June 26, 2018

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1696-P
P.O. Box 8016,
Baltimore, MD 21244-8016

RE: Comments on Proposed Rule, Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities FY 2019, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and SNF Payment Models Research; CMS-1696-P

Dear Ms. Verma:

LeadingAge appreciates the opportunity to provide feedback regarding the Fiscal Year (FY) 2019 Skilled Nursing Facility (SNF) Prospective Payment System (PPS) proposed rule. We offer these comments in the spirit of collaboration and look forward to working with the Centers for Medicare and Medicaid Services (CMS) to ensure a smooth and successful transition to the revised payment system.

The mission of LeadingAge is to be the trusted voice for aging. Our over 6,000 members and partners include nonprofit organizations representing the entire field of aging services, 38 state associations, hundreds of businesses, consumer groups, foundations and research centers. LeadingAge is also a part of the Global Ageing Network, whose membership spans 30 countries. LeadingAge is a 501(c)(3) tax-exempt charitable organization focused on education, advocacy and applied research.

Our comments will cover a number of the areas included in the rule:

I. Payment Items
    a. SNF Market Basket Update
    b. Application of the Quality Reporting Program Reduction - Market Basket Update Factor for FY2019
    c. Patient-Driven Payment Model (PDPM)
    d. Consolidated Billing
II. SNF Value-Based Payment (VBP) Program
III. SNF Quality Reporting Program (QRP)

I. Payment Items

a. **SNF Market Basket Update:** The SNF market basket update for FY 2019 is 2.4% based on the Bipartisan Budget Act of 2018. We are pleased to see this increase compared to prior law, which would have calculated the market basket update at 2.7% that would be adjusted down by a 0.8% multifactor productivity adjustment yielding a 1.9% update. This is an important update especially as our members are nonprofit SNFs, which according to MedPAC data have slim operating margins of 2.3% compared to 14.0% in for profit facilities, and as such are more profoundly impacted by the effects of the 2% sequestration plus potential reductions of up to 2% each for value-based payment and quality reporting program policies. We ask that CMS consider the unique situation of mission-driven, nonprofit providers, who are and have been strong community partners for decades meeting the post-acute needs of a wide variety of older adults without profit motivation, in creating payment policy.

b. **Application of the Quality Reporting Program Reduction - Market Basket Update Factor for FY 2019 (Section III.B.5):** Regarding the quality reporting program (QRP) reduction, CMS is proposing to apply a 2.0 percentage point reduction to the SNF market basket percentage for the fiscal year 2019 market basket update after adjusting for the multifactor productivity adjustment (MFP). LeadingAge notes that last year CMS reduced the market basket by the special rule for payment of 1.0% as opposed to the calculated market basket update of 2.0% during FY 2018. We recommend that CMS once again apply the reduction to the special rule for payment which would mean SNFs that did not submit would lose 2 percentage points from the 2.4% payment update resulting in a 0.4% update as opposed to the proposed -0.1% update.

c. **Patient-Driven Payment Model (PDPM):** As we stated in our comments regarding the Resident Classification System (RCS-I), LeadingAge supports the CMS goal of improving the accuracy of Medicare's SNF payments. In the advanced notice of proposed rulemaking from 2017, the goals CMS gave of 1) more accurately compensating SNFs, 2) reducing incentives for SNFs to deliver therapy based on financial considerations, rather than resident need, and 3) maintaining simplicity, to the extent possible, remain valid. We thank CMS for their attention to the comments that LeadingAge and others submitted regarding the RCS-I proposal and acknowledge the improvements made in the PDPM proposal. We seek to reiterate those themes in broad comments before offering our comments on the details of the proposal.

