into account the impact of the additional proposed changes to the clinical laboratory packaging policy.

For all these reasons, the AHA strongly opposes CMS's proposal to apply a 2 percentage point reduction to the OPPS conversion factor. As we explain above, the agency's proposed cut is ill-conceived and founded on questionable assumptions, a poorly described methodology and data that are not publically available.

PROPOSED AMBULATORY PAYMENT CLASSIFICATION (APC) RESTRUCTURING

CMS proposes to restructure the APC groupings for nine APC clinical families by using the same general principles it used in restructuring the ophthalmology and gynecology clinical families in CY 2015. As part of this restructuring, CMS also proposes to renumber several families of APCs to provide consecutive numbering for consecutive APC levels within the clinical family.

The proposed restructuring results in a massive movement of HCPCS codes between APCs, significant consolidation of APCs and substantial payment changes. **However, despite the scale of these proposed changes, CMS includes few specific details regarding why and how it is proposing to restructure the nine individual clinical families. Furthermore, neither the rule nor its addenda include adequate information about how the proposed restructuring affects the relative weights and payment rates for these services.**

Given the magnitude of these proposed changes, CMS's intention to implement them simultaneously and the possibility that these changes could cause a sweeping redistribution of payments across hospitals and hospital groups, we urge CMS to provide a more granular impact analysis in the final rule. **Specifically, the AHA recommends that the final rule include a separate impact analysis for each restructured APC clinical family showing the distributional impact of the restructuring across CMS's usual categories (such as urban/rural location, bed size, type of ownership and teaching status). As requested above, in future rulemaking, we urge CMS to provide additional rationale and a separate impact analysis for any significant shift in policy, such as the proposed APC restructuring.**

Proposed APC restructuring for nuclear medicine and positron emission tomography (PET). The AHA is concerned about CMS's proposed restructuring of the nuclear medicine and PET APCs. Since the inception of OPPS, the agency has recognized the clinical differences between these imaging modalities and maintained separate APCs for them. For CY 2016, CMS proposes to collapse the 17 different nuclear medicine and PET APCs into three levels; Level 1 through Level 3 Nuclear Medicine and Related Services (APCs 5591, 5592 and 5593). **The AHA believes that CMS's proposal inappropriately overlooks the clinical distinction between these modalities. Instead, the AHA recommends that CMS:**

- **Maintain a distinct APC for all PET procedures (CPT codes 78811-78816 78459, 78608, 78491, 78492, currently APC 0308)**
- **Maintain a distinct APC for therapeutic nuclear medicine procedures (CPT codes 79005-79999, currently APC 0407);**
- **Maintain individual APCs for diagnostic nuclear medicine tests (CPT codes 78013-78807); and**
- **Continue to use the individual cost centers and revenue codes for rate setting of APCs for each imaging modality.**

Maintaining separate APCs for each modality supports the clinical homogeneity of these APC payment groups and promotes accurate cost reporting and revenue coding on claims. PET and diagnostic and therapeutic nuclear medicine procedures are clinically distinct as evidenced by the existence of unique cost centers and revenue codes for each. Furthermore, these modalities involve distinct and separate types of resources. For instance, the technologists involved in nuclear medicine procedures require specific certification not required for PET procedures. Also, providers bear unique costs and regulatory controls for diagnostic and therapeutic radiopharmaceuticals, such as the costs associated with compliance with the Occupational Safety and Health Administration requirements for safe handling and disposal of isotopes. There are also differences between diagnostic and therapeutic nuclear medicine procedures, including the types and costs of radiopharmaceuticals used and the clinical purpose and intended outcome of procedures. Finally, PET procedures bear unique costs associated with their equipment.

PROPOSED CHANGES TO THE COMPREHENSIVE APCS

Proposed comprehensive observation service APC. CMS proposes to pay for all qualifying extended assessment and management encounters through a proposed new comprehensive APC (C-APC) 8011 (Comprehensive observation services) and to assign the services within this C-APC a proposed new status indicator (SI) "J2." J2 is intended to recognize instances in which a claim contains a specific combination of services that, when reported together on a hospital Medicare Part B outpatient claim, would allow for all other OPPS payable services and items reported on the claim (except for certain excluded services) to be deemed related services representing the components of a comprehensive service.

Among the proposed criteria for a claim to qualify for C-APC 8011 is that the claim *does not* contain a HCPCS code which has been assigned SI "T" (Procedure or service to which the multiple procedure reduction applies) that is reported with a date of service on the same day or one day earlier than the date of service associated with HCPCS code G0378 (Observation services, per hour). However, SI T procedures that are reported with a date of service *after* G0378 would have their cost packaged as part of C-APC 8011. Therefore, no separate payment would be made for such procedures. By contrast, in CY 2015, if a beneficiary receives services meeting the criteria for the existing composite APC 8009 (Extended assessment and management composite) and a SI T procedure is furnished as an outcome of observation, it would be separately paid, in addition to APC 8009.

Based on our analysis, we have found that SI T procedures are not often furnished after the date of service of G0378, but when they are, these procedures are associated with a high payment rate. Specifically, these procedures occurred in less than 5 percent of J2 claims. However, individually, many of these SI T procedures are high-cost procedures with payment rates over $2,000. For example, one procedure, CPT 93458 (L hrt artery/ventricle angio), has a payment rate of $2,576, and represents nearly 40 percent of the aggregate cost of these SI T procedures. In fact, many of the most costly SI T services performed after G0378 fall into the same APC as CPT 93458: APC 5188 (Diagnostic cardiac cath).

The AHA recommends that CMS exclude from the definition of C-APC 8011 all claims that include SI T procedures with a date of service after G0378. We believe that these SI T services are too costly to package into C-APC 8011. As previously noted, these procedures are infrequently performed after observation, but since they are high-cost services, compared to the C-APC 8011 payment rate, packaging their cost into C-APC 8011 is cause for concern. Excluding these SI T procedures from C-APC 8011 instead would help to preserves access in

those hospitals that perform a large proportion of these diagnostic cardiac catheterization services or the other procedures that have a SI T.

