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

RE: CMS-1665-P, Medicare Program; Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports.

CMS-1664-IFC, Medicare Program; Temporary Exception for Certain Severe Wound Discharges from Certain Long-Term Care Hospitals Required by the Consolidated Appropriations Act, 2016; Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board.

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including 271 long-term care hospitals (LTCHs), the American Hospital Association (AHA) appreciates the opportunity to comment on the LTCH provisions in the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2017 proposed rule for the inpatient and LTCH prospective payment systems (PPS). This letter addresses the LTCH payment and quality-reporting provisions in the proposed rule only. In addition, we provide feedback on the codes proposed in CMS's interim final rule with comment (IFC) that would, among other changes, implement the congressional mandate pertaining to site-neutral payments for severe wound cases in two rural LTCHs. We are submitting comments separately on the agency's inpatient PPS (IPPS) proposals.

While we support some of CMS's proposed changes, such as the agency's proposed methodology to revise and rebase the LTCH market basket and the changes proposed for the "cancer LTCH," we have concerns about others. For example, **we are very concerned about CMS's proposal to fully implement the "25% Rule," which may reduce access and**

payment for the very patients who the Congress has deemed appropriate for LTCH-level care and payment. As such, we urge CMS to rescind the 25% Rule. In addition, under the new dual-rate payment system, CMS proposes to continue applying two budget-neutrality adjustments (BNA), which result in the systematic underpayment of LTCH cases that fall in the site-neutral payment category by 5.1 percent. **Therefore, we urge CMS to eliminate the second of these duplicative BNA cuts.**

In addition, the AHA recommends that CMS make several improvements to the four new measures proposed for the FY 2018 and FY 2020 LTCH Quality Reporting Program (QRP). The measures should undergo additional reliability and validity testing, and CMS should conduct a "dry run" of the measures prior to implementation. We also urge CMS to examine the impact of socioeconomic factors on its Medicare spending per beneficiary, discharge to community and potentially preventable readmission measures, and incorporate socioeconomic adjustment as needed. Finally, we urge CMS to consider providing performance feedback data to LTCHs on a more frequent basis so they can more effectively monitor and improve performance.

PAYMENT-RELATED PROPOSALS

LTCH 25% RULE

The AHA is very concerned about CMS's proposal to implement the 25% Rule beginning Oct. 1, 2016. The 25% Rule is a misguided, arbitrary policy that, based on its flawed design, may lead to reduced access to care. In addition, it would impose a material payment penalty on LTCHs for care provided to patients who are medically appropriate for the LTCH setting. Further, there is an alternative to the 25% Rule already in place – the stringent LTCH payment system mandated by Congress with the Bipartisan Budget Act of 2013 (BiBA). Under this system being implemented with cost-reporting periods beginning on or after Oct. 1, 2015, in general, higher-acuity cases are paid the LTCH PPS standard federal payment rate and lower-acuity cases are paid a far lower "site-neutral" rate. During the first two cost-reporting periods under the policy, an LTCH's site-neutral cases are subject to a 50/50 blend of LTCH PPS standard and site neutral rates. **This LTCH site-neutral payment policy, unlike the 25% Rule, categorizes LTCH patients based on their medical acuity, and reduces payment for only those with lower medical acuity. Given the implementation of the BiBA provision, the 25% Rule, which uses arbitrary and non-clinical criteria, is no longer necessary and should be withdrawn.**

Policy Background. The 25% Rule, implemented in FY 2006 under CMS's own initiative, reduces LTCH payments to an "IPPS-equivalent" level for patients transferring from a general acute-care hospital to an LTCH and who exceed a particular referral threshold. The referral threshold varies by LTCH type – for example, rural LTCHs have a more lenient threshold of 50 percent. Currently, the policy is partially implemented at a more lenient level due to multiple congressional interventions that have temporarily blocked full implementation. However, these statutory delays are expiring with cost reporting periods beginning on or after Oct. 1, 2016 for

freestanding LTCHs, and for cost-reporting periods beginning on or after July 1, 2016 for co-located and satellite LTCHs. In the FY 2014 final rule for the LTCH PPS, CMS cited analysis by the Office of The Assistant Secretary for Planning and Evaluation, which estimated that, from 2010 through 2013, approximately 9 to 10 percent of LTCH admissions were not in compliance with the 25% Rule. A more current estimate of non-compliance has not been identified.

The 25% Rule Counters the Statutory Requirements on LTCH PPS Payment. In BiBA, Congress set a clear methodology for identifying the cases that are to be paid an LTCH PPS rate, rather than a site-neutral rate. As noted, the BiBA criteria distinguish patients according to their medical acuity, as indicated by intensive care use (ICU) use in the prior hospital stay and other metrics. Qualifying cases are mandated to receive a standard LTCH PPS rate. Yet, the 25% Rule would reduce this mandated payment for some qualifying cases to an IPPS-equivalent amount. **Thus, the 25% Rule payment cut directly contradicts the congressional requirements set forth in BiBA. For this, and other reasons noted below, we urge CMS to rescind the 25% Rule.**

CMS has the Authority to Rescind the 25% Rule. We undertook a legal analysis of Sec. 114(c) of P.L. 110-173 that indicates that CMS has the authority to rescind the 25% Rule, which was established through regulation in the FY 2004 final rule for the LTCH PPS. **Specifically, because the 25% Rule lacks a statutory mandate, the agency has the authority to rescind it – an action wholly urged by the AHA.** While several congressional bills have temporarily blocked full implementation of the 25% Rule, for a combined delay of nine years, the resulting statutory language did not mandate implementation of the policy.

