June 25, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1694-P
P.O. Box 8011
Baltimore, MD 21244–1850

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

Dear Ms. Verma:

On behalf of its 71 acute care hospital members, the New Jersey Hospital Association (NJHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital inpatient prospective payment system (PPS) proposed rule for fiscal year (FY) 2019.

While we support a number of the proposed rule's provisions, including the implementation of CMS's "meaningful measures" initiative, a we have concerns about others. In particular, NJHA has serious concerns about CMS's proposal to discontinue its policy on the imputed floor wage index and the agency's proposal to proceed in weighting Worksheet S-10 at two-thirds for Medicare DSH payments in FY 2019.

IMPUTED FLOOR WAGE INDEX POLICY

As we have outlined in an earlier comment letter (submitted under separate cover on May 18, 2018), NJHA is extremely disappointed that CMS has signaled its intention to discontinue its policy on the imputed floor. In the rulemaking process for the fiscal year 2005 inpatient prospective payment system (PPS), CMS proposed, then finalized, an "imputed" floor wage index policy for all-urban states. We applaud CMS's vision in recognizing the inequity inherent in the Medicare wage index system for all-urban states prior to FY 2005, and for establishing an internally-consistent approach to remedy the situation through the creation of the imputed floor wage index policy. As part of its rationale for implementing the imputed floor, CMS keenly acknowledged the competitive disadvantage suffered by all-urban states in the absence of an imputed floor wage index.

Referencing the existence of a single "predominant" labor market in New Jersey, CMS stated that such a situation, "forces hospitals that are not located in the predominant labor market area to compete for labor with hospitals that are located in that area." The agency elaborated that, "because there is no ''floor'' to protect those hospitals not located in the predominant labor market area from facing continued declines in their wage index, it becomes increasingly difficult for those hospitals to continue to compete for labor." Furthermore, CMS stated, "**we think it is also an anomaly that hospitals in all-urban States with predominant labor market areas do not have any type of protection, or "floor," from declines in their wage index. Therefore, we are adopting the logic similar to that articulated by Congress in the BBA and are adopting an imputed rural policy for a 3-year period** (emphasis added)." (69 FR 49110)

NJHA has strongly supported the imputed floor policy, which CMS has upheld for over a decade as a valuable method of maintaining equitable wage index protections for all-urban states consistent with those that exist for states with rural areas. New Jersey is one of three all-urban states, along with Delaware (per the "alternative methodology") and Rhode Island (per the "alternative methodology"), benefiting from these protections. The imputed floor wage index provision has been extended eight times since its initial three-year implementation beginning in FY 2005.

FY 2008	One-year extension
FY 2009	Three-year extension
FY 2012	Two-year extension
FY 2014	One-year extension
FY 2015	One-year extension
FY 2016	One-year extension
FY 2017	One-year extension
FY 2018	One-year extension

The unique financial conditions facing the New Jersey hospital field, including its close proximity to some of the most competitive and densely populated labor markets in the country, are just as challenging today as they were when CMS originally acknowledged these issues in creating the imputed floor. New Jersey is arguably the most unique market in the country, particularly for hospital labor. Several factors contribute to this uniqueness, and together they create a complex competition for labor that does not exist elsewhere. These factors include the following:

- Population Density – New Jersey is the most densely populated State in the nation, with 1,196 residents per square mile. In contrast, there are 87 residents per square mile when viewing the United States as a whole. Regionally, even neighboring States Pennsylvania and New York pale in comparison, with 284 and 411 residents per square mile, respectively.

- Commuting Ease – The entire State of New Jersey can be traversed from coast to coast in roughly one hour. With workers willing to travel longer and with greater access to highways and mass transit options, people are increasingly basing employment on who offers better wages. New Jersey hospitals compete for labor with hospitals in the first and fifth largest cities in the country: New York City and Philadelphia. Across these markets, 173 acute care hospitals compete for limited labor resources. The ease of commuting exacerbates an already-intense

workforce competition and drives up the cost of labor in the New York City-New Jersey-Philadelphia market.

- Prevalence of Teaching Programs – New Jersey as a State is more akin to a major northeastern city in terms of its hospital teaching program density. Sixty-eight percent of New Jersey hospitals have teaching programs. This is double the national average of 34 percent. One has to drill down to cities like Boston (64 percent) and Philadelphia (65 percent) to find regions with similar concentrations of teaching hospitals.

Population density, employment options and commuting ease serve to intensify the competition for New Jersey's finite pool of healthcare workers. It is prudent that the imputed floor policy continues to ensure that our state's hospitals are not artificially disadvantaged simply because of geography and population.

We would also like to bring to your attention the following additional policy views in favor of maintaining the imputed floor wage index policy.

- **"STATUS QUO"**
  In both the FY 2014 and FY 2015 final rules, CMS extended the imputed floor for an additional year, during which time the agency would continue to explore potential wage index reform. In April 2012, CMS submitted recommendations to Congress on ways to reform the Medicare area wage index. The agency's proposals would likely have obviated the need for an imputed floor, but since the report was submitted neither Congress nor CMS has taken action to effectuate the needed reforms. Therefore, because of the critical importance of the imputed floor to our hospitals, it is the position of the New Jersey Hospital Association that the imputed floor policy remains in effect until such time that comprehensive wage index reform is accomplished either through the regulatory process or by an Act of Congress. **CMS should maintain the status quo – including the imputed floor policy – throughout the entirety of the wage index system until such reform is achieved.**

- **TRANSFER OF PAYMENTS**
  In the FY 2019 IPPS proposed rule, CMS states that:

  > …the application of the rural and imputed floors requires transfer of payments from hospitals in States with rural hospitals but where the rural floor is not applied to hospitals in States where the rural or imputed floor is applied. For this reason, in this proposed rule, we are proposing not to apply an imputed floor to wage index calculations and payments for hospitals in all-urban States for FY 2019 and subsequent years. (83 FR 20363)

  By eliminating the imputed floor wage index, CMS is alleviating only a fraction of the combined payment transfer from application of the rural and imputed floors. According to data in the FY 2018 final IPPS rule, 17 New Jersey hospitals received the imputed floor. Combined, the three all-urban states of New Jersey, Rhode Island and Delaware accounted for less than 10 percent of the 400 hospitals nationally that received either the rural or imputed floor last year.

- **LOSS OF FUTURE PROTECTION / UNEVEN PLAYING FIELD**
  CMS also states that the imputed floor creates "a disadvantage in the application of the wage index to hospitals in States with rural hospitals but no urban hospitals receiving the rural floor." However, those urban hospitals retain all the future wage index protections associated with the rural floor. Eliminating the imputed floor would create the same uneven playing field that existed prior to 2005, in response to which CMS initially established the provision. The anomaly originally cited by CMS (i.e., that hospitals in all-urban states with predominant labor market areas do not have any type of protection, or "floor," from declines in their wage index) would exist again should the imputed floor be eliminated.