Further, doing so would be consistent with CMS's proposed policy for conditionally packaging the costs of the ancillary services APCs for Level 2 and Level 3 pathology. In that proposal, CMS decides, "to avoid packaging a subset of high-cost pathology services into lower cost and non-primary services (for example, low-cost imaging services) frequently billed with some of the services assigned to Level 3 and Level 4 pathology APCs, we are proposing to package Level 3 and 4 pathology services only when they are billed with a surgical service." That is, CMS made a reasonable decision to expand its ancillary services packaging policy to exceed its previous $100 threshold only where it made sense, being cautious not to inappropriately package high-cost services together with lower cost services.

Proposed data collection for non-primary services in C-APCs. CMS notes that services adjunctive to a comprehensive service often must be performed prior to delivery of that service – for example, testing leads for a pacemaker insertion or treatment planning services prior to radiation treatment. In order to prepare for future expansions of its C-APC policy, CMS proposes a data collection in which hospitals would be required to report a modifier for services that are adjunctive to a C-APC's primary procedure code (C-APC primary procedures are identified with a SI "J1") and that are billed on a different claim than the J1 service. Using these data, CMS plans in future rulemaking to create a single encounter payment for the J1 services that reflects all the resources of the primary services, including adjunctive services. At that time, CMS would discontinue separate payment for the packaged adjunctive services, even when furnished prior to delivery of the J1 service.

The AHA urges CMS not to implement the proposed non-primary services modifier. Implementing this proposed data collection policy in CY 2016 would cause widespread confusion among hospitals because CMS has provided inadequate definitions and guidance regarding what constitutes services adjunctive to J1 services. In the absence of more information, including clearly defining the scope of what it considers "adjunctive" and providing specific guidance on which services would be considered adjunctive to each of the current 811 J1 services, hospitals are unsure of where CMS intends to draw the line.

For example, a beneficiary with chest and abdominal pain presents to a provider-based clinic for evaluation and has an ultrasound at a department of the same hospital the following day resulting in a diagnosis of gallstones. Four days later, the patient has laparoscopic cholecystectomy at the same hospital, which is a J1 procedure. Are the provider-based clinic visit and/or the ultrasound "adjunctive" to the subsequent J1 surgical procedure? Another example would be if a beneficiary with coronary artery disease comes to the hospital emergency department (ED) with chest pain. He or she undergoes diagnostic testing and treatment in the ED, myocardial infarction is ruled out and the patient is referred to their cardiologist for outpatient follow-up. A week later the cardiologist performs a diagnostic cardiac catheterization and stents a coronary artery, which is a J1 procedure. Is the ED visit and the diagnostic testing done in the ED "adjunctive" to the subsequent coronary stent J1 procedure? Or are adjunctive services limited to only preoperative testing and planning services?

There are many other questions hospitals have raised about CMS's intentions regarding the use of this modifier. For instance, we are uncertain about whether the modifier would only apply to adjunctive services furnished prior to a J1 service or if it also is intended to extend to services

(for example, physical therapy) furnished after the J1 service and reported on a separate claim. Furthermore, would the modifier extend to services ordered by different clinicians within the same health care system? For example, for stenting procedures, beneficiaries may be sent for diagnostic tests prior to the stent implantation surgery. But sometimes diagnostic services are done by a diagnostic cardiologist and yet the implantation of the stent is done by an interventional cardiologist. Would the diagnostic services be considered adjunctive to the implantation of the stent and thus require the use of the modifier? What if the diagnostic testing services are furnished by a different provider than the J1 service?

Further, using the modifier would pose a significant operational burden for hospitals. Hospitals would need to manually identify every claim containing services that would be considered adjunctive to any of the 811 J1 services. This would be especially challenging if the adjunctive services were ordered by a different physician or furnished in a different part of the health care system. Services that may be considered adjunctive could be placed under many different accounts, including recurring service accounts and some in single visits. Also, as noted above, the staff who would be responsible for ensuring compliance with this CMS policy may be the same staff working on transition to ICD-10. We strongly believe that this is not the time to be making such significant and burdensome changes to the OPPS.

However, if CMS insists in moving forward with such a policy, we strongly urge the agency to do so slowly, taking only a small step in CY 2016. A step-wise approach would allow additional time for CMS to further clarify its policy with stakeholders while testing the use of the proposed modifier for a limited number of services. We believe that a reasonable first step would be to apply the modifier only to the specific planning and preparation services that CMS identifies as being adjunctive to the J1 procedure for the stereotactic radiosurgery (SRS) C-APC. Requiring the reporting of the proposed modifier only for these specific HCPCS codes would still be burdensome to hospitals in that it would require manual processing of some claims, but at least the adjunctive services are clearly defined in the proposed rule.

PROPOSED CHANGES TO LABORATORY TEST PACKAGING POLICIES

In CY 2014, CMS established a policy to conditionally package the costs of clinical diagnostic laboratory tests in the OPPS. Specifically, CMS pays separately for a laboratory test at the CLFS rate when: (1) it is the only service provided to a beneficiary on a given date of service, or (2) it is conducted on the same date of service as other OPPS payable services, but is ordered for a different purpose and by a practitioner different than the practitioner who ordered the other OPPS payable services. For CY 2016, CMS proposes several other revisions to its laboratory packaging policy.

Claims level packaging for laboratory tests. CMS proposes to expand its policy to package the costs of laboratory tests that are reported on the same claim with another OPPS payable service, regardless of its date of service. Hospitals would continue to report the "L1" modifier to identify any clinically "unrelated" laboratory tests that are furnished on the same claim as other OPPS payable services, but are ordered by a different practitioner and for a different purpose than the primary OPPS services.