The 25% Rule Inappropriately Cuts Payments for Medically Necessary Care. CMS's rationale for the 25% Rule has been that LTCHs provide medically unnecessary care when functioning as "step-down units" for nearby general acute-care hospitals. AHA's critique of the policy has been, and remains, that it arbitrarily cuts payments based on the origin of an LTCH patient and reduces access for patients who have medical necessity for LTCH services. In other words, it penalizes LTCHs and their patients simply for their referral source. The policy is wholly unrelated to the medical necessity of patients – absolutely nothing in it speaks to whether a particular patient requires LTCH care. In fact, in its March 2011 report to Congress, the Medicare Payment Advisory Commission (MedPAC) refers to the policy as "blunt' and "flawed" for this reason. **As such, instead of the 25% Rule, CMS should rely on clinical criteria to determine which patients warrant LTCH-level payment.**

The 25% Rule Does Not Align with the Current Policy Environment. Moreover, today's policy landscape for LTCHs is significantly different from that of 2003, when CMS first proposed the 25% Rule. Most notably, BiBA required CMS to implement specific patient criteria governing whether a case qualifies for full LTCH PPS payments, beginning with cost reports beginning Oct. 1, 2015. These new criteria are estimated to reduce payments for fully one out of two LTCH cases from LTCH levels to IPPS-equivalent levels. The prior absence of LTCH PPS payment criteria was regularly cited by CMS as part of its rationale for the 25% Rule. In other words,

CMS argued that the lack of LTCH criteria created the need for the 25% Rule in order to tighten access to this high-cost setting. However, it is clear that this need no longer exists.

Further, the scale of the site-neutral cuts is significant, even in the phase-in years. CMS estimates a 21.0 percent cut in FY 2017 and 14.8 percent cut in FY 2016 for site-neutral cases, relative to what they would have been paid the prior year. In addition, AHA's analysis of the FY 2015 MedPAR data indicated that site-neutral cases would face, on average, a 73 percent payment cut relative to LTCH PPS rates.[1] **Given the magnitude of the site-neutral cuts, it would be excessive for CMS to also apply the 25% Rule cuts to the LTCH field.** Combining site-neutral payment and the 25% Rule, would unjustifiably exacerbate the instability and strain the field is currently undergoing as they implement BiBA reforms.

Another transformative change for LTCHs, as well as for the full continuum of care, is the current development and implementation of alternative payment models that affect the way that post-acute care services are being used, and will be used in the future. These new models, such as bundled payment for patients commonly treated in post-acute care settings, are already affecting some LTCHs, depending on the nature of the models in local markets, by reducing utilization of the setting due to its high cost.

Further, the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 is moving the post-acute care field toward payment based on patients' clinical characteristics upon discharge from the prior hospital stay. Such a payment methodology would, like the BiBA criteria but unlike the 25% Rule, set payment levels based on a patient's clinical profile. The 25% Rule's reliance on the origin of the referral to set payments makes it an outdated policy in comparison to more recent, patient-centered post-acute payment policies. Collectively, these notable LTCH policy changes render the 25% Rule out of date and unnecessary. **Therefore, CMS should rescind the 25% Rule since it has been supplanted by clinically-based payment policies for LTCHs.**

If CMS chooses to retain the 25% Rule in regulation, we urge the agency to do so in the policy's current form only until BiBA's LTCH criteria and site-neutral payment are implemented and their impact is examined. Such a position was recommended by MedPAC in a June 2015 letter to CMS and reiterated in its June 2016 comment letter on this proposed rule. In addition, there is precedent for CMS to delay full implementation of the 25% Rule to allow for a clinically-based policy to become available. Specifically, in the FY 2013 final rule, the agency delayed for one year the full implementation of the 25% Rule to continue developing a methodology to identify those higher-acuity LTCH patients who warrant higher reimbursement, which the agency said could "render the 25-percent payment adjustment threshold policy unnecessary." Our legal

[1] Payments to site-neutral cases using the standard LTCH PPS rates were calculated assuming that these cases would continue to have the historically higher costs and lengths of stay that they exhibited before implementation of the two-tiered payment structure. On the other hand, blended site-neutral rate payments after implementation were calculated assuming that the costs and lengths of stay of the site-neutral cases would be similar to those of the IPPS cases in the same MS-DRG.

analysis found that CMS has the authority to both eliminate and delay full implementation of the policy.

It also is worth noting that BiBA required CMS to prepare a report to Congress on how the 25% Rule should be changed in light of BiBA's site-neutral payment rate requirements. In a July 2015 report to Congress, CMS indicated its plans to study the impact of site-neutral payment prior to determining the best next steps for the 25% Rule, including whether the rule remains necessary to deter inappropriate "patient shifting" from general acute-care hospitals to LTCHs. **Yet, the agency now proposes to implement the 25% Rule before site-neutral payment has been fully implemented and examined, which contradicts the plan CMS communicated to Congress.**

SITE-NEUTRAL CASES ARE BEING UNDERPAID DUE TO DUPLICATIVE BNAS

The AHA is very concerned about CMS's proposal to continue applying duplicative budget-neutrality adjustments (BNA) to the site-neutral portion of the blended payment to LTCH site-neutral cases. In its FY 2016 and FY 2017 rulemaking, CMS stated that its rationale for applying a 5.1 percent reduction (hereafter "5.1 percent BNA") to the site-neutral portion of the blended payment is to avoid any "increase in aggregate LTCH PPS payments." **However, as we have stated in the past, CMS's decision to apply two BNAs is yielding a material, unwarranted payment reduction to LTCH site-neutral cases.**

Specifically, as discussed at length in our comment letter on the FY 2016 LTCH PPS proposed rule and in other communications with CMS, these site-neutral cases are first subject to a 5.1 percent BNA when CMS sets the IPPS rates used to calculate the IPPS comparable per diem amount paid to site-neutral cases.[2] Then, within the LTCH PPS framework, they are subject to a second 5.1 percent BNA during the final stages of calculating the site-neutral payment blend. The result of these duplicative BNAs is that the site-neutral portion of the blended payment is subject to an additional and unwarranted reduction of 5.1 percent. **As such, we strongly urge CMS to withdraw application of the second 5.1 percent BNA to the site-neutral portion of the blended payments in FY 2017, and to immediately discontinue its use in FY 2016. In addition, we urge CMS to make a retroactive adjustment to the FY 2016 site neutral payments that have already occurred due to this error.**

MedPAC also believes that the second 5.1 percent BNA is duplicative. Specifically, in its May 31, 2016 comment letter on the FY 2017 IPPS/LTCH PPS proposed rule, the commission states that "[g]iven that the IPPS standard payment amount is already adjusted to account for HCO payments, CMS' proposal to reduce the site-neutral portion of the LTCH payment by a budget-neutrality adjustment of 0.949 is duplicative and exaggerates the disparity in payment rates

[2] The IPPS comparable per diem amount is calculated by dividing the sum of the applicable IPPS operating standardized amount and capital federal rate (adjusted for DRG weighting factors, geographic factors, indirect medical education costs and the costs of serving a disproportionate share of low-income patients) by the geometric mean length of stay for the specific DRG, and multiplying by the covered length of stay. This amount is capped at the full IPPS DRG amount. It is the operating standardized amount and capital federal rate that have already been reduced by 5.1 percent within the IPPS framework.

across provider settings. Given this duplication, CMS should not adjust the site-neutral rate further."