- **OTHER MEDICARE PROGRAMS ARE REDISTRIBUTIVE**
  There are many Medicare payment programs that redirect scarce Medicare funding to a class of unique hospitals. Not all states have hospitals that benefit from this funding. For example, CMS makes payments to Critical Access Hospitals (CAH) at a rate of 101 percent of their cost. New Jersey does not have any Critical Access Hospitals and therefore does not benefit from this program. While CAHs are paid outside the IPPS program, the dollars continue to come from a finite Medicare trust fund. This represents a transfer of payments from hospitals in states without any CAHs into states with CAHs similar to the transfer of payments CMS cites as its rational to discontinue the imputed floor.

There is precedent for CMS to restore, in the final rule, policies or provisions that were scheduled for elimination in the proposed rule. In the FY 2012 inpatient IPPS proposed rule, CMS stated that the imputed floor would expire on Sept. 30, 2011. However, in the final rule CMS announced that the imputed floor provision was extended for two additional years, through FY 2013 (Sept. 30, 2013). Then again, just last year CMS proposed to discontinue the imputed floor wage index in the proposed rule only to reverse itself in the FY 2018 final rule and extend the policy for an additional year.

NJHA and our member hospitals throughout the state have long maintained that the imputed floor wage index creates a climate of symmetry, equity and consistency in the Medicare reimbursement process. **We strongly urge CMS to rescind its proposal to discontinue the imputed floor wage index policy.**

DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENT CHANGES

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

TRANSITION TO WORKSHEET S-10
In FY 2018, CMS began incorporating the cost report Worksheet S-10 data on hospital charity care and bad debt to determine the amount of uncompensated care each hospital provides. For FY 2019, CMS proposes to continue phasing in the S-10 data and also to continue to use data from a rolling three-year period to estimate uncompensated care payments. Specifically, for FY 2019, CMS would use FY 2014

and 2015 Worksheet S-10 data in combination with FY 2013 Medicaid days and Supplemental Security Income (SSI) ratios to determine the distribution of uncompensated care payments.

CMS indicates its plans to selectively review Worksheet S-10 for hospitals with aberrant or extreme data, but does not indicate any plans to establish a desk audit process before it begins to use solely these data in distributing uncompensated care payments. NJHA urges CMS to consider our comments and to revisit its position. More specifically, **we urge CMS to allow providers to amend the FY 2016 cost reports at your very earliest convenience and articulate a process for audit of this data in the final rule.**

Generally speaking, NJHA continues to believe that, if reported in an accurate and consistent manner, the Worksheet S-10 data have the potential to serve as a more exact measure of hospital uncompensated care costs. However, as explained below, while NJHA applauds CMS's efforts to clarify the instructions, make significant changes in policy to allow for uninsured discounts and afford hospitals the opportunity to update their data, we remain concerned that – absent a systematic data audit – CMS continues to make more than $8 billion dollars in uncompensated care payments to hospitals based on data that are not yet reliable or valid for purposes of payment.

NJHA recognizes and understands CMS's position about the use of Worksheet S-10, as well as the concerns raised by stakeholders about continued use of proxy data. Though we would prefer that CMS discontinue the use of Worksheet S-10 data, we do not believe it is a solution the agency will consider. Therefore, absent delaying its use altogether we recommend that CMS strongly consider using the most recent year of Worksheet S-10 data (2015) – which is more likely to be consistently reported – instead of a combination of 2014 and 2015.

Specifically, NJHA opposes CMS's proposal to proceed in weighting Worksheet S-10 at two-thirds. We also believe the use of two years of unaudited Worksheet S-10 data presents a number of challenges. Instead, we suggest that CMS use one year of S-10 data (FY 2015), weighted at the current one-third, and low-income patient days, weighted at two-thirds, for FYs 2019 and 2020. NJHA agrees with continuing to use FY 2016 Medicare SSI days in combination with either FY 2012 and FY 2013 Medicaid inpatient days, weighted equally, or FY 2013 Medicaid inpatient days weighted at two-thirds. This is one of several options the agency should consider to afford CMS and hospitals additional time to improve CMS's ability to appropriately redistribute the uncompensated care pool to hospitals.

NJHA appreciates the agency's response to comments about the reporting instructions' lack of clarity, which resulted in variation in hospital reporting and unexplainable aberrant data. The late 2017 release of Transmittal 11, along with a *Medicare Learning Network Matters* article and frequently asked questions, was welcome and much-needed guidance for the field. We urge CMS to continue its efforts to engage with stakeholders in addressing these and other outstanding questions. Shared understanding of reporting expectations is the only way to ensure reliable and valid data reporting and auditing.

Following the release of these instructions, CMS allowed hospitals a brief, four-month period (Sept. 29, 2017, through Jan. 2, 2018) to resubmit both their FY 2014 and FY 2015 cost reports in accordance with the revised instructions outlined in Transmittal 11. Revisions submitted during that period were used in

the FY 2019 uncompensated care distribution analysis conducted by CMS as part of the rulemaking process**.** In conversations with hospitals and cost report experts around the country, NJHA has learned that – while these changes were welcome – many hospitals did not have sufficient time or internal financial or personnel resources to comply. While CMS notes that more than half of providers took this opportunity to amend their cost reports, it is clear that the accuracy of those updates remains in question.

In addition, it is our understanding that a subsequent review of data conducted by CMS and the Medicare Administrative Contractors (MACs) in March and April largely focused on the FY 2015 data, and perhaps paid much less attention to equally troubling FY 2014 data. While we do not know the scope of CMS's outreach to providers, we are concerned about the potential of significant differences in uncompensated care reporting from FY 2014 to FY 2015, not because of meaningful changes in how much uncompensated care individual hospitals actually provided but because of the differences in how hospitals completed and revised (or did not revise) their S-10 forms for the two years in question.

Despite CMS's national provider call and education provided by NJHA, other state hospital associations and numerous cost report experts, we believe the following factors have contributed to inaccurate reporting by many hospitals around the country:

- On average, it took cost report consultants – experts in the field of reporting – 50 to 80 hours per hospital client to pull data necessary for accurate reporting and compile supporting documentation in preparation for future audit. From Oct. 1 through Jan. 2, excluding holidays, only 62 business days were available to complete this work. There was simply not sufficient time for many hospitals and their partners to understand the changes and accurately report.
- Several hospitals in New Jersey and around the country were subject to EHR audits by the Office of Inspector General at various points throughout the year. Hospitals that were audited after the revised instructions were released reported that, following submission of revised Worksheet S-10 data, additional errors were found – attributable to the short timeline. Hospitals that had undergone an EHR audit prior to the release of updated instructions felt more prepared to respond under the short timeline but, after further review, also noted inconsistencies in their reporting.
- For the FY 2014 and 2015 cost report years, CMS also changed what hospitals can include in their reporting – most notably, whether hospitals may consider uninsured discounts. This required a complete review of patient-level data to ensure accurate reporting, a daunting and time-consuming task that, for some hospitals, was simply not achievable due to limited personnel and financial resources.
- Hospitals with inadequate internal financial management tracking systems were at an extreme disadvantage in meeting this timeline because much of their work had to be done manually, leading to further variation in reporting.