The AHA recommends that CMS maintain its current packaging of laboratory tests by date of service rather than extending packaging to the claim level at this time. While we support thoughtful and reasonable policies to expand laboratory packaging under the OPPS, we believe that CMS is moving too quickly to expand packaging, which is causing confusion about

its policies and allowing errors to occur. We encourage CMS to slow down so that it and the provider community have time to evaluate the impact of the agency's policies. The fact is, there already is ample amounts of laboratory packaging that occurs at the claims level in the OPPS, such as occurs in the C-APCs.

To support its proposal, CMS states, "Further, in reviewing our CY 2014 claims data, we observed hospitals indicating separate payment by reporting the 'L1' modifier for only a few laboratory tests reported on different days than an OPPS service. We conclude that hospitals generally do not view laboratory tests occurring on a different day than a primary service during an outpatient stay as a reason for separate payment." This is an incorrect interpretation of the claims data. Our members tell us that hospitals did not report the L1 modifier because they did not have the ability to track laboratory tests ordered on a different date; hence, there was no way to know whether these laboratory tests were related or not.

Further, as we explained above, in CY 2014, CMS's instructions on proper billing for both related and unrelated laboratory tests were confusing, especially due to the evolving coding and billing instructions issued after the final rule. In fact, CMS cites instances of this confusion in the rule. For example, the agency reports the submission of laboratory-only claims with no L1 modifier, which was incorrect coding in CY 2014. This is further evidence that the CY 2014 data is not appropriate to use as the basis for policy changes, including expanding laboratory packaging to the claim level.

In addition, requiring hospitals to expand their use of the L1 modifier to unrelated laboratory services that appear on the same claim with other separately payable OPPS services creates a greater administrative and operational burden for hospitals and health care systems. Hospital staff have to engage in manual claims review and handling in order to ensure that the L1 modifier is properly applied. **One far less burdensome option is to permit hospitals to bill more than one 13X hospital outpatient claim on the same date of service when unrelated laboratory services are furnished.** Currently, Medicare claims processing manual instructions require hospitals to combine laboratory tests provided to hospital outpatients on the same claim with other hospital outpatient services to the same beneficiary, regardless of whether the laboratory services are related or unrelated to the other services. The only exception to this policy is for non-patient specimens which are billed on a 14X bill type. Allowing providers to submit separate 13X hospital outpatient claims for unrelated laboratory services furnished on the same day would be much less burdensome for hospitals. It also would have the added benefit of providing clear verification that the services on the two claims are unrelated because each claim would:

- Have a different National Provider Identifier (NPI) number representing the appropriate ordering or performing physician; and
- Be based on different physician orders and include separate diagnosis codes.

<u>Proposed conditional packaging SI "Q4"</u>. CMS proposes to implement claims processing edits through a new conditional packaging status indicator Q4 that would identify 13X bill type claims (outpatient hospital) which include only laboratory test HCPCS codes that are payable under the CLFS. In these instances, the Medicare claims processing software would automatically change the SI to "A" (not paid under OPPS; paid under a fee schedule or payment system other than OPPS) and pay them separately at the CLFS payment rates. **The AHA supports CMS's proposal to use the new conditional packaging SI Q4.** Doing so would eliminate some hospital burden as the SI Q4 automatically appends to services that would be separately paid at

the CLFS rate, and hospitals would no longer have to report the L1 modifier for encounters where laboratory tests are the only services provided to the beneficiary.

High-cost laboratory services. **The AHA urges CMS to evaluate whether it is appropriate to package high-cost laboratory tests into lower cost APCs, such as those assigned SI "Q1" ("STV-packaged") and SI "Q2" ("T-packaged") before it takes any further steps to expand laboratory test packaging to the claims level.** Services assigned SI Q1 and Q2 are ancillary services, some of which have relatively low costs, such as x-rays. Thus, CMS is proposing to package certain high-cost laboratory tests, which are ancillary services themselves, into other ancillary services. Over time, this could distort the geometric mean cost of these ancillary services, particularly if CMS expands laboratory packaging to the claims level.

Finally, the AHA requests CMS clarify the following issue. We presume that if a hospital unnecessarily reports the L1 modifier on a claim that includes only SI Q4 laboratory tests, that the laboratory tests on the claim would be automatically paid at the CLFS rate rather than the claim being returned to the provider for correction.

Other proposed changes to the laboratory packaging policy. **The AHA supports CMS's proposal to change its current laboratory packaging policy to exclude all codes that describe molecular pathology tests, including new codes.** We agree with CMS that these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than more common and routine laboratory tests that CMS packages. **Further, the AHA also supports CMS's proposal to exclude preventive laboratory tests from packaging.** This would ensure that CMS's laboratory packaging policy is consistent with its policy for packaging ancillary service APCs.

PROPOSED ADJUSTMENT TO OPPS PAYMENT FOR DISCONTINUED DEVICE-INTENSIVE PROCEDURES

CMS proposes that for procedures involving implantable devices that are assigned to a device-intensive APC, it would reduce the APC payment amount for discontinued device-dependent procedures where anesthesia has not been administered to the patient (modifier 73) or where the procedure does not require anesthesia (modifier 52). Specifically, the APC payment amount would be reduced by 100 percent of the device offset amount prior to applying the additional payment adjustments that otherwise apply when the procedure is discontinued. CMS reasons that in the majority of cases, the device was not used and remains sterile such that it could be used for another case. The agency speculates that "In these circumstances, under current policy, hospitals could be paid twice by Medicare for the same device, once for the initial procedure that was discontinued and again when the device is actually used." CMS would not deduct the device offset amount from a procedure that was discontinued after anesthesia was administered (modifier 74) because it is likely that devices associated with such procedures may no longer be sterile and could not be restocked and used for another case.

The AHA urges the agency not to finalize this proposal. In the absence of a study or other evidence that demonstrates that devices remain sterile in procedures involving modifiers 73 and 52, it is inappropriate to implement these payment reductions. Indeed, we believe that CMS's presumption may be incorrect. For example, nurses may very well be unpacking and breaching the sterility of implantable devices well before anesthesia is started on a patient.