   Payment Accuracy: We appreciate the updated data that is taken into account as compared to the RCS-I proposal. However, we have concerns that the PDPM approach was modeled on only one year (FY 2017) of data. We recommend that CMS consider including either partial FY 2018 or FY 2016 data to ensure that the model is stable when considering the impact of changing resident populations over time. Greater confidence in the model could be instilled in the provider community if more robust data are utilized in the modeling. Absent is the discussion of how the model might be re-calibrated over time with operational experience. A common

concern that LeadingAge has shared in the past is the infrequency of rebasing the current RUG-IV model. Given the limitations of the data used in the modeling of the PDPM, we ask that CMS stay closely attentive to the effects of the PDPM on Medicare beneficiaries and providers operating under the new approach. We recommend that a discussion of how CMS intends to ensure payment accuracy of this model into the future be provided prior to finalizing the rule so that providers have confidence in the robustness of the PDPM.

Resident Characteristics as the Basis for Payment: LeadingAge strongly supports quality services being delivered – and reimbursed – based on resident characteristics and appropriate clinical practices. We welcome the improvements made from the RCS-I proposal related to using SNF-specific reasons for the stay and incorporation of therapy minutes in the discharge MDS assessment. As with payment accuracy concerns, LeadingAge recommends that CMS carefully monitor the effects of the PDPM model as it relates to access to SNF services across the range of Medicare beneficiaries who qualify for SNF services. We believe that all beneficiaries who could benefit from SNF services ought to be able to access those services without barriers caused by payment systems. Some access concerns could be envisioned for Medicare beneficiaries who are likely to need a full 100-day benefit period due to the declining payment of the variable per diem policy. We recommend CMS further examine the effects of that portion of the model on the subset of beneficiaries whose stay is greater than 60 days.

Simplification: The PDPM is responsive to critiques that we had for the RCS-I in some ways. We are pleased to see a reduction in the number of classification categories without much loss of predictive power of the model. However, other aspects, particularly the reliance on ICD-10-CM and ICD-10-PCS codes and lack of clarity around the criteria that trigger the need for the Interim Payment Assessment (IPA), add additional levels of complexity that will require significant training time to be able to successfully operate under the proposed model. We suggest that due to the complexity of the PDPM, CMS begin to release additional training and guidance on the model as soon as possible.

Below are some specific comments and questions on the proposed PDPM model.

Clinical Classification for PT, OT, & SLP: Given SNFs' lack of experience in ICD-10 coding, we suggest that CMS consider adding checklist items to Section I of the admission assessment particularly for PT, OT, and SLP component classification, as well as comorbidities and conditions that apply to the SLP and NTA component classification. This would not preclude providers from entering ICD-10-CM codes into Section I8000 of the MDS (as proposed) that map to any of the PT, OT, SLP or NTA condition or comorbidity groups if they have the health information technology and interoperability capabilities that would permit this to be accomplished efficiently.

The specific descriptive condition and comorbidity checklist items recommended to be added to Section I of the MDS by component are:

- PDPM Clinical Category (NPRM Table 14, PDPM Calculation Worksheet pp. 5,9,13)
    - Major Joint Replacement or Spinal Surgery
    - Non-Orthopedic Surgery
    - Acute Neurologic
    - Non-Surgical Orthopedic/Musculoskeletal
    - Orthopedic Surgery (Except Major Joint Other Orthopedic Replacement or Spinal Surgery)
    - Acute Infections
    - Cancer
    - Pulmonary
    - Cardiovascular and Coagulations
    - Other Medical Management
- SLP-Related Comorbidities (NPRM Table 22 & PDPM Calculation Worksheet pp. 14-16)
    - Laryngeal Cancer
    - Apraxia
    - Dysphagia
    - ALS
    - Oral Cancers
    - Speech and Language Deficits
- NTA Conditions (NPRM Table 27 & PDPM Calculation Workbook pp. 19-20)
    - Lung Transplant Status
    - Major Organ Transplant Status, Except Lung
    - Opportunistic Infections
    - Bone/Joint/Muscle Infections/Necrosis - Except: Aseptic Necrosis of Bone
    - Chronic Myeloid Leukemia
    - Endocarditis
    - Immune Disorders
    - End-Stage Liver Disease
    - Narcolepsy and Cataplexy
    - Cystic Fibrosis
    - Specified Hereditary Metabolic/Immune Disorders
    - Morbid Obesity
    - Psoriatic Arthropathy and Systemic Sclerosis
    - Chronic Pancreatitis
    - Proliferative Diabetic Retinopathy and Vitreous Hemorrhage
    - Complications of Specified Implanted Device or Graft
    - Inflammatory Bowel Disease
    - Aseptic Necrosis of Bone
    - Cardio-Respiratory Failure and Shock