While the policy and instructional changes made by CMS have significantly improved shared understanding of expectations for reporting, we believe the agency underestimates the significant impact this has had on the data reported. Therefore, **we believe it remains premature – and inconsistent with sound financial management concepts – to distribute more than $8.25 billion in federal uncompensated care payments based on largely unaudited Worksheet S-10 data**.

NJHA continues to believe that reliable and valid data are achievable if we continue to examine the data and ask critical questions. Regardless of our disagreement over CMS's current proposed policy position to continue to use this data, we endeavor to ensure compliance with the policies once they are adopted. NJHA believes the agency is falling short in ensuring adherence to its newly revised instructions, putting providers at risk of future audits. We also understand that hospitals have a significant role to play in improving the data, and stand ready to work with the agency in doing so. However, as stated previously, **we believe that CMS and hospitals need additional time to understand these shortcomings and make mid-course corrections. This is the only way to avoid significant payment variations that will occur from year to year for so many hospitals across the country, exposing them to substantial financial risk and jeopardizing access to care for Medicare beneficiaries.**

In our endeavor to contribute to the understanding of the reported data's shortcomings, the California Hospital Association (CHA) contracted with Toyon & Associates – a nationally recognized cost report and reimbursement firm based in California – to review the Worksheet S-10 data as well as cost reports resubmitted by hospitals following Transmittal 11's release. CHA's analysis focused on DSH hospitals for which Worksheet S-10 data are used to determine uncompensated care payments.

The analysis indicated that there continue to be major shortcomings in the Worksheet S-10 data and continued confusion among hospitals about how to accurately fill out certain elements of the Worksheet S-10 cost report. CMS's assumption – that because half of hospitals submitted revised cost reports, those reports must be accurate – is flawed, as evidenced by the data analysis. We believe the problems with the Worksheet S-10 data are more widespread than CMS plans to address before FY 2019. Additionally, we believe its plan to selectively review cost reports with the most aberrant data or the largest increases in uncompensated cost reports following Transmittal 11 is insufficient, given the magnitude of the inconsistencies and the importance of accurately allocating over $8 billion dollars in uncompensated care funds to hospitals.

In the proposed rule, CMS indicates that it has instructed the MACs to review situations in which a hospital has an extremely high ratio of uncompensated care costs to total operating costs. If the hospital cannot justify its reported uncompensated care amount, CMS proposes to use the ratio of uncompensated care costs to total costs from a different year (either FY 2015, FY 2016 or FY 2017) and apply it to the hospital's operating cost for the aberrant year. CMS indicates that it plans to employ a similar process for reviewing data from hospitals that had the largest increases in uncompensated care costs as a result of resubmitting their FY 2014 or FY 2015 cost reports. That is, if the hospital cannot justify its reported costs, CMS will use the hospital's ratio of uncompensated care costs to total costs from a different year and apply it to the hospital's operating cost for the aberrant year.

NJHA does not believe that CMS's suggested actions will sufficiently address the data problem with Worksheet S-10. CMS and the MACs need additional time to understand the data reported so that appropriate trim policies can be implemented going forward.

Rather than addressing only the most extreme cases, **NJHA recommends slowing the transition to use of Worksheet S-10 to allow for further examination of the data and development of an action plan to make improvements over time.** In addition, using one year of data allows for closer examination and development of effective policies. We understand that this process will take time and will evolve,

but – absent additional work to improve the data – we do not support the speed at which the agency is moving to fully implement use of Worksheet S-10 data.

NJHA urges CMS to work with the field in investing resources to improve the data's accuracy. We look forward to working with CMS on additional refinements, but – at a minimum – suggest that the agency:

- Include edits to ensure internal consistency between the same amounts reported on different worksheets.
- Include edits within the cost report to ensure that reported amounts and calculated amounts are equal, or that data entry is not permitted for amounts that can be calculated from other information on the cost report.
- Begin immediately to establish a desk review audit similar to that used for the wage index.

Worksheet S-10 data are now the source of uncompensated care information for all hospitals. This data set is publicly available and downloadable. It will be accessed by various stakeholders, media, researchers, state and federal agencies, and others. Hospitals and CMS must work together to ensure its accuracy, as the current variation is unexplainable due to multiple policy and instruction changes that have occurred in the last 18 months. While we are not surprised that the data remain a challenge, we do believe they can, and will, improve over time. CMS must make this an agency priority and dedicate the resources necessary to undertake this work.

In the meantime, overstatement of uncompensated care for any single hospital rewards that hospital with higher payments, at the expense of all other hospitals – even those that have reported uncompensated costs correctly. Similarly, a hospital that underreports uncompensated care payment disadvantages itself and rewards all other hospitals with higher uncompensated care payments, even if those hospitals reported uncompensated costs incorrectly. **Not auditing these data is inconsistent with ensuring proper payments. It is critical that CMS ensure these data are reported consistently, accurately and according to government auditing standards as soon as possible.**

To summarize, NJHA recommends that CMS use one year of Worksheet S-10 data (FY 2015), weighted at one-third, and low-income patient days, weighted at two-thirds, for FYs 2019 and 2020. This proposal has the following advantages:

- Hospitals have been given more of an opportunity to fix potential issues associated with FY 2015 S-10 worksheet data. The analysis by the California Hospital Association found it to be slightly more accurate than FY 2014 data. However, we acknowledge that this may disadvantage some hospitals that had the resources to update both years of data and believe their reporting is accurate.
- This proposal allows time, over the next two years, to fully audit FY 2016 data to establish a baseline for subsequent audits. We urge the agency to engage in provider education simultaneously with these audits to ensure shared expectations and understanding of reporting instructions.
- It is consistent with CMS's prior statements to begin a desk review audit process analogous to the IPPS wage index on FY 2017 Worksheet S-10 data that will be used for the FY 2021 payment distribution.

- It avoids distributing more than $8 billion based on data that are clearly erroneous and inconsistently reported. It would also improve the likelihood that data are distributed in a manner consistent with government accounting practices.
- It avoids using FY 2014 low-income patient data, which are affected by Medicaid expansion under the ACA – a major concern motivating CMS to move to using Worksheet S-10 data beginning with FY 2018.

In FY 2021, CMS could reevaluate the quality of the Worksheet S-10 data and either 1) phase-in the new data over a multi-year period to minimize annual payment redistribution and allow continued improvements in data quality, or 2) consider moving to one year of Worksheet S-10 data, dependent on consistency and quality, as suggested in the FY 2019 IPPS proposed rule.