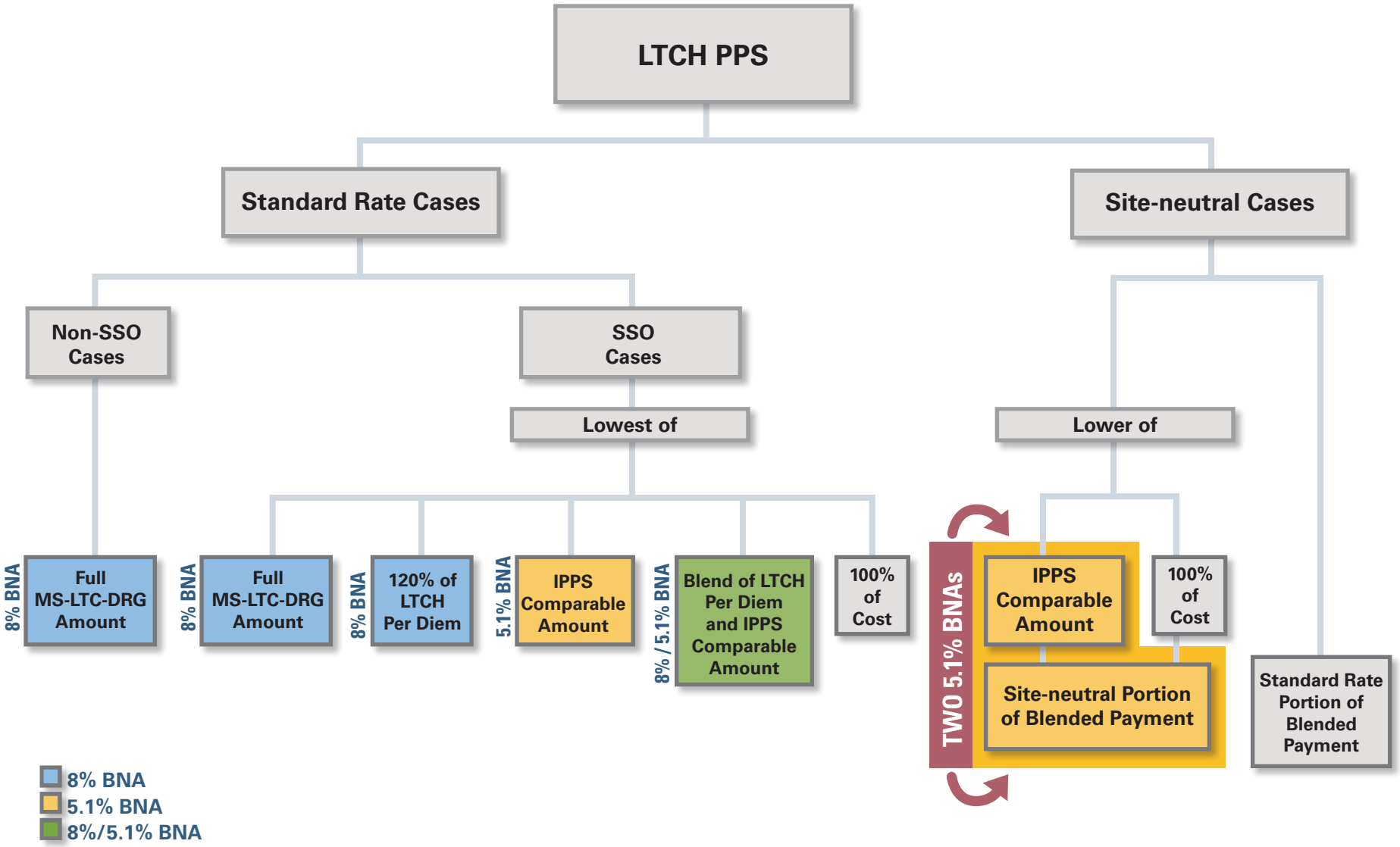
Failure of CMS to Establish Baseline for Site-neutral Payments. When setting LTCH site-neutral rates under the new two-tiered payment structure in its FY 2016 rulemaking, CMS failed to justify applying two 5.1 percent BNAs to the site-neutral portion of the blend. Thus far, to explain its approach, CMS has noted the objective of preventing aggregate LTCH PPS payments from increasing. However, CMS has not provided a reduced "baseline" against which the agency or stakeholders could measure such an increase. In our FY 2016 comment letter, we presented several analyses showing that the second BNA is inappropriately lowering the site-neutral payment rate.

CMS Applies BNAs Inconsistently Between Standard Rate Cases and Site-neutral Cases. The table on the next page outlines and compares BNAs for the two types of cases paid under the two-tiered payment system for LTCHs: standard rate cases and site-neutral cases. Shaded cells indicate the application of a BNA. When calculating any of the LTCH PPS standard rate payments (shown on the left side of the table), only one BNA applies[3]. Similarly, when pricing out the LTCH PPS short-stay outliers (also on the left side of the table) that are paid either an IPPS comparable amount or cost (similar to what site-neutral cases are being paid), only one BNA applies. However, by contrast, when calculating rates for site-neutral cases paid the IPPS comparable amount, two BNAs apply.

When calculating rates for site-neutral cases paid cost, one BNA applies, but even that application is inappropriate – cost-based payment should not be subject to this 5.1 BNA. **Hence, CMS's inconsistent BNA methodologies yield not only a payment disparity between standard rate and site-neutral cases, but also between the standard rate and site-neutral portions of the blend for site-neutral cases.**

[3] The LTCH standard federal payment rate, at the implementation of the LTCH PPS, was adjusted downward by a reduction factor of 8 percent to fund the estimated proportion of outlier payments under the LTCH PPS. Although never described in rulemaking by CMS as a "high cost outlier BNA," for purposes of this illustration we use the term "8% BNA" to describe it.