- Myelodysplastic Syndromes and Myelofibrosis
- Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies
- Diabetic Retinopathy - Except: Proliferative Diabetic Retinopathy and Vitreous Hemorrhage
- Severe Skin Burn or Condition
- Intractable Epilepsy
- Disorders of Immunity - Except: RxCC97: Immune Disorders
- Cirrhosis of Liver
- Respiratory Arrest
- Pulmonary Fibrosis and Other Chronic Lung Disorders

Changes to the MDS Assessment Schedule: LeadingAge members have asked a number of questions about the impact of the proposed changes to the MDS assessment schedule. While the proposed changes suggest that fewer assessments would be required under the model, members are unsure if the tracking of criteria to determine if an Interim Payment Assessment (IPA) should be performed could add back the burden reduced through fewer assessments. Some SNFs suggest that nurses might need to perform more assessments just to determine if an IPA is required. In addition to the complexity of the IPA, both the admission and discharge assessments have added complexity in the proposed model. LeadingAge recommends that CMS issue clear criteria for when an IPA should be initiated and which assessment elements will impact payment. In addition, CMS should provide corresponding training and guidance on these new standards well in advance of implementation. While our members would appreciate less administrative burden, there could be significant impacts to their reimbursement if they do not fully understand when these IPAs should and can be initiated.

Under the current payment models, if a change is somehow missed on an earlier assessment, it can be captured on future assessments. Has CMS considered developing a process for correcting initial assessment errors to ensure resource needs are accurately captured and reflected in the new model? In addition, a question was raised about whether CMS has considered the interplay between the PDPM assessments and those required under OBRA. For example, would an OBRA assessment for a clinical change in status have any impact on payment under the PDPM?

Transition to PDPM: With the aim of a smooth transition to a revised SNF payment system and in the collaborative spirit that CMS has operated under for years through the technical expert panels and advanced notice of proposed rule making, we recommend that CMS form a PDPM implementation working group to engage in the many issues that need to be clarified to successfully implement a revision of the magnitude proposed. This group could be comprised of SNF PPS stakeholders, representatives from states including the Medicaid and survey agencies, referral sources including hospitals, payment representatives including Medicare Advantage

plans, and organizations that represent and/or serve older adults who are the predominant users of Medicare post-acute care services.

We ask that you offer further communication around transition plan development, a transition timeline, implementation, and post-implementation technical assistance. LeadingAge and its members have concerns about the feasibility of a successful implementation by October 1, 2019 without significant efforts on the part of CMS and all stakeholders. Adequate time is necessary for SNFs, their business partners, and vendors to update systems to implement the new payment models. Staff will need to be trained to be successful in the new MDS assessment expectations and gain an understanding of which assessment elements effect payment to ensure that the correct payment is claimed for the resident. PDPM is complex and stakeholder input could aid CMS with its efforts as well as reduce unintended consequences for residents. We recommend mirroring the stakeholder engagement process CMS used for the transition from cost-based payment to the current RUG payment system.

Medicare Advantage and Special Needs Plans often base what they pay SNFs upon Medicare fee-for-service rates including sometimes clustering RUGs categories for payment purposes. Therefore, we recommend CMS consider developing tools to educate the plans on the new payment model and possibly provide a crosswalk for SNFs and plans from RUGs-IV to PDPM to ensure a smoother transition to this new payment methodology.