Furthermore, there is evidence that CMS assumptions leading to its proposed policy change are incorrect. That is, hospitals will report a charge using revenue code 278 if a device was unpacked; otherwise hospitals will not report the charge. In our analysis, we found approximately 1,500 claims that had a device-intensive procedure code reporting either modifier 52 or 73; CMS would presume that the devices on these claims were not used. However, about two-thirds of the time, these claims also contained a charge using revenue code 278, indicating that the device was actually unpacked, is no longer sterile, and could not be used for another case. We urge CMS to conduct a more detailed analysis of this policy to better understand whether devices indeed can be used for another case.

LUNG CANCER SCREENING WITH LOW-DOSE CT

CMS notes that Medicare coverage for lung cancer screening with low-dose CT was approved in a national coverage determination (NCD) on Feb. 5. In the rule, CMS proposes two HCPCS G-codes describing the services and identifies the APCs to which the services would be assigned. However, final HCPCS G-codes and their APC assignment will not be effective under this rule until Jan. 1, 2016. In the absence of final G-codes, hospitals that furnish these services could have been holding claims for up to 11 months. The maximum period for submission of all Medicare claims is no more than 12 months (one calendar year) after the date services were furnished.

The AHA recommends that in both the final rule and in appropriate transmittals, CMS make the effective date for the new HCPCS G-codes for lung cancer screening retroactive to the February NCD date. We also recommend that the agency extend the one-year claims filing deadline by at least an additional quarter in CY 2016 to allow hospitals adequate time to file the held claims.

In addition, we recommend that CMS ensure that the new G-codes are included in the final list of preventive services that are excluded from packaging under the C-APCs.

CHANGES TO PAYMENT FOR CT

CMS proposes to implement a provision of the Protecting Access to Medicare Act of 2014 (PAMA) which requires a reduction in payment amounts for CT services that are furnished using equipment that fails to meet each of the attributes of National Electrical Manufacturers Association Standard XR-29-2013. CMS proposes to establish a new modifier for claims that describes CT services furnished using noncompliant equipment which would result in the applicable payment reduction (5 percent in 2016 and 15 percent in 2017 and subsequent years).

While the AHA understands that this proposal is required by law, we are concerned about the timing and burden associated with this requirement. We, therefore, request that CMS delay the use of the modifier and the related payment reductions by at least a year.

Hospitals will have had less than two years since PAMA was enacted to purchase and put into place compliant CT equipment. While the AHA does not have data indicating the proportion of CT services currently furnished on noncompliant equipment, we know that many hospitals plan to upgrade their equipment, but doing so is costly. One health system estimates that purchasing and putting into use compliant equipment would cost between $200,000 and $500,000 per unit. Making large capital expenditures within a hospital or health system can take more than two

years, particularly when other priorities to improve patient care also involve large capital expenditures.

Further, we are concerned that using the proposed modifier will pose significant administrative and operational burdens for hospitals. Normally, radiology services are posted to a beneficiary's account automatically. However, applying a modifier to services furnished with noncompliant equipment would require manual claims handling, which will be particularly difficult for facilities that have both compliant and noncompliant CT equipment. In order to code correctly, the technicians performing the service would have to provide a notation in the chart or patient record in order to identify whether the service was furnished on compliant equipment. If multiple CT scans were done during a beneficiary encounter, some on compliant equipment and some on noncompliant equipment, the process would become even more complex.

In addition, the use of the modifier raises questions about how CMS plans to apply it. Normally multiple CT scans furnished during the same patient encounter would be paid under composite APC 8005 (CT and CTA without contrast composite) or APC 8006 (CT and CTA with contrast composite). However, it is unclear how CMS will reimburse providers if multiple CT imaging services are furnished during a single beneficiary encounter, using both compliant and noncompliant equipment. **We urge CMS to clarify its payment policy in these circumstances.**

ADVANCED CARE PLANNING CODES

The AHA recommends that advanced care planning codes be separately payable under OPPS and assigned to an appropriate APC. In the proposed rule, CMS assigns the new CPT codes for advance care planning: CPT 99497 (Advance care planning including the explanation and discussion of advanced directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate) and CPT 99498 (Advance care planning, each additional 30 minutes) as having SI "N." This SI means these are packaged services under the OPPS, with no separate payment permitted. By contrast, CMS proposes these services for payment under the Medicare Physician Fee Schedule for CY 2016.

These are critically important services for beneficiaries with progressive or terminal illnesses, such as cancer, and have been shown to have a significant, positive impact on patient quality of care. Advanced care planning services are provided in hospitals, including cancer centers, by physicians, non-physician practitioners and other staff, under the order and medical management of the beneficiary's treating provider. Often a team approach is used, involving coordination between the beneficiary's physicians, non-physician practitioners (such as clinical social workers or clinical nurse specialists) and other licensed and credentialed hospital staff such as registered nurses. These services involve extensive discussions with patients and their family members regarding short-term and long-term treatment options. As the patients' conditions progress or as treatments fail, there may be additional discussions regarding other options, such as hospice and palliative care.

The AHA believes that these important services should be separately payable, in the same way that CMS allows separate APC payment for hospital outpatient clinic visits, transitional care management services and chronic care management services. Doing so would encourage more providers to offer this important service as well as allow CMS to collect data on these services.

PROPOSED PAYMENTS FOR BLOOD AND BLOOD PRODUCTS

CMS has proposed steep reductions in the payment rates for all blood components commonly provided in the hospital outpatient setting. These proposed cuts, ranging from 23 percent to 66 percent, would result in payments that are less than the acquisition costs for most of these products and, in some cases, less than the cost to produce the products. **Therefore, the AHA is concerned that the agency may have made errors in determining these rates.** Furthermore, with the expected introduction of additional blood safety measures already approved by the Food and Drug Administration, such as pathogen reduction for platelets, and those we believe will soon be mandated, including testing for Babesia infection of blood donors, it is likely that the cost of these products will continue to increase, making the proposed payment rates even more inadequate. **To ensure continued beneficiary access to all blood and blood products, we strongly urge CMS to review its data and calculations and correct any errors found.**

OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

The Tax Relief and Health Care Act of 2006 requires CMS to establish a program under which hospitals must report data on the quality of outpatient care in order to receive the full annual update to the OPPS payment rate. Hospitals failing to report the data incur a reduction in their annual payment update factor of 2 percentage points.