TECHNICAL COMMENTS RELATED TO THE WORKSHEET S-10

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

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

DSH SUPPLEMENTAL PUBLIC USE FILES

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

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

amounts for most of the providers do not match with AHA's calculations. **NJHA suggests CMS verify the accuracy of these values, such as in the example above, in the FY 2019 final rule.**

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM

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

MOVING CMS QUALITY MEASUREMENT TOWARDS MEANINGFUL MEASURES

NJHA applauds CMS for beginning to use its "Meaningful Measures" framework to streamline the measures used in its hospital quality reporting and value programs. NJHA supports agency efforts to reduce and prioritize the measures used in its quality programs so that they focus on the issues that matter the most to improving care and outcomes. CMS's Meaningful Measures framework identifies six overarching quality priorities and 19 specific measurement areas aligned with those priorities. The priorities CMS identified are intended to cut across the full continuum of its quality measurement programs – hospitals, physicians, post-acute care and health plans. **NJHA is pleased that most of the "meaningful measure" priority areas are ones that the American Hospital Association has consistently recommended to the agency.**

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

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

PROPOSED MEASURE REMOVALS

NJHA supports CMS's proposed removal of 39 measures from the IQR program for FYs 2020 through FY 2023. Of the 39 measures proposed for removal, 18 measures would be removed from hospital quality programs altogether because they are "topped out" in performance, do not lead to better care or have costs that outweigh their value. The remaining 21 measures would be "de-duplicated." That is, the measures would be removed from the IQR program, but retained in only one of the other hospital measurement programs (i.e., VBP, HAC or HRRP). We agree with CMS's assessment of the 18 measures that would be removed altogether. We also agree that de-duplication can reduce administrative

burden because hospitals would no longer receive multiple preview reports on the same measures that might contain slightly different performance data.

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

- The timing of the removal of the 18 measures from Hospital Compare. The website is updated quarterly, so CMS should clarify what the final quarter of publicly-reported data would be for each measure
- How the 21 de-duplicated measures will be displayed on *Hospital Compare.* In the proposed rule, CMS indicates that all of the de-duplicated measures will continue to be publicly reported on *Hospital Compare.* However, the website currently has two different ways of reporting information. IQR measures are displayed on *Hospital Compare* itself with graphics that show how individual hospital performance compares to others. However, performance results for VBP, HAC and HRRP are displayed by linking to interactive spreadsheets on data.cms.gov. Those spreadsheets are not nearly as user-friendly as the *Hospital Compare* website itself. Thus, we encourage CMS to explore whether it can retain measure data reporting in the more user-friendly format used for IQR measures.
- How the measure removals would impact Hospital Overall Star Ratings. Lastly, we note that many of the measures proposed for removal from the IQR are used in CMS's Overall Hospital Star Rating. The current methodology for star ratings suggests that CMS draws measures from only the IQR and outpatient quality reporting (OQR) programs. As a result, it is not clear whether the measures would remain in the star ratings methodology, or whether the methodology would be altered to include measures that are in one of the value payment programs.

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

POTENTIAL FUTURE IQR MEASURES

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

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

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

While risk adjustment can help, we know of no risk adjustment method that is up to the task of adjusting for the many varied clinical and sociodemographic differences that may put a patient at a higher risk of death, even if the patient receives perfect care. Thus, this measure might actually serve to obscure any meaningful differences in performance. In fact, a technical report on the measures released in November 2017 show that of the 4,793 hospitals included in the analysis, only 102 (2.1 percent) show up in the better than average category, and only 6 hospitals in the worse than average category (0.1 percent), leaving over 97 percent of hospitals as not statistically different from one another.

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

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

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

eCQMs IN THE IQR PROGRAM

For the FY 2021 payment determination, CMS proposes to continue the FY 2020 IQR Program requirement, specifically that hospitals will report on a minimum four self-selected eCQMs from the 15 eCQMs available for reporting to the IQR Program. CMS proposes hospitals submit one self-selected quarter of eCQM data from calendar year (CY) 2019. CMS does not propose any changes to the

submission deadlines. CMS also does not propose changes to sampling or case threshold policies. CMS proposes to continue the alignment of eCQM reporting requirements in the Hospital IQR Program and the Promoting Interoperability Programs. **NJHA supports continuation of current eCQM reporting policies for the CY 2019 reporting period. We also recommend that CMS monitor the transition to the 2015 edition EHR and the shift to the Clinical Quality Language (CQL).**

For the FY 2022 payment determination, CMS proposes to require hospitals to report on a minimum of four self-selected eCQMs from eight eCQMs proposed to be available for reporting to the IQR Program. **NJHA supports the proposal to remove seven eCQMs as the reduction aligns with the Meaningful Measures framework. We also support the proposal as it reiterates our view that two years is required between an eCQM included in a final rule and the start of hospital eCQM reporting.** We recommend that CMS continue to evaluate eCQM data submitted and findings from the eCQM validation process to inform future program requirements and to inform hospitals about successful practices in eCQM reporting. NJHA also supports the continued alignment of eCQM reporting requirements in Hospital IQR and the Promoting Interoperability Programs.

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

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

Expand Meaningful Engagement Opportunities with Hospitals. Hospitals continue to demonstrate their willingness to participate in initiatives aimed at improving existing eCQMs. However, the participation will be enriched when hospitals are able to discuss eCQM improvement in the context of data from prior eCQM data submissions and an opportunity to inform future eCQM priorities that reduce reporting burden and advance improvements in the quality of care. **NJHA recommends that CMS develop a**

long-term strategy for eCQMs that applies the Meaningful Measures framework to eCQMs, the development of metrics to inform the readiness of eCQM data for public reporting and an ongoing role for hospital engagement.

Increase Opportunities for Hospitals to Participate in eCQM Testing and Innovative Uses of Health Information Technology (IT). In the request for comment, CMS asks how to encourage hospitals to engage in testing new eCQMs and what could incentivize or reward innovative uses of health IT. **NJHA recommends that hospitals participating in eCQM testing or engaging in innovative use of health IT receive credit for meeting the eCQM reporting requirement in the Promoting Interoperability Programs.** We recommend that CMS work with hospitals to identify areas of innovative use of health IT that align with the Meaningful Measures framework. We also recommend that CMS work with their federal partners to encourage health IT vendors to support hospitals in their efforts to use eCQMs and health IT to address the highest priority areas for quality measurement and improvement.

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

HOSPITAL VBP PROGRAM

As required by the ACA, CMS proposes to fund the FY 2019 VBP program by reducing base operating DRG payment amounts to participating hospitals by 2.0 percent. The VBP program is budget neutral; all funds withheld must be paid out to hospitals. CMS proposes to remove a total of 10 measures from the VBP, including all 7 measures used in the "safety of care" measure domain. Those 7 measures would be retained in the HAC Reduction Program. CMS also proposes to re-weight VBP's measure domains.

PROPOSED MEASURE REMOVALS

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

NJHA also supports the proposed removal of the three condition-specific episode-based payment measures related to heart attack, heart failure, and pneumonia from the VBP. While we continue to agree that well-designed measures of cost and resource use can assist with assessing the value of care, we have long been concerned that the overlap between these condition-specific measures and Medicare spending per beneficiary (MSPB) measure may lead to unnecessary confusion among hospitals and patients.