Interrupted Stay Policy: CMS proposes implementing an interrupted stay policy as part of the SNF PPS. Its effective date is scheduled to coincide with the implementation of the SNF PDPM. Specifically, the policy would treat cases where a resident leaves the SNF and returns within a 3-day window as a continuation. Residents who return after the 3-day window or are readmitted to a different SNF will be treated as a new stay and require a new 5-day assessment to be conducted. The 3-day period would begin on the calendar day of discharge and additionally include the 2 immediately following calendar days. LeadingAge is concerned about this approach as it does not account for the cause of the readmission and is not clear how this policy will interact with the IPA criteria.

For example, if someone is admitted to the SNF following a hospitalization for a respiratory condition, but is readmitted due to a fall with injury, then the rates determined for the original admission may not accurately reflect the resource needs of the beneficiary upon their return. Under this example, would the new additional diagnoses trigger a new initial assessment if less than 3 days has passed or be governed by the IPA criteria? Issues could arise if an IPA does not return the NTA component to day 1. If a patient requires a new high cost medication or piece of equipment, the inability to return to day 1 could result in an array of unintended issues. These include discharge to a hospital (which CMS has noted is a concern with the proposed interrupted stay policy) and reluctance to admit patients who are at high risk of changes in care needs. LeadingAge asks CMS to provide further guidance about how the IPA and interrupted stay policies would work together.

d. Consolidated Billing: The consolidated billing provisions of Medicare Part A include a number of individual high-cost, low probability services that are excluded from SNF consolidated billing within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We suggest CMS conduct a broad review of new chemotherapy drugs and their costs to determine if they should be added to the exclusion list, as new drugs are being added regularly and do not always have their own HCPCS code.

One specific example, that could be illustrative of others, is the chemotherapy agent Revlimid (a/k/a Lenalidomide) be added to the list of exclusions from consolidated billing requirements. This is labeled under National Drug Code # 59572-0410-28 by the Celgene Corporation. We could not locate a HCPCS code for this agent other than J8999 (Prescription drug, oral, chemotherapeutic, Not Otherwise Specified). The average wholesale price for a 28-day supply of Revlimid 10 mg capsules exceeds $18,000. We believe that this agent meets the statutory criteria of high cost and low probability in the SNF setting. This request has been made previously and was not adopted. We speculate that this might be due to the J8999 code covering a number of specific chemotherapy drugs not all of which are high cost and low probability. If adding this HCPCS code to the exclusion list is not an option for that reason, we suggest establishing a separate code for this particular drug and including that new code on the exclusion list.

II. SNF Value-Based Payment Program

Calculating a performance score for SNFs that have few eligible stays: CMS has proposed an alternate approach to calculating a performance score for SNFs that have low volume of eligible SNF stays under two circumstances:

For SNFs that lack sufficient baseline period data because they were newly-opened during the baseline period, only open a short time, or other reasons, CMS is proposing to not measure these SNFs on improvement for that program year, only measuring their achievement. While LeadingAge agrees there would be insufficient data for a proper year-over-year comparison, we do not understand why the approach for this group of low-volume SNFs is different from the proposed approach for those that consistently have low-volume. We continue to have concerns with the scores assigned to date for these low-volume SNFs. For example, it continues to be challenging to explain why a SNF with 9 eligible stays and no readmissions has an 18.24% readmission rate, as one of our members has experienced.

CMS proposes to assign low-volume SNFs a performance score that assures the low-volume SNF's per diem rate is not reduced, as if the VBP program did not apply to the facility. CMS also considered an alternative approach assigning a performance score to low-volume SNFs that would result in them receiving an incentive payment of 1.2%, translating to a 0.8% reduction in the SNFs' per diem rates. If CMS were to pursue this alternative approach, only $1 million would be returned to low-volume

SNFs regardless of actual readmission performance. LeadingAge supports holding harmless low-volume SNFs by assigning a performance score that ensures the low-volume SNF receives its full rate. Given how easily a performance score could be skewed by a single readmission, we think this is the most appropriate approach. This policy appears consistent with that which exempts critical access hospitals (CAHs) from the hospital readmission reduction program. Many low-volume SNFs are located in rural or frontier areas with CAHs. This equal footing is important as hospitals, physicians, and post-acute care providers share responsibility for preventing hospital readmissions. LeadingAge opposes the alternative approach considered by CMS that would have arbitrarily reduced the Medicare rates for these SNFs regardless of their performance with no opportunity to earn back the reduced amount.