CMS proposes to add two new measures to the program – one assessing whether radiation therapy is delivered in appropriate doses to patients with bone cancers, and another measuring whether the medical records of emergency department patients transferred to another health care facility include certain clinical and administrative data. CMS also proposes the removal of one measure, and several changes to OQR program administrative requirements.

Focusing the OQR on measures that matter. **The AHA urges CMS to streamline and refocus the OQR program measure set so that it aligns with concrete national priority areas for improvement across the entire health care system. America's hospitals remain committed to the foundational goals of the OQR program – to provide the public and hospitals with *accurate* and *comparable* information for improving quality on *important* areas. For this reason, we are concerned that measures have proliferated in the OQR without a well-articulated link to national priorities or goals.**

Since the program's inception, the number of OQR measures has more than doubled from 11 measures in CY 2009 to the 27 proposed measures for CY 2019. The heterogeneity of the measure set lacks a strong focus, as the measures assess topics ranging from ED throughput and cataract care to hospital visits following colonoscopies. When considered in isolation of national goals, many OQR measures may seem to address compelling quality issues. For example, given the high volume of colonoscopies performed, it may seem reasonable for CMS to adopt OP-32 to measure the re-hospitalization rate following such procedures. Yet, the data CMS cited to support the addition of OP-32 to the OQR suggests the hospital visit rates after outpatient colonoscopy range from 0.8 to 1.0 percent in the seven to 14 days after the procedure. Certainly, hospitals aim to avoid unnecessary hospitalizations after colonoscopies. But the relative infrequency of such re-hospitalizations suggests the attention and effort garnered from the inclusion of OP-32 in a national program like the OQR could be better spent on other topics with a clearer and more pressing need for improvement.

The AHA has repeatedly urged CMS to identify concrete, actionable national goals for quality improvement, and to use those goals to select a small number of reliable, accurate and care-setting appropriate measures to ensure each relevant part of the health care

system contributes to the overall goals. For this reason, we again strongly urge CMS to consider adopting the recommendations outlined in the Institute of Medicine's (IOM) *Vital Signs* report for streamlining and focusing national quality measurement efforts. If adopted, the report's recommendations would facilitate better use of quality measures by all stakeholders to advance health care.

The *Vital Signs* report notes that progress in improving the quality of health care has been stymied by discordant, uncoordinated measurement requirements from CMS and others. Hospitals and other care providers spend significant resources interpreting measure specifications, training staff on reporting requirements and collecting data. Resources spent on these activities are not available to engage in important opportunities to improve care. To ensure that all parts of the health care system – hospitals, physicians, the federal government, private payers and others – are working in concert to address priority issues, the *Vital Signs* report recommends 15 "Core Measure" areas with 39 associated priority measures. Each stakeholder would be measured on the areas most relevant to their role in achieving common goals and objectives. The recommended core measure areas that appear to be most salient to hospitals, and where CMS may wish to focus future OQR measurement efforts, include patient safety, evidence-based care, preventive services, population spending, and care matched to patient goals. These core areas could be updated over time, "retiring" areas where sufficient progress has been achieved, and replacing them with new core areas that address emerging issues.

In 2014, the AHA engaged its membership in an effort to identify the highest priority measures of hospital care that they believed would most effectively contribute to better outcomes and better health for the patients they serve. The priority measure areas they identified align well with the core measure areas in the *Vital Signs* report. A mapping of the IOM core measure areas and AHA priority list is provided in the table below. The AHA priority measures may help provide the agency with a concrete starting point for re-orienting the OQR measure set.

Mapping of IOM *Vital Signs* Core Measure Areas and AHA Priority Measures
Life expectancy
Risk Adjusted Mortality
Wellbeing
Diabetes Control
Overweight & Obesity
Obesity
Addictive Behavior
Unintended Pregnancy
Healthy Communities
Preventative Services
Care Access
Readmission Rates
Effective Patient Transitions
Patient Safety
Harm Rates
Infection Rates
Medication Errors
Evidence-based Care
Adherence to Guidelines for Commonly Overused Procedures
Care Matched to Patient Goals
End of Life Preferences
Personal Spending
Population Spending
Cost Per Case or Episode
Health Literacy

Blue = IOM Core Measure Area
***Red* =** AHA Priority Measure

To be clear, the IOM *Vital Signs* report is intended to provide measurement priorities for *all* health care stakeholders, and not just hospitals. We strongly caution CMS against using the IOM list to measure hospitals on aspects of care that may be beyond the scope of their operations. For example, in applying measures of cost and resource use to hospitals, CMS must ensure it is focused on the hospital, and not the entirety of the delivery system. CMS also should ensure measures such as readmissions are appropriately adjusted for factors beyond the control of hospital that can affect performance, such as sociodemographic factors. Nevertheless, the *Vital Signs* report provides an important uniting framework that will help make all stakeholders more accountable and engaged in measurement and improvement.

The AHA is eager to work with the agency to help it implement the *Vital Signs* recommendations. The recent collaboration of America's hospitals and CMS in the Hospital Engagement Network (HEN) shows the great potential for a focused, deliberate approach to quality measurement and improvement. Indeed, the HEN program prevented an estimated 92,000 instances of harm and saved an estimated $988 million. We also believe an OQR program focused on publicly reporting hospital progress on the core areas most relevant to achieving national priorities would provide the patients and communities we serve with far more meaningful and accurate information than the OQR program provides today.