PROPOSED VBP MEASURE DOMAIN REWEIGHTING

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

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

NJHA urges CMS to adopt its alternative approach of weighting all three measure domains equally. It appears that CMS's preferred approach of increasing the clinical domain to 50 percent would result in significantly more hospitals experiencing a loss under the VBP program. With this methodology, we estimate that only 44 percent of hospitals would experience a gain under VBP, while 56 percent would incur a loss. In contrast, the equal domain weighting approach would result in a roughly 50/50 distribution of VBP gains and losses.

Furthermore, NJHA does not agree with the GAO's assessment that hospitals that score well on the efficiency/cost domain should be deemed unworthy of a gain under the VBP program. The whole point of the VBP program is to assess hospitals on a variety of performance indicators, and reward them for both their achievement versus other hospitals, and improvement from their own baseline. It seems arbitrary for CMS to engineer a scoring methodology to systematically disadvantage those hospitals that have made strides in managing their costs effectively. We believe the equal weighting approach provides a more balanced and equitable assessment of hospital performance.

MODERNIZING THE HOSPITAL CONSUMER ASSESSMENT OF PROVIDERS AND SYSTEMS SURVEY

CMS does not propose changes to the HCAHPS survey and would retain it in both the IQR and VBP programs. **While NJHA continues to support the use of the HCAHPS, we believe the agency should undertake a review of how it uses all surveys in the CAHPS family, and consider approaches to modernizing how the survey is administered. This assessment should begin with an examination of CAHPS survey requirements across all of its reporting programs to minimize the number of surveys that patients must respond to in a given time.** A patient's course of care often crosses multiple care settings and providers within a given time period, and the CAHPS program has surveys for

nearly every setting. Indeed, CAHPS includes surveys for physicians, hospitals, dialysis facilities and home health agencies. Patients who receive care in two or more of these settings could receive multiple surveys. Typically, surveys are not distributed until days or weeks after a patient has received their care. This may create confusion about which provider or facility is actually being assessed. A patient may inadvertently attribute a positive or negative experience to the wrong provider.

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

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

HOSPITAL-ACQUIRED CONDITION (HAC) REDUCTION PROGRAM

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

GENERAL CONSIDERATIONS

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

NJHA continues to support quality measurement and pay-for-performance programs that effectively promote improvement, especially value-based approaches that measure both a hospital's actual performance, as well as how much it has improved over a baseline period.

For this reason, we have long opposed the arbitrary statutory design of the HAC Reduction Program, which imposes penalties on 25 percent of hospitals each year, regardless of whether hospitals have improved performance, and regardless of whether performance across the field is consistently good. In addition, we are concerned that CMS's implementation of the program has unfairly placed teaching hospitals, large hospitals, small hospitals and hospitals caring for larger number of poor patients at greater risk of a penalty as a result of faulty measurement, not bad performance.

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

ELIMINATION OF MEASURE DOMAINS

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

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

Furthermore, NJHA continues to urge CMS to remove the deeply flawed patient safety indicator (PSI) composite measure from the HAC program and any hospital reporting or pay-for-performance program. NJHA has long been concerned by the significant limitations of PSI 90 as a

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

Examples of the inconsistency of the results of PSI component measures with clinical reality abound.[1] One recent study that validated the results generated by PSI 3 (pressure ulcer rates) using direct patient surveillance found that PSI 3 frequently misclassified hospital performance.[2] And another recent study showed that performance on the PSI measures is more a function of bed size than of underlying quality performance.[3] It is not surprising, then, that a CMS-commissioned study showed that many of the individual components of PSI-90 have low levels of reliability when applied to Medicare claims data.[4]

MEASURE VALIDATION REQUIREMENTS FOR HAI MEASURES

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

HOSPITAL READMISSIONS REDUCTION PROGRAM (HRRP)

The HRRP imposes penalties of up to 3.0 percent of base inpatient PPS payments for having "excess" readmissions rates for selected conditions when compared to expected rates. CMS proposes only minor updates to the program for FY 2019. Additionally, CMS will continue to implement the socioeconomic

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[1] See for example:
Ramanathan R et al. Validity of Agency for Healthcare Research and Quality Patient Safety Indicators at an academic medical center. The American Surgeon. 2013 Jun; 79(6):578-82.
Cevasco M et al. Validity of the AHRQ Patient Safety Indicator "central venous catheter-related bloodstream infections. Journal of the American College of Surgeons. 2011 Jun;212(6):984-90;
Kaafarani H et al. Validity of Selected Patient Safety Indicators: Opportunities and Concerns. Journal of the American College of Surgeons. 2011 Jun; 212(6):924-34.
Utter GH, Zrelak PA, Baron R, et al. Positive predictive value of the AHRQ accidental puncture or laceration patient safety indicator. Ann Surg. 2009;250(6):1041-1045
Rajaram R et al. Concerns About Using the Patient Safety Indicator-90 Composite in Pay-for-Performance Programs. Journal of the American Medical Association. 2015; 313(9):897-898.
[2] Meddings JA et al. Hospital Report Cards for Hospital-Acquired Pressure Ulcers: How Good are the Grades. Annals of Internal Medicine. 519(8):505-13. October 2013.
[3] Koenig L et al. Complication Rates, Hospital Size and Bias in the CMS Hospital-Acquired Condition Reduction Program. American Journal of Healthcare Quality. Dec. 19, 2016.
[4] See http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf

adjustment approach mandated by the 21st Century Cures Act of 2016 that it adopted in the FY 2018 inpatient PPS final rule.

PROPOSED FY 2019 PERFORMANCE PERIOD

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

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

REFINING SOCIOECONOMIC ADJUSTMENT

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

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

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

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

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

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

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

PROMOTING INTEROPERABILITY PROGRAM

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

- **Removing objectives and measures that hold hospitals responsible for the actions of others;**
- **Shifting the program to a performance-based scoring methodology that eliminates required thresholds and permits hospitals to get credit for building performance in some areas while earning additional points in areas of strong performance;**
- **Establishing a threshold of 50 points to meet the measure scoring requirements and avoid payment penalties; and**

- **Setting the reporting period to be of a minimum of any continuous 90-day period in calendar years (CYs) 2019 and 2020.**

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

NJHA RECOMMENDATIONS SUPPORTING THE TRANSITION TO THE PROMOTING INTEROPERABILITY PROGRAM

NJHA shares CMS's view that eligible hospitals (EHs) and eligible professionals will benefit from additional time to implement and optimize the 2015 edition certified EHR technology. Experience to date indicates that the transition to a new edition of certified EHR technology is challenging due to lack of vendor readiness, the necessity to update other systems to support the new data requirements, the time required review and modify workflows and build performance. We are concerned that the 2019 transition will present additional challenges due to new reporting requirements and requirements to use EHR functionality that was not included in the 2015 edition certification criteria. To address these challenges and to provide additional relief to providers, NJHA offers several recommendations intended to facilitate an effective transition to the Promoting Interoperability Program and the safe use of 2015 edition certified EHRs.