Site-neutral Cases Are the Only LTCH Cases Subject to Two Budget Neutrality Adjustments (BNA)



Even High-cost Outlier Payments to Site-neutral Cases are Being Inappropriately Reduced. Standard rate cases receive a base MS-LTC-DRG amount plus high-cost outlier payments, if applicable, without any further reduction in payment. However site-neutral cases are reimbursed either cost, or the IPPS comparable per diem amount plus a high-cost outlier payment, if applicable. CMS then reduces this *entire* site-neutral payment by a further 5.1 percent. This means that even the high-cost outlier amount itself is being reduced further, which is totally inconsistent with high-cost outlier payments for other LTCH and IPPS cases. **There is simply no justification that can be made for the second 5.1 percent BNA.**

Estimate of Fiscal Impact of Duplicative BNA. Using the FY 2015 MedPAR data, we estimate that the second BNA within the LTCH framework reduces site-neutral payments by approximately $30-$50 million per year. This estimate assumes full implementation of site-neutral payment, with no blended payments, and the range reflects the varied impact of incorporating costs that are similar to IPPS levels versus historical LTCH costs. This unwarranted reduction is especially egregious as it will be made in perpetuity.

REQUEST FOR ADDITIONAL DATA

As we did in our comments on the FY 2016 proposed rule, we again urge CMS to release additional data to enable the AHA and other stakeholders to conduct a full analysis of CMS's LTCH proposals in the rule. We appreciate that CMS added a flag to the LTCH MedPAR data that identifies whether a patient will be paid at the standard payment or site-neutral payment rate. However, more information is needed to enable the field to fully replicate the proposed policies, including verifying the accuracy of CMS's payment flag.

In particular, we request that CMS:

- **Add encrypted beneficiary ID and admission and discharge dates to both the national and LTCH MedPAR data sets**. These data are necessary to ascertain which cases were immediately discharged from an IPPS hospital. While CMS does release these data for a prior time period (via the SAF file data set), the data must be present in the MedPAR data sets that are used for rulemaking, especially as we attempt to study changes in volume, referral patterns and other developments related to site-neutral payment.

  Since there are LTCH patients who also could be discharged from IPPS hospital to an LTCH in one year but not discharged from the LTCH until the subsequent year, we request that CMS make available at least two years of national MedPAR data with the encrypted beneficiary ID and admission and discharge dates, so that we can match patients with the previous years' IPPS discharge.

- **Add a variable indicating the number of ICU days in the prior IPPS hospital stay to the LTCH MedPAR**. For those LTCHs that lack the ability to acquire and analyze large Medicare data sets, this would help determine which criteria were used to qualify for site-neutral payment, in addition to other analyses.

QUALITY REPORTING-RELATED PROPOSALS

LTCH QUALITY REPORTING PROGRAM (LTCH QRP)

The Affordable Care Act mandated that reporting of quality measures for LTCHs begin no later than FY 2014. Failure to comply with LTCH QRP requirements will result in a 2.0 percentage point reduction to the LTCH's annual market-basket update.

CMS proposes a total of four new measures for the LTCH QRP to meet the requirements of the IMPACT Act of 2014. Three of the measures would be added to the FY 2018 LTCH QRP, while one would be added for the FY 2020 program. The IMPACT Act is intended to foster greater standardization and alignment of measures across CMS's post-acute care quality reporting programs, including the LTCH QRP.

FY 2018 MEASUREMENT PROPOSALS

CMS proposes three new measures for the FY 2018 LTCH QRP – Medicare spending per beneficiary, discharge to community and potentially preventable readmissions. All three measures are calculated using Medicare claims data, and do not require the submission of additional data by LTCHs. **While the AHA appreciates that CMS proposes these measures to fulfill its statutory requirements under the IMPACT Act, we believe all three need significant improvement prior to their implementation.** We first comment on several issues pertaining to all three measures, then provide measure-specific comments.

Overarching Measure Issues.

Measure Testing. **The AHA strongly urges that all three measures be tested for reliability and validity, and that full information about measure testing be made publicly available prior to implementation. Furthermore, we urge that the measures undergo field testing with post-acute care providers prior to implementation.** The draft measure documents provided on CMS's website provide a variety of information about the measure cohorts, exclusions and risk adjustment variables that are proposed for the measures. However, the draft specifications provide very limited data that would enable the field to evaluate measure design decisions. For example, there are few descriptive statistics showing the distribution of performance by characteristics like bed size or urban/rural status. We also lack information on the level of statistical significance of the variables chosen for most of the risk adjustment models. This information is critical to understanding whether the measure adequately adjusts for clinical and other factors beyond the control of providers.

Given that the measures will be publicly reported, it is imperative that they provide an accurate portrayal of provider performance. For this reason, CMS must ensure that the measure is fully tested, and that the results of that testing are fully transparent so that all stakeholders have an opportunity to suggest meaningful improvements to the measure. Indeed,

these data also would be expected to be submitted as part of the National Quality Forum (NQF) endorsement process, and the AHA strongly recommends that all measures in CMS programs receive NQF endorsement prior to implementation.

In addition, we recommend CMS conduct a "dry run" in which all LTCHs providers are given confidential preview reports of their performance prior to publicly reporting the measure. CMS has used dry runs in the past – including in its post-acute care quality reporting programs – for new measures so that providers can become familiar with the methodology, understand the measure results, know how well they are performing, and have an opportunity to give CMS feedback on potential technical issues with the measures. Given the relative novelty of all three measures in the LTCH QRP, we believe a dry run would be a crucially important step to enhancing the understanding and credibility of the measures.

Socioeconomic Adjustment. **The AHA believes LTCH performance on all three measures may be impacted by socioeconomic factors. We urge CMS to assess each measure for the impact of such factors, and incorporate socioeconomic adjustment where necessary.** For example, in submitting the proposed measures for NQF endorsement, the agency could take advantage of the NQF's socioeconomic adjustment "trial period." As part of the trial period, NQF is asking for measure developers to conduct a conceptual and empirical analysis of the impact of socioeconomic status on measure performance when measures are submitted for NQF review.