Proposed New Measure for CY 2018. **The AHA believes OP-33 – External Beam Radiotherapy (EBRT) for Bone Metastases – may be an appropriate addition to the OQR program in the future. However, before adopting the measure, we urge CMS to reassess whether OP-33 addresses an issue of sufficiently broad scope and priority that it merits inclusion in the OQR, and to ensure the measure is feasible to collect in the Hospital Outpatient Department (HOPD) setting**. OP-33 assesses the percentage of patients with painful bone metastases with no previous radiation to the same site who receive EBRT using certain "fractionation," or dosing, schedules. The intent of the measure is to ensure that hospitals deliver no more radiation therapy to bone metastasis patients than is necessary.

The measure focuses on evidence-based care and patient safety, two areas included in the IOM *Vital Signs* report. Furthermore, the measure is endorsed by the National Quality Forum (NQF), and supported by the multi-stakeholder Measure Applications Partnership (MAP) for inclusion in the OQR. Lastly, the current OQR lacks measures of cancer care, and given that many patients obtain cancer treatments in HOPDs, measures of cancer care may be appropriate for the OQR.

However, the point of the *Vital Signs* report is that CMS and others should not simply hold up individual measures and decide if they have appealing characteristics. Instead, CMS and other stakeholders should be identifying the most important aspects of performance that will lead to better outcomes for groups of patients, and then choose the measures that will help drive performance forward so that individuals are leading longer, healthier lives. In that sense, it is not clear why CMS has chosen this measure rather than measures of treatment for different types of cancer or different aspects of cancer treatment. Is ensuring appropriate dosing for EBR treatment the most important thing providers can do to extend the life of cancer patients? If not, then what is and how do we measure that? CMS provides no estimate in the proposed rule of the number of patients that may be included in the measure, and only very limited information on the performance gap. Without this information, we do not know whether the measure affects a

significant number of patients, or whether there is a significant performance shortfall for these patients. As noted in the *Vital Signs* report, measures in national programs must have a meaningful impact on the health care system as a whole.

The AHA also is concerned about the feasibility of collecting this measure data. Specifically, some HOPDs may not know the detailed clinical information needed to exclude certain patients from the measure's denominator. The measure specifically excludes the following patient types:

- Patients with previous radiation treatment to the same anatomic site;
- Patients with femoral axis cortical involvement greater than 3 cm in length;
- Patients who have undergone a surgical stabilization procedure; and
- Patients with spinal cord compression, cauda equina compression or radicular pain

While these exclusions appear to be appropriate, many patients may not receive EBRT in the same HOPD where they receive their other cancer care. As a result, the HOPD may not have access to the detailed patient medical record information needed to capture the exclusions. This would compromise the accuracy of measure data. At a minimum, we urge CMS to further test the measure in HOPDs to determine whether facilities are able to capture all of the exclusions called for in the measure.

Proposed New Measure for CY 2019. **The AHA does not support the addition of OP-34 – ED Transfer Communication – to the OQR program at this time. We certainly agree that transitions in care is a topic deserving of the attention and focus from national programs. However, we are concerned the implementation of this measure would duplicate, and potentially conflict with, other CMS efforts aimed at improving care transitions.**

A chart-abstracted measure, OP-34 assesses the percentage of patients transferred from an ED to another health care facility for which there is documentation that specific administrative and clinical information was communicated to the receiving hospital in an appropriate timeframe. To collect measure data for OP-34, hospitals would be expected to review the charts of patients transferred from the ED to other facilities, and answer yes or no to whether 27 individual elements – grouped into seven subsections – are recorded in the medical record and transmitted to the receiving facility within certain timeframes. CMS suggests it is proposing the measure to help reduce gaps in information transmitted at the time of care transitions, thereby mitigating the risk of adverse safety events and avoidable hospital readmissions. We appreciate that CMS has proposed a measure that is NQF-endorsed, and supported for use in the OQR by the MAP.

Nevertheless, hospitals are involved in numerous activities that involve the collection and use of the data OP-34 seeks to assess. We are concerned that the adoption of OP-34 would divert attention and resources from those activities, and lead to an inconsistent approach to improving care transitions across the delivery system. Most notably, several meaningful use requirements in the Medicare EHR Incentive Program, as well as the EHR Certification Program, require hospitals to have EHRs that collect and transmit many of the data elements collected by OP-34. Indeed, one of the objectives of meaningful use is to produce a summary of care document to be used at the time of care transitions. Other meaningful use objectives also overlap extensively with OP-34. A detailed crosswalk of the data elements collected in OP-34 with relevant meaningful use and EHR Certification requirements can be found in Appendix 2 of this comment letter.

Notwithstanding the AHA's long-standing concerns with several Medicare EHR Incentive Program policies, we strongly believe in the long-term goal of using EHRs to improve care. EHRs have particular promise in supporting information exchange across the delivery system during times of care transition and throughout a patient's course of treatment. Furthermore, hospitals are making extensive investments in information technology to respond to mandates and improve their EHRs. Indeed, the AHA estimates that between 2010 and 2013 hospitals collectively spent $47 billion each year on information technology. For these reasons, we believe the best way to achieve CMS's stated goal of filling information gaps at the times of transition is to use well-designed policies in the EHR Incentive program to promote the collection and sharing of accurate and relevant data during transitions in care.

Proposed Measure Removal. **The AHA applauds CMS's proposal to remove OP-15 – Use of Brain CT in the ED for Atraumatic Headache, from the OQR beginning with the CY 2017 program.** OP-15, which is calculated using Medicare claims data, has been suspended from the OQR for several years and the measure results have never been publicly reported. Additionally, OP-15 lacks NQF endorsement, is an inaccurate measure of hospital performance, and fails to align with clinical practice guidelines. For largely the same reasons, the MAP also recommended the measure's removal from the OQR.

While we are pleased with the agency's proposal to remove OP-15, the AHA once again urges CMS to remove several other measures from the OQR program, based on recommendations from the MAP. In early 2012, the MAP conducted a review of measures from CMS, including measures in the current OQR program. The MAP suggested that the seven previously finalized OQR measures listed below were directionally correct, but not appropriate for use in the OQR program as currently constructed.