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

Objective	**Measures**	**Maximum Points**
e-Prescribing	e-Prescribing Query of PDMP Verify Opioid Treatment Agreement	20 points in 2019 (includes 10 bonus points for new opioid measures) 15 points in 2020
Health information exchange	Create and Send Summary of Care Receive Summary of Care and Conduct Clinical Information Reconciliation	40 points
Provider to patient exchange	Provide Patients Electronic Access to Their Health Information	40 points in 2019, 35 points in 2020

Public health and clinical data exchange	Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Registry Reporting Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Results Reporting	10 points
EHs must report on all required objectives and measures. An overall score of 50 or more points would be sufficient to meet meaningful use and avoid a Medicare payment penalty. The Protecting Patient Health Information objective does not have a performance-based measure but EHs are required to attest to meeting the Security Risk Analysis measure requirements.		

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

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

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

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

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

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

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

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

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

PROVIDE ADDITIONAL FLEXIBILITY TO SUPPORT HEALTH INFORMATION EXCHANGE

CMS proposes two measures for health information exchange in support of transitions of care or referrals to another care setting. The first measure requires the creation and sending of a summary of care record using certified EHR. The second measure requires the receipt and clinical information reconciliation of the information received in the electronic summary of care record. The 2015 edition EHR certification criteria that support the creation, sending and receipt of a summary of care record is limited to the consolidated continuity of care document (C-CDA), referral summary and discharge summary document. Other document templates are available, but EHRs are not required to be certified to support them. The ONC Trusted Exchange Framework and Common Agreement (TEFCA) may create opportunities for EHs to utilize other formats or mechanisms to enable health information

exchange. As an interim step in this journey, **NJHA recommends that CMS allow EHs and EPs to use certified EHR technology or other options supported by health information technology to meet CY 2019 reporting requirements. Specifically, we urge CMS to permit the choice to use any of the HL7 formats available to meet the health information create and electronically send a summary of care in support of transitions of care.**

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

INCREASE CONFIDENCE IN THE SECURITY OF PROVIDER TO PATIENT EXCHANGE

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

(i) "The patient (or patient-authorized representative) is provided timely access to view online, download and transmit his or her health information; and"

(ii) "The eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API [application programming interface] in the eligible hospital or CAH's CEHRT."

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

New Jersey's hospitals and health systems are committed to moving forward with new forms of sharing health information with individuals. However, we believe that CMS must balance the pace for moving in this positive direction with the real and developing risks that this approach raises for systems security and the confidentiality of health information. To ensure a successful transition, stakeholders must work together to develop a secure app ecosystem and health care providers must

move forward deliberately to gain experience in using these tools. And the federal government must make clear how necessary measures providers must take to secure systems will be evaluated when the rules against information blocking are enforced in the emerging API environment.

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

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

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

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

Systems security. In recent years the health care sector has been under attack by cyber criminals and nation states looking to infiltrate systems and steal patient data. Connecting a wide-range of unfamiliar, and frequently untested, apps that are presented by patients creates a significant and real risk that can serve as a possible point of entry for malware into systems. According to Symantec, mobile devices, which are the primary platform for apps, are now a key target for cyber attacks, with the "number of new mobile malware variants increased by 54 percent in 2017, as compared to 2016. And last year, an average of 24,000 malicious mobile applications were blocked each day."[5]

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

Finally, as the global WannaCry cyber attack experience showed, the impact of malware can move far beyond information systems to affect health care operations and even patient safety. The risk landscape is constantly changing, as cyber criminals identify previously unknown vulnerabilities and new forms of attack. For these reasons, the federal government has declared health care and public health to be a part of the nation's critical infrastructure that must be diligent in protecting against cyber attack.

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

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

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

While ONC has released a voluntary model privacy notice for app companies, use of this notice is not required. Recent studies have shown that the majority of health apps on the market today do not have adequate privacy policies and routinely share sensitive health information with third parties. In one study of diabetes apps, almost 80 percent did not even have privacy policies, and about half of those with a privacy policy indicated that they would share data with third parties. Only a handful indicated that they would ask for permission from the individual before sharing personal health information.[6] Research also shows that individuals generally do not fully understand the privacy policies presented by commercial app companies, and from a practical point of view have no option but to agree to them if they want to use a product.[7] And, recent headlines indicate that even large technologies companies, such as Facebook, have shared people's data without their consent, while the Federal Trade Commission is reportedly investigating the privacy practices of companies that collect and analyze genetic information from consumers.

While we understand that patients have the right to share their data as they see fit, and may be willing to take the risk of less privacy when using commercial apps, we believe that significant consumer education efforts are needed to help individuals understand the vastly different, and less stringent,

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

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

federal privacy requirements for entities not covered by HIPAA. **Therefore, to address concerns about patient privacy, we recommend that CMS work with the FTC, which provides consumer protection, and the Office for Civil Rights (OCR) to provide model language that health care providers can present to their patients that choose to access their data via an app.** This language should clearly explain that data shared with and held by the commercial app is no longer protected by HIPAA, but is governed by the privacy policy and terms of service of the commercial app company. The language also should make clear that the health care provider bears no responsibility for the use of patient data by the commercial app company and that any concerns about how data are used once shared with an app should be directed to the FTC.

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

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

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

Secure app ecosystem. To ensure a robust, secure set of tools for individuals to engage with hospitals and health systems via apps, stakeholders will need to work together to build an app ecosystem that is based on a rigorous and continuous vetting process that takes into account evolving risks. This could be done in the public sector, through certification, or through a public-private partnership. There are examples of this type of approach in other sectors, such as the Payment Card Industry Data Security Standard for processing bank cards. Any entity that wants to process bank card payments must attest to following these standards.

In the health sector, Medicare has developed a vetting process for apps that connect to Medicare claims data via the Blue Button 2.0 API. CMS will not connect any app that meets the technical specifications to its API. Rather, it has developed a process to evaluate apps before they are connected, and applies a

number of security and privacy requirements. The full guidelines for Blue Button developers are available at https://bludbutton.cms.gov/developers/. However, as an overview, Medicare requires the following:

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

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

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

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

OFFER ADDITIONAL SCORING OPPORTUNITIES FOR PUBLIC HEALTH AND CLINICAL DATA REPORTING

The final Stage 3 requirements, adopted in the FY 2018 rule, state that hospitals and CAHs must report any three measures for the Public Health and Clinical Data Exchange Reporting objective. CMS now proposes to require EHs and CAHs to report the Syndromic Surveillance measure and select one additional measure, eliminating the flexibility for EHs to select from all available measures. Hospitals

and health systems devoted time to determine the measures to report and resources for technology and interfaces to be able to report the selected measures. The availability of exclusions for the measures in this objective is an acknowledgement of the lack of uniform readiness for acceptance of the specific standards required to meet the certified EHR definition or the lack of readiness to receive reported data six months prior to the start of the reporting period. **NJHA recommends that CMS permit EHs to report any two measures to meet the Public Health and Clinical Data Exchange requirements for CY 2019 and CY 2020.**

Additionally, we recommend that CMS permit the option for EHs to report additional measures and receive bonus points for CY 2019 and CY 2020. This recommendation will leverage the work undertaken to prepare for Public Health and Clinical Data Exchange reporting and will spur the continued preparation on the part of public health to receive electronic data from EHRs. Given the continued engagement by hospitals and public health departments to improve the infrastructure that supports this aspect of health information exchange, **NJHA recommends that CMS not pursue a proposal in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022.** The willingness of hospitals to share data with public health entities is, in part, dependent on the willingness of health IT vendors and the infrastructure for health information exchange to support health information exchange that contributes to the health of the nation. We recommend that CMS continue to analyze the attestation data from EHs and CAHs for the Public Health and Clinical Data Exchange reporting and continue working with federal partners and state governments to build public health department capacity to receive automated reporting.