The evidence continues to mount that socioeconomic factors beyond providers' control – such as the availability of primary care, physical therapy, easy access to medications and appropriate food, and other supportive services – influence performance on outcome measures. For example, in January 2016, the National Academy of Medicine (NAM) released the first in a planned series of reports that identifies "social risk factors" affecting the health outcomes of Medicare beneficiaries and methods to account for these factors in Medicare payment programs. Through a comprehensive review of available literature, the NAM's expert panel found evidence that a wide variety of social risk factors may influence performance on certain health care outcome measures, such as readmissions, costs and patient experience of care. These community issues are reflected in readily available proxy data on socioeconomic status, such as U.S. Census-derived data on income and education level, and claims-derived data on the proportion of patients dually eligible for Medicare and Medicaid. Furthermore, the agency recently adopted a proposal to provide an "interim" adjustment for socioeconomic factors for several measures in the Medicare Advantage Star Rating program. Yet, to date, CMS has resisted calls to incorporate sociodemographic adjustment into the quality measurement programs for LTCHs, hospitals and other providers.

We are concerned that without socioeconomic adjustment, providers caring for poorer and sicker patients will appear to perform worse on some outcome measures than others treating a different patient population. Indeed, measures that fail to adjust for sociodemographic factors when there is a conceptual and empirical relationship between those factors and the measure outcome lack credibility, unfairly portray the performance of providers caring for more complex and challenging patient populations, and may serve to exacerbate health care disparities.

More Frequent Measure Data. **We encourage CMS to consider providing patient-level measure data to LTCHs on a more frequent basis, such as quarterly.** For most of the claims-based measures used in CMS's programs, the agency gives providers performance data on an annual basis. However, to make effective use of the measures to improve performance, LTCHs and other providers need timelier data to understand whether interventions are having an effect. Thus, we encourage the agency to explore the feasibility of more frequent performance reports on all three measures.

Medicare Spending per Beneficiary for LTCHs (MSPB-LTCH). **The AHA urges CMS to carefully evaluate the MSPB measure's clinical risk adjustment approach.** We encourage the agency to work with providers to explore the feasibility of incorporating an adjustment for patient functional status. We believe patient functional status is an important determinant of patient outcomes. CMS could examine whether reliable information on functional status could be collected from claims data. In addition, given that LTCHs and other post-acute care providers are required by CMS to collect information on functional status as part of patient assessments, CMS should explore whether it is feasible and not overly burdensome to providers to incorporate information from these assessments into the risk model.

Discharge to Community. **The AHA urges CMS to carefully assess the reliability and validity of patient discharge codes used to calculate the discharge to community measure.** The measure assesses the percentage of Medicare fee-for-service (FFS) patients discharged from LTCHs to home or home health care (i.e., "community discharges") with no unplanned re-hospitalizations or deaths within 31 days of discharge. CMS would identify community discharges using patient discharge status codes recorded on Medicare FFS claims. However, as noted by MedPAC and in other published studies, patient status discharge codes often lack reliability. Given that they are so integral to the calculation of the discharge to community measure, CMS must test the measure to ensure it provides an accurate portrayal of performance.

Potentially Preventable Readmissions (PPRs). **The AHA is concerned by the overlap of the proposed PPR measure with the existing LTCH QRP all-cause readmission measure. We believe using two distinct readmission measures – with results that are likely to differ – may make it confusing for LTCHs to track and improve their performance. We urge the agency to implement a single readmission measure in the LTCH QRP.** The proposed measure assesses the risk-adjusted rate of unplanned PPRs to short-stay acute care hospitals and LTCHs in the 30 days after LTCH discharge. The measure includes only those patients whose LTCH stay was preceded by a "prior proximal" acute care hospital stay in the 30 days prior to LTCH admission. However, the proposed measure differs from the all-cause, unplanned readmission measure previously added to the LTCH QRP in that it includes only those readmissions considered to be potentially preventable.

The AHA has long urged that readmission measurement focus on those readmissions that are truly preventable. Over time, the PPR measure may prove to be superior to the all-cause readmission measure. However, we urge continued evaluation of the measure. **In particular, the categories and lists of "potentially preventable readmissions" should be based on careful evaluation by clinical experts and detailed testing.** We appreciate that a technical expert panel

was consulted on the list of categories and codes of readmissions considered "potential preventable." However, we strongly encourage CMS to undertake additional empirical testing to ensure there is evidence that the codes actually are associated with the identified categories.

Lastly, the AHA urges CMS to review the various readmission measures used across its post-acute measurement programs to ensure they create consistent improvement incentives across the system. We note that the QRPs for LTCHs, inpatient rehabilitation facilities (IRFs) and home health agencies, as well as the skilled-nursing facility (SNF) value-based purchasing (VBP) program all include finalized or proposed readmission measures. While the basic construction of the measures is similar, there are some important differences. For example, while CMS has proposed PPR measures for LTCHs, IRFs and SNFs that assess readmissions following discharge from facilities, the agency uses a readmission measure in the SNF VBP that assesses readmissions in the 30 days following acute care hospital discharge. The agency also has proposed a "within stay" readmission measure for IRFs. Yet, to date, there has not been an assessment of whether the differences in measurement across these providers are appropriate and facilitate readmission reduction efforts. Given the value and importance of readmission reduction, we encourage CMS to work with post-acute care providers, hospitals and other stakeholders to evaluate whether the readmission measurement is being structured in a way that helps, and not hinders, effective collaboration.

FY 2020 MEASUREMENT PROPOSAL

Drug Regimen Review with Follow-up on Clinically Significant Issues. **The AHA urges CMS to provide a more specific definition of "clinically significant issues" in the drug regimen review measure. We are concerned that a lack of this specific definition will make it challenging to collect reliable and accurate measure data.** The proposed measure assesses the percentage of LTCH stays for which all of the following things are true:

- Drug regimen review was conducted at the time of admission;
- *For clinically significant issues identified at admission*, the LTCH contacted a physician (or physician-designee) by midnight of the next calendar day and completed prescribed/ recommended actions in response to the identified issues; and
- *For other issues identified during LTCH stay*, the facility contacted a physician (or physician-designee) and completed prescribed/recommended actions by midnight of the next calendar day each time potential clinically significant medication issues were identified.

