June 25, 2018

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

RE: RIN 0938-AT27 Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

Dear Ms. Verma:

On behalf of the organizations and individuals signing below, the Patient Safety Action Network appreciates the opportunity to comment on these proposed regulations. For many years, we have advocated for public reporting of medical harm and programs that hold hospitals accountable for high quality safe care through financial incentives. We strongly support CMS in its efforts to create a national system that informs the public about hospital performance.

Our position in general is that consumers and patients need more information about medical harm, not less. Current public reporting covers only a fraction of the estimated eight million patients harmed each year while being treated in hospitals for some other condition. These proposed regulations take us in the wrong direction by eliminating many of the measures relating to medical errors and hospital-acquired infections from important CMS programs. Every effort should be made to retain outcome metrics, which require hospitals to undertake a large number of processes to obtain a good outcome. There would be less impact on patient safety and relieve a greater burden of facility reporting, if CMS focused on eliminating process metrics instead.

We believe that current hospital "pay for performance" programs are essential tools for improving patient safety. However, the penalties now assessed in these programs in no way approach the cost of subsequent treatment needed by patients, the cost to Medicare/other insurers or the cost to the health care system overall. For that reason, we strongly oppose eliminating the patient safety measures from the Inpatient Quality Reporting (IQR) program, and we disagree with those who view the IQR program as "duplicative." We need more of these programs, not fewer.

Many of the metrics slated for elimination measure "complications" which, according to the proposal, is one of the stated focuses of the initiative that CMS wants to continue. These metrics include measures of hospital-acquired infections caused by drug resistant organisms. This is an epidemic that is not under control and reducing financial incentives for preventing such infections by eliminating these metrics from even one of the IPPS Value Purchasing programs seems unwise. Additionally, very few medical error/ serious adverse event measures currently exist. The proposed elimination of these particular metrics from the Hospital IQR Program is of

paramount concern. Take, for example, the Patient Safety Indicator for reporting the rates of Pressure Ulcers (PSI-03). This information may no longer be available to the public, despite the fact that AHRQ's 2016 report on Hospital Acquired Conditions found this to be the second most common adverse event that occurs in hospitals. Further, there is no burden on the hospitals in claims-based outcome measures and these should be retained.

There is concern regarding the removal of metrics from the IQR since it is the original statutory mechanism that requires this data to be made public on Hospital Compare. While these reporting and payment programs were created at different times and through different laws, they are all somewhat interconnected.

Removing these IQR reporting requirements could eventually lead to less information to the public, depriving consumers of valuable information needed to select a provider and removing the incentive for hospitals to improve their ratings. Policymakers and agencies like CDC rely on this information to track prevention efforts, and hospitals will no longer be able to compare themselves with other hospitals on these particular measures.

For example, these changes could have an impact in states that have changed their laws to be in sync with CMS regulations. The HAC Reduction Program was created by the Patient Protection and Affordable Care Act, which also required this information to be publicly reported on *Hospital Compare*. Even though the agency states strong continued support for this important patient safety program, Congress' continued efforts to repeal the PPACA could put it in jeopardy. If these infection and medical error measures are eliminated in the IQR program, we could be left with nothing in place to incentivize hospitals to report them.

In addition, when reporting hospital-acquired infections, all facilities submit their data to NHSN only once and that data is used for the various programs. Therefore, combining these metrics into a single program does not relieve a significant burden on facilities. However, removing the IQR patient safety measures does create a loss of incentives to strive for excellence, since the HAC program only penalizes poor performing hospitals and does not have financial rewards for high quality.

Finally, with regard to CMS' new Meaningful Measures Initiative, we object to several of the criteria being used to justify elimination of measures here and in the future. The foundation used to determine which measures should be retired should be fully defined and backed by facts.