REVISE THE PROPOSAL FOR CY 2020 REPORTING REQUIREMENTS

In the proposed rule, CMS proposes Promoting Interoperability Program requirements for the CY 2020 reporting period. At this time, EHs lack widespread experience with the 2015 edition certified EHR and do not have experience with the new performance-based scoring methodology. **NJHA recommends that CMS examine the experience from the CY 2019 reporting period to inform proposed program requirements for the CY 2020 reporting period.** For example, the TEFCA, under development by ONC may be deployed during CY 2019. The TEFCA, as drafted, provides an opportunity to reconsider interoperability and health information exchange beyond point-to-point exchange of documents. This development could initiate a re-evaluation of the characteristics of successful health information interoperability.

RETAIN AND MODIFY THE EXCEPTION FOR LIMITED ACCESS TO BROADBAND.

CMS proposes to remove the exclusion criterion related to broadband availability, which was set at 4 Mbps of broadband availability within the county in which the facility is located (as opposed to availability for the provider). **We recommend that CMS retain the exception and examine whether it will need to be modified over time, as the use of telehealth and other modalities dependent on Internet access increases.** According to the Federal Communication Commission's most recent "Broadband Progress Report", the existing community speed benchmark is 25 Mbps download/3 Mbps upload (25 Mbps/3 Mbps) for what it considers as fixed broadband. Over 24 million Americans still lack fixed terrestrial broadband at speeds of 25 Mbps/3 Mbps, with deployment in rural areas and Tribal lands lagging behind that of urban areas (see https://apps.fcc.gov/edocs_public/attachmatch/FCC-18-10A1.pdf). With respect to Healthcare providers specifically, the FCC's 2012 *Healthcare Connect Fund* included a needs assessment of "health care provider (HCP) needs for broadband capability in light of

the current and future state of telemedicine, telehealth, and health care information technology (Health IT)." The assessment found that the optimal bandwidth needs for the transmission of HD video consultation averages 22 Mbps. The report also notes that a minimum speed of 10 Mbps symmetrical is necessary to support the majority of telehealth applications, but emphasizes that larger facilities utilizing multiple concurrent technologies and connections may require upwards of 100 Mbps (see https://apps.fcc.gov/edocs_public/attachmatch/FCC-12-150A1.pdf at §§ 6-12). Thus, in the future, CMS may need to deploy an exception based on the bandwidth available to the health care provider, at higher speeds. In the interim, we recommend maintaining the existing exception.

REQUIREMENTS FOR HOSPITALS TO MAKE THEIR CHARGES PUBLIC

In proposed rule, CMS announced updated guidelines for hospital compliance with existing transparency requirements. Specifically, effective January 1, 2019, hospitals must post a list of their current standard charges on the internet in a machine-readable format. The agency also solicited input on ways to make more useful pricing information available to consumers. The agency seeks input on how to define "standard charges;" how hospitals can best enable patients to use charge and cost information; whether providers should be required to disclose out-of-pocket costs before a service is furnished; and how the agency can best enforce these requirements, among other issues.

NJHA supports improving patients' access to information on their out-of-pocket costs for care. Hospitals and health systems are already working towards this goal, including by having financial counselors work directly with patients and their health plans and by exploring the development of web-based tools. However, the proposal to post standard charges will not advance these efforts. Nationally, more than 90 percent of individuals are enrolled in some form of health coverage, with different cost-sharing requirements. What a patient pays out-of-pocket is dependent on the benefit structure of his or her coverage. In short, we are concerned that posting standard charges or some median or average negotiated rate would, at best, assist a very small percentage of patients. At worst, this information could confuse patients and negatively impact their decisions about whether to pursue care at all.

We also caution the agency to consider the implications of pricing information on patient decision-making as it pursues transparency initiatives. Evidence is mounting that increased exposure to upfront costs may result in patients delaying or altogether foregoing care, including necessary care. The Department of Health and Human Services (HHS) and the White House acknowledged this challenge in the recent *Blueprint to Lower Drug Prices*. Specifically, the *Blueprint* noted that cost burden is "not only a financial challenge, but a health issue as well: One study found that consumers asked to pay $50 or more at the pharmacy counter are four times more likely to abandon the prescription than a consumer charged $10."[8] While we do not suggest that we refrain from sharing price information, we encourage a measured approach. In particular, we urge the agency to explore how best to inform patients about other considerations in addition to cost. Specifically, patients should understand the importance of following through with the prescribed course of care, as well as how to evaluate the quality of different providers.

[8] U.S. Department of Health & Human Services, "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," May 2018. Accessed at: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf

We encourage HHS to assist the field in improving health care literacy and expanding the knowledge base about the impact of pricing information on patient decision-making.

Below, we provide more detailed comments on how patients access out-of-pocket cost information today, the challenges associated with providing upfront out-of-pocket estimates for health care services, and ways in which we can better provide this information to patients.

Standard Charges. CMS seeks input on how to define "standard charges" for purposes of price transparency requirements, including what the agency should require hospitals publicly post in machine-readable format. As noted above, charge information is not going to help the vast majority of individuals. Instead, the most relevant information is their potential out-of-pocket costs for a given service or course of treatment. More than 90 percent of individuals in the U.S. have health coverage, and their payer – whether Medicare, Medicaid or a private insurance plan – establishes their cost-sharing obligations, which takes into account whether the plan covers the service, whether the provider is in the plan's network, the plan's cost-sharing requirements and, if applicable, where the individual is in their deductible. Hospitals contract with more than 1,300 payers nationally, and the vast majority offer multiple (sometimes dozens or more) health plans with different benefit structures. Payers are the best source of information on what a covered individual's out-of-pocket costs may be for a given service.

Despite this, patients do ask providers for cost estimates and will continue to do so. Hospitals and health systems help patients obtain answers to these questions by working with insurers. Once a provider has identified the patient's need for a specific diagnostic service or care protocol, hospital financial counselors help patients work with their insurer to establish what the patient's cost-sharing obligation may be. This is a hands-on process with hospital staff connecting with insurers via their websites and call centers to obtain patient-specific information. Financial counselors may need to repeat this process multiple times, as the course of care may change for any number of reasons. For these patients, a list of standard charges would be meaningless.

For the 10 percent of the population that is uninsured, availability of standard pricing information could be helpful and is already available consistent with federal law. Providers can and do respond to inquiries from uninsured individuals with information on their standard charges, as well as information on any financial assistance policies the hospital may offer.