To report the measure, LTCHs would be expected to complete three items on the LTCH CARE Data Set that reflect the above activities. However, the items themselves provide no specific indication of what issues may be considered clinically significant. The measure specifications provided by CMS also do not concretely define a "clinically significant" drug issue. Without these definitions, there are likely to be variations in measure performance that are not based on differences in care, but rather on differences in data collection.

PROPOSAL PERTAINING TO THE "CANCER LTCH"

The BiBA granted CMS the authority to pay the single cancer LTCH using a methodology similar to the cost-based rates paid under the Tax Equity and Fiscal Responsibility Act (TEFRA), which were in effect prior to the 2003 implementation of the LTCH PPS. As such, since Jan. 1, 2015, this LTCH has been paid using TEFRA-like, cost-based reimbursement for both operating and capital-related costs. The proposed rule would align the "limitation on hospital charges to beneficiaries" provisions for this hospital with those of other TEFRA hospitals. **The AHA endorses this proposed change.** We also express our appreciation for the efforts made by both CMS and MAC National Government Services for assisting this hospital with the challenges associated with converting this hospital to TEFRA payments.

INTERIM FINAL RULE ON SEVERE WOUND CASES IN CERTAIN LTCHS

On April 21, CMS issued an interim final rule regarding temporary exceptions to payments for certain severe wound discharged from certain LTCHs, as mandated by the Consolidated Appropriations Act of 2016, in addition to other provisions. Under this rule, severe wound cases discharged from two specific rural, co-located LTCHs prior to Jan. 1, 2017, would be paid LTCH PPS rates rather than site-neutral payments. CMS has indicated that as many as five additional hospitals may qualify for this relief if they change to a rural classification.

The statute defines a "severe wound" as "a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, infected wound, fistula, osteomyelitis or wound with morbid obesity as identified in the claim from the long-term care hospital." For six of these eight statutory categories,[4] severe wounds can be identified through the use of specific ICD-10-CM codes, which are reported in the LTCH claim. The list of ICD-10-CM diagnosis codes CMS proposes to include in these categories can be found in the table "Severe Wound Diagnosis Codes by Category for Implementation of Section 231 of Public Law 114-113" posted on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html under the regulation "CMS-1664-IFC."

However, we have identified a number of ICD-10-CM codes that we believe should be included in the above six categories of "severe wounds," but that CMS did not include in the list. We respectfully request that consideration be given to adding the codes identified to the specific categories below.

Stage 3 and Stage 4 Wounds. CMS has appropriately included ICD-10-CM diagnosis for stage 3 and stage 4 pressure ulcers in the stage 3 and 4 wound categories. However, ICD-10-CM has additional codes for non-pressure chronic ulcers that represent the same degree of severity and

[4] Stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, fistula, and osteomyelitis

are similar to other codes on the list, but are omitted. We believe the codes listed below also represent valid diagnoses and should be excluded from the site-neutral payment rate.

Table 1: List of additional ICD-10-CM Codes for Stage 3 and Stage 4 Wounds

L97.112	Non-pressure chronic ulcer of right thigh with fat layer exposed
L97.113	Non-pressure chronic ulcer of right thigh with necrosis of muscle
L97.114	Non-pressure chronic ulcer of left thigh with necrosis of bone
L97.122	Non-pressure chronic ulcer of left thigh with fat layer exposed
L97.123	Non-pressure chronic ulcer of left thigh with necrosis of muscle
L97.124	Non-pressure chronic ulcer of right thigh with necrosis of bone
L97.912	Non-pressure chronic ulcer of unspecified part of unspecified part right lower leg with - fat layer exposed
L97.913	Non-pressure chronic ulcer of unspecified part of unspecified part right lower leg with – necrosis of muscle
L97.914	Non-pressure Ulcer of unspecified part of unspecified part right lower leg with – necrosis of bone
L97.922	Non-pressure chronic ulcer of unspecified part of unspecified part left lower leg with – fat layer exposed
L97.923	Non-pressure chronic ulcer of unspecified part of unspecified part left lower leg with – necrosis of muscle
L97.924	Non-pressure chronic ulcer of unspecified part of unspecified part left lower leg with – necrosis of bone

Nonhealing Surgical Wounds. From FY 1997 until FY 2015, nonhealing surgical wounds were identified through a single ICD-9-CM code – 998.83, Nonhealing surgical wounds. The code was created to identify patients with postsurgical wounds that were either healing slowly or not healing at all. However, the code did not identify the part of the body where the wound was located. With the implementation of ICD-10-CM, there is no longer a similar code, as it was assumed that the more specific ICD-10-CM codes would identify the reason for the nonhealing (e.g., diabetes, infection, etc.) and/or the specific body system where the wound was located.

The *Coding Clinic for ICD-10-CM and ICD-10-PCS* Editorial Advisory Board (which has representation from CMS and the Centers for Disease Control and Prevention as the ICD-10-CM and ICD-10-PCS code set maintainers) provided the following guidance in the First Quarter 2014 issue:

> *Question:*
> *How should a nonhealing surgical wound be coded?*
>
> *Answer:*
> *ICD-10-CM does not provide a specific code to describe nonhealing surgical wound. Assign code T81.89X-, Other complications of procedures, not elsewhere classified, for an unspecified nonhealing surgical wound. If a postsurgical wound*

> *does not heal due to infection, assign code T81.4XX-, Infection following a procedure. If the wound was closed at one time and is no longer closed, it is coded as disruption. In that case, code T81.3-, Disruption of wound, not elsewhere classified, should be assigned.*

It now appears as if a code capturing the same information as "nonhealing surgical wound" in ICD-9-CM is still needed. A proposal for such a code was introduced at the March 2016 meeting of the ICD-10-CM and ICD-10-PCS Coordination and Maintenance Committee, the federal committee co-chaired by CMS and the Centers for Disease Control and Prevention (CDC) to entertain proposals to update the code set. If approved, such code would not become effective until FY 2018. Until such time, the following ICD-10-CM codes should be used to identify nonhealing surgical wounds:

Table 2: List of additional ICD-10-CM Codes for Nonhealing Surgical Wounds

T81.30XA	Disruption of wound, unspecified, initial encounter
T81.30XD	Disruption of wound, unspecified, subsequent encounter
T81.31XA	Disruption of external operation (surgical) wound, not elsewhere classified, initial encounter
T81.31XD	Disruption of external operation (surgical) wound, not elsewhere classified, subsequent encounter.
T81.32XA	Disruption of internal operation (surgical) wound, not elsewhere classified, initial encounter
T81.32XD	Disruption of internal operation (surgical) wound, not elsewhere classified, subsequent encounter
T81.4XXA	Infection following a procedure, initial encounter
T81.4XXD	Infection following a procedure, subsequent encounter
T81.89XA	Other complications of procedures, not elsewhere classified, initial encounter
T81.89XD	Other complications of procedures, not elsewhere classified, subsequent encounter

Osteomyelitis. The IFC equates ICD-10-CM codes for "osteomyelitis" with ICD-10-CM codes for "fistula," stating that "under our definition of wound, the ICD-10 diagnosis codes used to identify severe wounds in the osteomyelitis category are also part of the ICD-10 diagnosis codes used to identify severe wounds in the fistula category so no separate identification of ICD-10 codes for osteomyelitis is necessary." However, ICD-10-CM classifies separately acute osteomyelitis and chronic osteomyelitis with codes distinctly different from the codes for fistula listed in the IFC. The following ICD-10-CM codes should be additionally recognized to identify osteomyelitis.

Table 3: List of additional ICD-10-CM Codes for Osteomyelitis

M86.10	Other acute Osteomyelitis, unspecified site
M86.111	Other acute Osteomyelitis, right shoulder
M86.112	Other acute Osteomyelitis, left shoulder
M86.119	Other acute Osteomyelitis, shoulder
M86.121	Other acute osteomyelitis, right humerus
M86.122	Other acute osteomyelitis, left humerus
M86.129	Other acute osteomyelitis, unspecified humerus
M86.131	Other acute osteomyelitis, right radius and ulna
M86.132	Other acute osteomyelitis, left radius and ulna
M86.139	Other acute osteomyelitis, unspecified radius and ulna
M86.141	Other acute osteomyelitis, Right hand
M86.142	Other acute osteomyelitis, Left hand
M86.149	Other acute osteomyelitis, unspecified hand
M86.151	Other acute osteomyelitis, right femur
M86.152	Other acute osteomyelitis, left femur
M86.159	Other acute osteomyelitis, unspecified femur
M86.161	Other acute osteomyelitis, right tibia and fibula
M86.162	Other acute osteomyelitis, left tibia and fibula
M86.169	Other acute osteomyelitis, unspecified tibia and fibula
M86.171	Other acute osteomyelitis right ankle and foot
M86.172	Other acute osteomyelitis, left ankle and foot
M86.179	Other acute osteomyelitis, unspecified ankle and foot
M86.18	Other acute osteomyelitis, other site
M86.19	Other acute osteomyelitis, multiple sites
M86.60	Other chronic Osteomyelitis, unspecified site
M86.611	Other chronic Osteomyelitis, right shoulder
M86.612	Other chronic Osteomyelitis, left shoulder
M86.619	Other chronic Osteomyelitis, shoulder
M86.621	Other chronic osteomyelitis, right humerus
M86.622	Other chronic osteomyelitis, left humerus
M86.629	Other chronic osteomyelitis, unspecified humerus
M86.631	Other chronic osteomyelitis, right radius and ulna
M86.632	Other chronic osteomyelitis, left radius and ulna
M86.639	Other chronic osteomyelitis, unspecified radius and ulna
M86.641	Other chronic osteomyelitis, Right hand
M86.642	Other chronic osteomyelitis, Left hand
M86.649	Other chronic osteomyelitis, unspecified hand
M86.651	Other chronic osteomyelitis, right thigh

M86.652	Other chronic osteomyelitis, left thigh
M86.659	Other chronic osteomyelitis, unspecified thigh
M86.661	Other chronic osteomyelitis, right tibia and fibula
M86.662	Other chronic osteomyelitis, left tibia and fibula
M86.669	Other chronic osteomyelitis, unspecified tibia and fibula
M86.671	Other chronic osteomyelitis right tibia and fibula
M86.672	Other chronic osteomyelitis, left tibia and fibula
M86.679	Other chronic osteomyelitis, unspecified tibia and fibula
M86.68	Other chronic osteomyelitis, other site
M86.69	Other chronic osteomyelitis, multiple sites
M86.9	Osteomyelitis, unspecified

Infected Wound Codes. ICD-10-CM provides codes that combine the concept of infected wound and the type of device or surgery the wound is related to. We believe that many of these codes meet the definition of "infected wound" and should be additionally recognized to meet the intent of the IFC.

Table 4: List of additional ICD-10-CM Codes for Infected Wound

T82.6XXA	Infection and inflammatory reaction due to cardiac valve prosthesis, initial encounter
T82.6XXD	Infection and inflammatory reaction due to cardiac valve prosthesis, subsequent encounter
T82.7XXA	Infection and inflammatory reaction due to cardiac and vascular devices, implants and grafts, initial encounter
T82.7XXD	Infection and inflammatory reaction due to cardiac and vascular devices, implants and grafts, initial encounter
T83.51XA	Infection and inflammatory reaction due to indwelling urinary catheter, initial encounter
T83.51XD	Infection and inflammatory reaction due to indwelling urinary catheter, subsequent encounter
T83.59XA	Infection and inflammatory reaction due to prosthetic device implant and graft in urinary system, initial encounter
T83.59XD	Infection and inflammatory reaction due to prosthetic device implant and graft in urinary system, subsequent encounter
T83.6XXA	Infection and inflammatory reaction due to prosthetic device, implant and graft in genital tract, initial encounter
T83.6XXD	Infection and inflammatory reaction due to prosthetic device, implant and graft in genital tract, subsequent encounter