III. SNF Quality Reporting Program

Notifications of non-compliance and CMS reconsideration decisions: Currently, CMS notifies SNFs of their non-compliance with the SNF QRP in two ways through the QIES ASAP system and the U.S. Postal Service. CMS is proposing to add a third option, email from the Medicare Administrative Contractor (MAC), with the caveat that upon finalizing this provision they will notify SNFs by at least one of these methods. This proposed change is in response to provider feedback. CMS is also proposing to make this same change for communicating its final decisions related to SNF QRP reconsideration requests.

LeadingAge supports CMS adding email notification by the MAC as another way to notify providers of their non-compliance and for reconsideration options. However, with this proposed change, CMS will go from providing notification in two ways to only being required to notify through one method. If there is to be only one communication method the provider should have the ability to choose their preferred method. Otherwise, there is a risk that the appropriate leader in an organization may never see the notification and could miss the opportunity to submit a request for reconsideration. We would recommend that CMS either specify at least one method that will always be used to notify SNFs of noncompliance, allow the provider to select its preferred method of communication, and/or use all three.

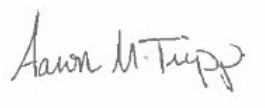
Public Display of SNF QRP Measures: CMS indicated last year its plans to publicly report FY 2017 data for Medicare spending per beneficiary and discharge to community measures on Nursing Home Compare beginning in calendar year (CY) 2018. CMS proposes in this rule to begin reporting two years' worth of data instead of one year beginning in CY 2019. This change would ensure that data on these measures are reported for roughly 95% of SNFs and the measures are aligned with the display periods for inpatient rehabilitation facilitates and long-term care hospitals.

LeadingAge supports using two years of data for Medicare spending per beneficiary and discharge to community information. However, we ask for clarification on the

intent to list the average Medicare spending per beneficiary for each of two years or to average the spending over the two years and only report one number. We do not support the latter approach as it raises concerns that this data would not accurately reflect changing practice patterns related to length of stay and readmission rates. As such it would be less useful to both the public and providers.

Again, LeadingAge appreciates the opportunity to submit comments on the proposed rule. We look forward to continuing our positive working relationship with CMS as SNF payment system revisions evolve. In addition to our feedback on the proposed rule, our responses to the request for information on promoting interoperability and electronic healthcare information exchange. Please do not hesitate to contact us if you wish to discuss any of these comments further.

Sincerely,



Aaron M. Tripp
Director, Long-Term Care Policy & Analytics

Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

LeadingAge applauds CMS for seeking input on how to improve interoperability. LeadingAge suggests the following principles should guide the development of interoperability standards as CMS seeks to expand these expectations to long-term and post-acute care (LTPAC) providers:
1) sufficient time for compliance should be provided and implementation timelines should be weighed against other regulatory compliance issues providers face;
2) cost-benefit analyses should be conducted to ensure that the gain is worth the cost;
3) CMS should use payment incentives versus mandates to move compliance; this should be true particularly for LTPAC and other providers that never received EHR adoption incentives;
4) expectations for compliance with these standards should apply to all providers not just LTPAC, as the focus is the exchange of communication between settings;
5) interoperability requirements should allow for more than one option for compliance;
6) to the extent possible, interoperability standards should align with other provider expectations and reporting requirements (e.g., IMPACT Act); and
7) CMS needs to help change the culture of distrust where receiving providers do not look at patient information and run their own assessments.