> Factor 6: "Collection or public reporting of a measure leads to negative unintended consequences other than patient harm." Hospitals often claim unintended consequences as a reason to oppose various measures without offering any evidence backing up their claims. If this is to be used as a legitimate factor, CMS should only use documented evidence of real consequences, not imagined or speculative ones.
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> Factor 8 (proposed): "The costs associated with a measure outweigh the benefit of its continued use in the program." The fundamental flaw with this factor is that it only takes into consideration the costs to hospitals/providers associated with collection and analysis of data related to these measures and compliance with regulations. Also, the costs to CMS for maintaining the website and oversight of the measures. There is no

reference to the cost to patients or to the Medicare program that has to pay for the treatment people need following these events. When harmed patients lose their jobs, their homes, their ability to move about – shouldn't those costs get factored in when it comes to considering the burden?

We strongly encourage the agency to reconsider how these factors are defined.

Long Term Care Hospitals (LTCH) Quality Reporting Program

We have similar concerns about the proposed elimination of metrics for the Long Term Care Hospitals (LTCH) and the provider-oriented criteria CMS is using to determine which measures should be eliminated. We oppose adding Factor 8 (p. 20512: "the costs associated with a measure outweigh the benefit of its continued use in the program") for the same reasons as stated above. It only takes into account the "burden" to hospitals for reporting the harm they caused without fully accounting for the burden to patients who are harmed, their families, and the Medicare program that has to pay for these patients' care, sometimes for years. The fewer the adverse events, the less work it will be to report them.

Once again – we need more measures for these providers not fewer. And we need more financial incentives in place to spur higher quality care and hold them accountable when they fail to prevent errors and infections.

We oppose the proposal to eliminate the NHSN MRSA Bloodstream Outcome Measure (NQF #1716) for LTCHs in favor of the NHSN CLABSI Outcome Measure (NQF #0139). One factor CMS uses to determine whether a measure should be eliminated is if another measure exists "that is more strongly associated with desired patient outcomes for the particular topic." (p. 20511, Federal Register). We disagree that the NHSN CLABSI Measure is more strongly associated with the desired patient outcome for bloodstream infections than the NHSN Facility-wide Inpatient Hospital-Onset MRSA Bacteremia Measure. The proposal claims that these two measures capture the same type of MRSA infection and "results in the data submission on two measures that cover the same quality issue." We do not feel the underlying assumption that the CLABSI metric can substitute for the MRSA bloodstream metric is valid. Although MRSA infections are a subset of total CLABSI infections, the two outcome metrics are entirely different since they measure and are dependent upon different processes for prevention. The CLABSI Outcome metric is largely dependent upon following procedural protocols and while performance on the MRSA Facility Wide Bloodstream metric is dependent upon epidemiological tracking, isolation, decolonization, environmental cleaning along with many other factors.

In addition, we oppose eliminating the LTCH metric for Ventilator-Associated Events (VAE). Preventing these events is also dependent upon specific processes, which are different from those needed to prevent Central Line Infections. These deadly infections are a significant infection-related problem in these facilities. Knowledge of the incidence of these deadly infections is very important for epidemiological tracking.

We appreciate the agency's statement of support for continuing and growing the Hospital Acquired Conditions Reduction Program. We agree with this statement in the proposal: "…continued efforts to reduce HACs are vital to improving patients' quality of care and reducing complications and mortality, while simultaneously decreasing costs. The reduction of HACs is an

important marker of quality of care and has a positive impact on both patient outcomes and cost of care. Our goal for the HAC Reduction Program is to heighten the awareness of HACs and reduce the number of incidences that occur." We support the development of electronic clinical quality measures (eCQMs) in the future for this program and encourage these to focus on preventable common medical errors for which we have few measures, such as medication errors.

It is very important for these patient safety metrics to be readily available to the public in an understandable format. It is equally important that financial incentives remain in place to encourage safer care, because currently Medicare patients and the Medicare program bear most of the cost of this harm. All too often the patients get lost in the statistics. Patients are the beneficiaries of these critical public reporting and pay for performance programs. If the proposals to eliminate these measures are adopted, the real impact will be on the safety of future patients.

Sincerely,

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