T84.50XA	Infection and inflammatory reaction due to unspecified internal joint prosthesis, initial encounter
T84.50XD	Infection and inflammatory reaction due to unspecified internal joint prosthesis, subsequent encounter
T84.60XA	Infection and inflammatory reaction due to internal fixation device of unspecified site, initial encounter
T84.60XD	Infection and inflammatory reaction due to internal fixation device of unspecified site, subsequent encounter
T84.7XXA	Infection and inflammatory reaction due to other internal orthopedic prosthetic devices, implants and grafts, initial encounter
T84.7XXD	Infection and inflammatory reaction due to other internal orthopedic prosthetic devices, implants and grafts, subsequent encounter
T85.71XA	Infection and inflammatory reaction due to peritoneal dialysis catheter, initial encounter
T85.71XD	Infection and inflammatory reaction due to peritoneal dialysis catheter, initial encounter
T85.79XA	Infection and inflammatory reaction due to other internal prosthetic device, implants and grafts, initial encounter
T85.79XD	Infection and inflammatory reaction due to other internal prosthetic devices, implants and grafts, subsequent encounter

Miscellaneous Additional Codes. ICD-10-CM includes codes that represent severe wounds, gangrene or other types of ulcers representing a variety of etiologies. Some of the codes represent severe wound conditions such as necrotizing fasciitis, complications of skin grafts, or codes that combine the etiology and manifestation. We believe that the following codes would meet the definition of "severe wound" and should be additionally recognized to meet the intent of the IFC.

Table 5: List of Miscellaneous Additional ICD-10-CM Codes for Severe Wound

I70.261	Atherosclerosis of native arteries of extremities with gangrene, right leg
I70.262	Atherosclerosis of native arteries of extremities with gangrene, left leg
I70.263	Atherosclerosis of native arteries of extremities with gangrene, bilateral legs
I70.268	Atherosclerosis of native arteries of extremities with gangrene, other extremity
I70.269	Atherosclerosis of native arteries of extremities with gangrene, unspecified extremity
I73.01	Raynaud's syndrome with gangrene
I96	Gangrene, not elsewhere classified
M72.6	Necrotizing fasciitis

T85.613A	Breakdown (mechanical) of artificial skin graft and decellularized allodermis, initial encounter
T85.613D	Breakdown (mechanical) of artificial skin graft and decellularized allodermis, subsequent encounter
T85.623A	Displacement of artificial skin graft and decellularized allodermis, initial encounter
T85.623D	Displacement of artificial skin graft and decellularized allodermis, subsequent encounter
T85.693A	Other mechanical complication of artificial skin graft and decellularized allodermis, initial encounter
T85.693D	Other mechanical complication of artificial skin graft and decellularized allodermis, subsequent encounter

Codes to Be Used In Addition to Ulcer or Gangrene Code**.** ICD-10-CM contains a number of rules referred as "sequencing" that require codes to be assigned in a specific order. These rules are governed by instructions such as "code first" or "use additional code" notes that will guide the user to assign diagnosis codes in a specific sequence. The following diagnosis codes fall into that category and should be included in the IFC rule, as sequencing rules dictate that these codes should be the principal diagnosis and therefore sequenced first followed by the specific code to capture the severe wound (ulcer or gangrene).

Table 6: List of Codes to Be Used in Addition to Ulcer of Gangrene Code

E10.622	Type 1 diabetes mellitus with other skin ulcer
E08.52	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy with Gangrene
E08.621	Diabetes mellitus due to underlying condition with foot ulcer
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E09.52	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy with gangrene
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.621	Type 1 diabetes mellitus with foot ulcer
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E13.52	Other specified diabetes mellitus with diabetic peripheral angiopathy with gangrene

E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer
I70.231	Atherosclerosis of native arteries of right leg with ulceration of thigh
I70.232	Atherosclerosis of native arteries of right leg with ulceration of calf
I70.233	Atherosclerosis of native arteries of right leg with ulceration of ankle
I70.234	Atherosclerosis of native arteries of right leg with ulceration of heel and midfoot
I70.235	Atherosclerosis of native arteries of right leg with ulceration of other part of foot
I70.238	Atherosclerosis of native arteries of right leg with ulceration of other part of lower right leg
I70.239	Atherosclerosis of native arteries of right leg with ulceration of unspecified site
I70.241	Atherosclerosis of native arteries of left leg with ulceration of thigh
I70.242	Atherosclerosis of native arteries of left leg with ulceration of calf
I70.243	Atherosclerosis of native arteries of left leg with ulceration of ankle
I70.244	Atherosclerosis of native arteries of left leg with ulceration of heel and midfoot
I70.245	Atherosclerosis of native arteries of left leg with ulceration of other part of foot
I70.248	Atherosclerosis of native arteries of left leg with ulceration of other part of lower left leg
I70.249	Atherosclerosis of native arteries of left leg with ulceration of unspecified site
I70.25	Atherosclerosis of native arteries of other extremities with ulceration
I87.311	Chronic venous hypertension (idiopathic) with ulcer of right lower extremity
I87.312	Chronic venous hypertension (idiopathic) with ulcer of left lower extremity
I87.313	Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity
I87.319	Chronic venous hypertension (idiopathic) with ulcer of unspecified lower extremity
I87.331	Chronic venous hypertension (idiopathic) with ulcer and inflammation of right lower extremity
I87.332	Chronic venous hypertension (idiopathic) with ulcer and inflammation of left lower extremity
I87.333	Chronic venous hypertension (idiopathic) with ulcer and inflammation of bilateral lower extremity
I87.339	Chronic venous hypertension (idiopathic) with ulcer and inflammation of unspecified lower extremity

We thank you for the opportunity to comment on the proposed and interim final rules. We also express our appreciation for the assistance provided by CMS staff in response to questions about the rules. If you have any questions concerning our comments, please feel free to contact Rochelle Archuleta, director of policy, at rarchuleta@aha.org regarding the payment provisions, Akin Demehin, senior associate director of policy, at ademehin@aha.org regarding the quality-related provisions, or Nelly Leon-Chisen, AHA director of coding and classification, at nleon@aha.org, regarding the IFC.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President