Broadly, we would also like CMS through the Center for Medicare and Medicaid Innovation (CMMI) to consider using a technical expert panel (TEP) to develop the standards, expectations and measurements. Such a TEP should be representative of all providers who will be involved in the information exchange activities in order to identify early any operational challenges to proposed requirements. As the health care sector appears to be in a perpetual state of change management, we would ask CMS to consider carefully the timing of any implementation and enforcement of compliance so as not to overburden providers and in order to achieve an optimal result.

In addition to our comments below to each of the questions posed by the RFI, we have also submitted more detailed comments related to the Health Information Technology components of this RFI as co-signers the LTPAC HIT Collaborative comment letter.

Question 1: If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in Section 4004 of the 21st Century Cures Act?

While establishing a new CoP/CfC/RfP standard is the most powerful incentive that CMS has to promote information sharing, we do not believe that it will necessarily reduce information blocking. However, it offers extraordinary value and should be adopted as it provides a compelling business case for interoperability. We ask CMS to carefully consider the timing of implementation of enforcement for such a change and the factors that hinder providers from complying. These factors include but are not limited to: lack of funding or incentives to make the needed HIT investments, limited access to low-cost HIT options, access to affordable broadband/internet services, and a lack of a commonly shared vocabulary for use across the multiple domains of health care and support services. We are optimistic that API (Application

Program Interface)-based information sharing will continue to evolve and will likely solve the "technological and cost" barriers to electronic information sharing for those who did not receive Meaningful Use funds.

The greater challenge will be building a semantically standardized vocabulary. However, the extensive work that has already been done provides a strong foundation upon which to achieve this essential step to achieving interoperability. Changes to the CoP/CfC/RfP standards will not directly address this gap. However, announcing a change to the CoP/CfC/RfP standards to be implemented by a certain date could be an important driver for creating and adopting a common vocabulary that can be used for quality reporting, clinical care and regulatory requirements.

Consistent with the 21st Century Cures Act and keeping in mind the primary objective of sharing HIT – to ensure better person-centered care, we would encourage CMS to clarify that "information exchange" includes "information access" when documents aren't exchanged, but information is still available to the receiver. In the short run, the important part is that providers across the continuum of care and services have timely access to needed patient information not how that information is shared. Ideally, we want the process for sharing to be as efficient and real-time, as possible.

Question 2: Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?

Yes, CMS should propose new standards to ensure that individuals (et al.) have access to their own health information. We suggest the goal should be one portal that ensures interoperability, includes all providers serving the individual, and can be used by all providers and the consumer (et al).

Question 3: Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, HIPAA, and implementation of relevant policies in the 21st Century Cures Act?

There is not a compelling business case for hospitals to drive interoperability despite meaningful use requirements. It is likely that revised CoP/CfC/RfP standards will be necessary when the required data sets have been standardized and incorporated into certified EHRs, if done thoughtfully building on clear definitions, standardized data sets, and implemented in a phased manner within a reasonable implementation timeframe. Otherwise, we are concerned that it might negatively impact healthcare providers who do not have sufficient resources to comply and may consequently negatively affect access to care for Medicare patients. This might be especially concerning for smaller and rural healthcare providers, where there are already access challenges.

Question 4: What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?

Base implementation on the establishment of standardized essential data sets. It may be possible to phase in requirements such as, Phase 1: individual identification, authentication and authorization, Phase 2: allergies, medications, precautions, Phase 3: condition-specific data sets, and so on. It is likely to be at least two years before some datasets are available. Non-eligible providers will probably need an additional 2-3 years (4-5 years total) with the appropriate incentives and technical support. However, the first 2 years should focus on designing incentives, pilot testing and demonstrations to be launched as soon as the standardized data sets are available. Generally speaking, the implementation timeline should take into account the cost of implementation, the availability of the tools, hardware, and software required for compliance and alignment of this implementation with other regulatory requirements placed upon the providers.

Question 5: Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?