Patient Information on Charges and Cost. CMS posed a number of questions related to the types of information would be most beneficial to patients, how hospitals can best enable patients to use charge information, and how CMS and providers can help third parties create patient-friendly interfaces with these data. The agency also seeks information on whether and how health care providers should be required to inform patients what their out-of-pocket costs for a service will be before those patients are furnished that service, among other related questions.

As noted above, NJHA believes that out-of-pocket cost information is the most relevant pricing information for patients. A number of tools already exist to provide this information, including web-based tools developed by hospitals and health systems, commercial payers and third-party vendors. However, we note that these tools appear to have minimal uptake by patients. Our own examination of a number of these tools suggest that patients may encounter a number of challenges that are not the fault

of the tools, but rather reflect the nature of health care. Specifically, there is a lot of uncertainty in health care. The path to diagnosis and treatment can vary significantly based on the underlying health issue and the appropriate care pathway for a given individual. Research suggests that few health care services are "shoppable." In fact, some researchers estimate that as little as 7 percent of health care services would meet the criteria.[9] While these tools can generally provide accurate price estimates for a small set of discrete services, the estimates vary widely for more complicated or variable sets of services.

We encourage software developers and other technical experts to work with providers and insurers on tools that they can use to help respond to patient pricing inquiries. For example, software developers may help develop a web-based portal that connects providers to multiple insurers' information, as opposed to providers needing to reach out individually to each insurer. To the extent CMS is interested in price comparison tools, we note that only insurers, including CMS for the Medicare population, have complete information about what their enrollees may pay for the same service at different in-network providers

Transparency in Medicare Payment. The agency seeks information on whether health care providers should provide patients with information on what Medicare pays for a particular service and, if so, the steps that would be needed to operationalize this.

Given that Medicare uses a standard cost-sharing amount for inpatient services, we do not believe that any new information or tools need to be developed for Medicare beneficiaries seeking inpatient care. With respect to outpatient care, we note that the standard cost-sharing structure of a 20 percent copay eases providers' abilities to provide an initial out-of-pocket cost estimate to Medicare beneficiaries for a discrete Part B service. However, nearly 80 percent of Medicare beneficiaries have some form of supplemental coverage and may actually owe a different amount. As a result, providers would again need to work with the patient's supplemental payer to determine the specific individual's cost-sharing obligation for a service.

Compliance with Transparency Requirements. CMS solicits input on how it can best enforce any requirements related to price transparency.

Given the challenges associated with making price information more easily accessible, we discourage CMS from taking a punitive approach against providers who cannot meet all patient expectations for price transparency at this time. First, as we have previously mentioned, providing exact cost estimates for most services is not possible given the inherent uncertainty of health care and the fact that providers do not have access to all health plans' cost-sharing requirements. Second, the challenge may relate to a patient's lack of understanding of their health coverage. Hospitals and health systems report that an increasing number of patients, particularly those in high-deductible health plans, are surprised by their out-of-pocket cost, because they do not understand how their coverage works.

[9] Health Care Cost Institute, "Spending on Shoppable Services in Health Care," March 2016. Accessed at: http://www.healthcostinstitute.org/files/Shoppable%20Services%20IB%203.2.16_0.pdf

Instead of focusing on punitive measures, we encourage CMS to convene providers, insurers, patients, and employers to explore ways to increase patients' health care literacy, especially around their health plan benefit design.

Supplemental Coverage (Medigap). The agency seeks input on how price transparency proposals should work in the scenario where a beneficiary has supplemental coverage. The Medigap scenario provides just another example of why providers must work with payers to determine accurate patient-level cost information. We reiterate that this is often a manual process that relies on hospital financial counselors working directly with patients and the payers to develop out-of-pocket cost estimates.

NJHA reiterates our recommendation that the agency convene a multi-stakeholder process to discuss how we can work together to improve health care literacy broadly and, more specifically, better articulate information on health plan benefit structure and cost-sharing.

REQUEST FOR PUBLIC COMMENTS ON WAGE INDEX DISPARITIES

As noted in the proposed rule, a key component of transforming the delivery system to focus more on patient-centered care is ensuring the accuracy and appropriateness of provider payments. Within the Medicare program, the area wage index (AWI) serves the vital role of adjusting Medicare reimbursement rates to account for geographic differences in the wages paid to healthcare workers.

CMS notes in the proposed rule that a significant amount of time has elapsed since the Medicare Payment Advisory Commission, Acumen, the Institute of Medicine and CMS examined disparities between AWI values for individual hospitals and among different geographic areas. For that reason, it invites the public to submit comments and suggestions for regulatory and policy changes to the Medicare wage index that address these issues and include, if practicable, supporting data and specific recommendations.

Sometimes geographic areas that are adjacent to one another are assigned vastly different area wage indexes. To remedy this, over the years various policy exceptions have been created to promote equity in hospital payments. Today there are numerous exceptions and adjustments for which a hospital may be eligible in order to receive a higher wage index value, including reclassifications, frontier states, Lugar counties (rural to urban), Section 401 hospitals (urban to rural), rural floors, imputed rural floors, and out-migration adjustments.

Despite the frustration that surrounds the current wage index system and its many exceptions, there is no question that CMS must account for regional differences in the cost of wages when it reimburses hospitals for the care they provide. NJHA offers the following comments and recommendations for CMS to consider in future discussions around potential changes to existing wage index policies:

- NJHA strongly believes that it is critical to maintain a wage index exception process that allows hospitals in areas with misrepresentative indexes to seek redress.

- Changes in Medicare wage index policy should include some type of hold-harmless or transitional provision. As wage index changes would likely redistribute large amounts of funds, hold-harmless and/or transitional provisions would be necessary to allow hospitals to fully prepare for and adjust to the new system.

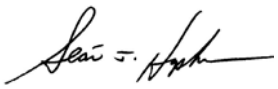
- It is important for the wage index itself to be as accurate as possible by ensuring that both hospitals and Medicare are able to use consistent definitions, methodologies, rules and interpretations for the acquisition and application of wage data.

- In order to assure that the adjustments made by the Medicare wage index are correct, hospitals must be able to examine and verify the data used to construct the index. The wage index has a significant impact on the payments hospitals receive under the inpatient and outpatient prospective payment systems. The hospital wage index is also used in other PPS systems (for example, inpatient rehabilitation facilities, long-term care hospitals and inpatient psychiatric facilities). It is important that the process of calculating wage index values be transparent so that the data used may be examined and verified.

- CMS should continue to use the Core Based Statistical Area (CBSA) definitions (as established by the Office of Management and Budget (OMB) and updated following each decennial census) as the basis for grouping hospitals into geographic labor markets within the Medicare wage index system.

The New Jersey Hospital Association appreciates the opportunity to comment on the CMS's hospital inpatient prospective payment system proposed rule for FY 2019. If you have any questions, please contact me at 609-275-4022 or shopkins@njha.com, or Roger Sarao, vice president, Economic & Financial Information, at 609-275-4026 or rsarao@njha.com.

Sincerely,



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