OQR Measures Not Recommended by the MAP
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-14: Simultaneous Use of Brain CT and Sinus CT
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
OP-22: ED Patient Left Without Being Seen
OP-25: Safe Surgery Checklist Use

The AHA has commented to CMS on several occasions that the imaging efficiency measures (OP-9, OP-10, OP-14) should not be included in the OQR program because several of them have failed the NQF-endorsement process. Further, we continue to hear from members that the implementation of OP-20, OP-22 and OP-25 has been difficult and produced results that are not accurate or suitable for public reporting. Finally, the 2013 MAP assessment recommended the removal of OP-22 because the measure lost NQF endorsement. **Given this assessment and the MAP recommendations, the AHA urges CMS to remove these six measures (see chart above) immediately from the OQR program.**

OQR Withdrawal Date. **The AHA supports CMS's proposal to change the OQR withdrawal date from Nov. 1 to Aug. 31 of the year prior to each payment determination year.** CMS proposes the change to foster alignment and consistency with the ASC Quality Reporting (ASCQR) program.

Timing of Annual Payment Update (APU) Determination. **The AHA supports CMS's proposed changes to the calendar year quarters of OQR data used to determine each hospital APU.** The agency specifically proposes to base APU determinations on data from quarter 2 of the two years prior to the payment year to quarter 1 of the year prior to payment determination. Because the data submission deadline for quarter 1 data is Aug. 1 of each year, the proposal would provide a total of five months between the time the final quarter of data used in APU determinations are submitted and when CMS must apply the APU. We agree this approach significantly improves upon CMS's existing policies, which provide only two months between the time the final quarter of data are submitted and when the APU is applied.

APPENDIX 1:

Request for Information Related to the 0.2 Percent Payment Reduction

Outpatient Issues

1. How was encounter defined?
2. How was long stay defined, is it a stay that is more than two days?
   - What variables were used to measure long stays?
   - What thresholds were used for those variables? If based on hours, how many hours?
3. What data were used?
4. What "completion factor" was used, if any?
5. What other limitations or adjustments to the data were made by CMS (e.g. release date)?
6. Was CMS concerned with the large drop-off in observation cases (volume and percent) in the fourth quarter of CY 2014?
   - If so, how was this addressed?
   - If not, why not?
   - Did this affect CMS's estimates?
   - What other information is required in order to replicate CMS's estimates? What assumptions were made?

Inpatient Issues

1. When looking at short stay cases, did CMS make any restrictions, e.g. surgical DRGs only, excluding death, excluding transfers, anything else?
2. What data were used, and was all the data used available to the public? It appears CMS may have included data from quarter 4 of CY 2014, indicating that CMS used data that is not yet publicly available.
3. What was the run-out period on the data?
4. Did CMS make any restrictions on the type of providers?
   - Were Critical Access Hospitals or any other type of hospital removed?
   - Were Maryland hospitals removed in order to be consistent with the OPPS data?
5. Did CMS intend the length of stay ranges to overlap? For example, on page 670 of the display copy of the CY 2016 outpatient PPS proposed rule, CMS describes changes in "proportion of 2-4 day stays", but also says that there is no change in "inpatient stays of 4 days or more"). Both ranges include 4 days, was that intentional?
   - If not, what should the correct lengths of stay ranges be?
6. What information is necessary to know in order to replicate CMS's estimates?
   - What assumptions were made?
7. CMS says that there was no effective change for stays lasting four or more days, but does not provide the actual estimate. What was CMS's actual estimate?

General Issues

1. What methodology did CMS use to attempt to adjust for the lags and complete the data?
   - CMS notes that "fully incurred experience … could result in a different outcome." How sensitive is CMS's methodology to those changes? What is the

range of estimates that CMS got depending on different assumptions? Would any of those lead to different conclusions on the results?

APPENDIX 2: CROSSWALK OF OP-34 DATA ELEMENTS WITH MEANINGFUL USE AND EHR CERTIFICATION REQUIREMENTS

OP-34 Measure Element	Meaningful Use Requirement	EHR Certification Requirement
Subsection 1 – Administrative Communication		
Nurse to nurse Communication		
Physician to physician communication	MU Objective: The eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral. MU Measure: 1. The EP, eligible hospital, or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals. 2. The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10% of such transitions and referrals either-- (a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. 3. An EP, eligible hospital or CAH must satisfy one of the two following criteria: (A) Conducts one or more successful electronic exchanges of a summary of care document, as part of which is counted in "measure 2" (for EPs the measure at §495.6(j)(14)(ii)(B) and for eligible hospitals and CAHs the measure at §495.6(l)(11)(ii)(B)) with a recipient who has EHR technology that was developed designed by a different EHR technology developer than the	**Transitions of care: (b)(1) – receive, display, and incorporate transition of care/referral summaries**. (i) Receive. EHR technology must be able to electronically receive transition of care/referral summaries in accordance with: (A) The standard specified in § 170.202(a). (B) Optional. The standards specified in § 170.202(a) and (b). (C) Optional. The standards specified in § 170.202(b) and (c). (ii) Display. EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: § 170.205(a)(1), § 170.205(a)(2), and § 170.205(a)(3). (iii) Incorporate. Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3), EHR technology must be able to: (A) Correct patient. Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient. (B) Data incorporation. Electronically incorporate the following data expressed according to the specified standard(s): (1) Medications. At a minimum, the version of the standard specified in §170.207(d)(2); (2) Problems. At a minimum, the version of the standard specified in §170.207(a)(3); (3) Medication allergies. At a minimum, the version of the standard specified in §170.207(d)(2). (C) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary

OP-34 Measure Element	Meaningful Use Requirement	EHR Certification Requirement
	sender's EHR technology certified to 45 CFR 170.314(b)(2).	received and formatted in accordance with the standard adopted at § 170.205(a)(3). **Transitions of care: (b)(2) – create and transmit transition of care/referral summaries** (i) Create. Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3) that includes, at a minimum, the Common MU Data Set** and the following data expressed, where applicable, according to the specified standard(s): (A) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified § 170.207(a)(3); (B) Immunizations. The standard specified in § 170.207(e)(2); (C) Cognitive status; (D) Functional status; and (E) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information. (F) Inpatient setting only. Discharge instructions (ii) Transmit. Enable a user to electronically transmit the transition of care/referral summary created in paragraph (b)(2)(i) of this section in accordance with: (A) The standard specified in § 170.202(a). (B) Optional. The standards specified in § 170.202(a) and (b). (C) Optional. The standards specified in § 170.202(b) and (c). **Problem list** Enable a user to electronically record, change, and access a patient's problem list: (i) Ambulatory setting. Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3); or (ii) Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3). **Medication list**

OP-34 Measure Element	Meaningful Use Requirement	EHR Certification Requirement
		Enable a user to electronically record, change, and access a patient's active medication list as well as medication history: (i) Ambulatory setting. Over multiple encounters; or (ii) Inpatient setting. For the duration of an entire hospitalization. **Medication allergy list** Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history: (i) Ambulatory setting. Over multiple encounters; or Inpatient setting. For the duration of an entire hospitalization.
Subsection 2 – Patient Information		
Name	MU Objective: Record the following Demographics – preferred language, sex, race, ethnicity, date of birth, date and preliminary cause of death in the event of mortality in the EH or CAH. MU Measure: More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have demographics recorded as structured data.	Technology should enable whether a patient declines to specify race and/or ethnicity and whether a patient declines to specify a preferred language. Standards: § 170.207(f) – OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997. § 170.207(g) – ISO 639-2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639-1.
Address		
Age		
Gender		
Significant others contact information		
Insurance		
Subsection 3- Vital Signs		
Pulse		
Respiratory Rate		
Blood pressure	MU Objective: Record and chart changes in vital signs. MU Measure: More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.	Height/length, weight, and blood pressure must be recorded in numerical values only.

OP-34 Measure Element	Meaningful Use Requirement	EHR Certification Requirement
	Also included is calculation and display of BMI and plot and display growth charts for patients 0-20 years.	
Oxygen saturation		
Temperature		
Glasgow score or other neurological assessment for trauma, cognitively altered, or neuro patients only		
Subsection 4 – Medication Information		
Medications administered in ED	MU Objective: Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR). MU Measure: More than 10 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period for which all doses are tracked using electronic medication administration record (eMAR).	Inpatient setting only — electronic medication administration record. (i**) In combination with an assistive technology that provides automated information on the "rights" specified in paragraphs (a)(16)(i)(A) through (E) of this section, enable a user to electronically verify the following before administering medication(s)**: (A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered. (B) Right medication. The medication to be administered matches the medication ordered for the patient. (C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient. (D) Right route. The route of medication delivery matches the route specified in the medication order. (E) Right time. The time that the medication was ordered to be administered compared to the current time. **(ii) Right documentation. Electronically record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.**
Allergies		
Home medications		
Subsection 5 – Physician or practitioner generated information		
History and physical	MU Objective: Use clinical decision support to improve performance on high priority health conditions. MU Measure: 1. Implement five clinical decision support interventions related to four or more clinical quality measures at a	**Clinical decision support.** (i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy

OP-34 Measure Element	Meaningful Use Requirement	EHR Certification Requirement
	relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP, eligible hospital or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. It is suggested that one of the five clinical decision support interventions be related to improving healthcare efficiency. 2. The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug allergy interaction checks for the entire EHR reporting period.	contraindication checking) based on each one and at least one combination of the following data: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) Demographics; (E) Laboratory tests and values/results; and (F) Vital signs. (ii)Linked referential clinical decision support. (A) EHR technology must be able to: (1) Electronically identify for a user diagnostic and therapeutic reference information; or (2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (2). (B) For paragraph (a)(8)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section. (iii) Clinical decision support configuration. (A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role. (B) EHR technology must enable interventions to be electronically triggered: (1) Based on the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section. (2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(iii) of this section. (3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(5)(i)(A)(1) of this section. (iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(8)(i)-

OP-34 Measure Element	Meaningful Use Requirement	EHR Certification Requirement
		(iii) of this section must automatically and electronically occur when a user is interacting with EHR technology. (v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources: (A) For evidence-based decision support interventions under paragraph (a)(8)(i) of this section: (1) Bibliographic citation of the intervention (clinical research/guideline); (2) Developer of the intervention (translation from clinical research/guideline); (3) Funding source of the intervention development technical implementation; and (4) Release and, if applicable, revision date(s) of the intervention or reference source. (B) For linked referential clinical decision support in paragraph (a)(8)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph(a)(2) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline). **Drug-drug, drug-allergy interaction checks**. 1. Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list. 2. Adjustments. (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted. (B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.
Reason for transfer and/or plan of care		
Subsection 6 – Nurse generated information		
Assessment / interventions / response		
Sensory status		
Immobilizations		
Respiratory support		
Oral limitations		

OP-34 Measure Element	Meaningful Use Requirement	EHR Certification Requirement
Subsection 7 - Procedures and tests		
Tests and procedures done	MU Objective: Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines. MU Measure: More than 60 percent of medication, 30 percent of laboratory, and 30 percent of radiology orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE. MU Objective: Incorporate clinical lab-test results into Certified EHR Technology as structured data. MU Measure: More than 55 percent of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data.	Enable a user to electronically record, change, and access the following order types, at a minimum: (i) Medications; (ii) Laboratory; and (iii) Radiology/imaging. Incorporate laboratory tests and values/results. (i) Receive results. (A) Ambulatory setting only. (1) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j) and, at a minimum, the version of the standard specified in § 170.207(c)(2). (2) Electronically display the tests and values/results received in human readable format. (B) Inpatient setting only. Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format (ii) Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7). (iii) Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.
Tests and procedure results sent		