Yes; again, if done thoughtfully building on clear definitions, standardized data sets, and implemented in a phased manner and within a reasonable implementation timeframe. Otherwise, we are concerned that it might negatively impact healthcare providers who do not have sufficient resources to comply, and may consequently negatively affect access to care for Medicare patients. This might be especially concerning for smaller and rural healthcare providers, where there are already access challenges.

Question 6: Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?

Yes. Although the ultimate goal is electronic sharing that is machine-readable and enables decision support and system-wide analytics, the reality is there will always be some stakeholders (individuals, family members, support service providers as well as smaller organizations) for whom interoperability is not feasible or cases where the electronic health record systems fail or are offline. Fundamentally, we should not lose sight that optimal patient care is the real goal and should not be jeopardized for the desired principle of electronic sharing. Instead providing incentives to providers to substantially comply should be the preferred approach. The most important attributes for the electronic sharing of information are that the information is semantically standardized and that it is shared. Fax and secure email, like ONC-Direct, might be

reasonable for some participants, potentially in the interim, while adoption of more and better interoperable technologies continues to rise. Sharing is more important than the process used.

Question 7: Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?

Identification, authentication and authorization standards are essential. HIPAA-compliant communication guidelines could be very helpful. Ultimately, legal liability drives some of the duplicative assessments because the receiving provider does not know if they can trust the transmitted data on the patient. Are there things we can do to protect providers who rely on such data? Can we establish interoperability expectations without addressing the need for broadband access in rural and frontier communities?

Question 8: What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements, should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP including CEHRT hardship or small practices be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

It is reasonable to provide for exemptions. Because interoperability is fundamentally local, different communities may have different interoperability requirements to participate in shared care that are necessary to provide care sufficient to produce good outcomes. It is likely that members of a community will be encouraged to adopt its standard. As long as the community is achieving good outcomes, it is less important how the information is shared. If CoPs are changed, providers not eligible for health IT adoption incentives should be exempt for the first few years to give them the opportunity to adopt the appropriate technology and catch up to their trading partners who have received adoption incentives. Additionally, providers in more rural or frontier communities that lack reliable internet/broadband access should also be exempted.

Question 9: We would also like to directly address the issue of communication between hospitals (as well as the other providers and suppliers across the continuum of patient care) and their patients and caregivers. MyHealthEData is a government-wide initiative aimed at breaking down barriers that contribute to preventing patients from being able to access and control their medical records. Privacy and security of patient data will be at the center of all CMS efforts in this area. CMS must protect the confidentiality of patient data, and CMS is completely aligned with the Department of Veterans Affairs (VA), the National Institutes of Health (NIH), ONC, and the rest of the federal government, on this objective.

MyHealthEData would benefit from the common vocabulary more than from technology.
One suggestion to keep the information exchange process simple and manageable for both the sending and receiving parties is to use a standardized concise transfer form similar to the Status, Background, Assessments, and Recommendation (SBAR) document during transitions of care from LTPAC to hospitals in a timely manner.

LeadingAge believes strongly that patients and their family caregivers should have easy access to their health information. They should be able to contribute and update certain information within these files to reflect preferences, changes in condition, track vitals (e.g. blood pressure, etc.), as they play a critical role in accurately diagnosing and self-adherence to any treatment plan.

Question 10: To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. We are particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcome the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers.

Semantically standardized vocabulary is the foundation of interoperability. CMS has an essential role to play in proposing essential data elements and helping to steward them through the USCDI process. CMMI and PCORI could serve as test venues for proposed data elements, incentive payment strategies for providers who were ineligible for Meaningful Use incentives, and to identify gaps.

CMS could play a critical role in providing guidance on HIPAA-compliant ways to exchange data. We underestimate how important it is to communicate with patients about the option of accessing their health data online. For example, one patient was given a form and told they needed to sign it so the hospital could "put all their health care data on the internet." From the patient's point of view, this meant on a non-secure website that the whole world could see and refused to give permission to set up online access. Guidance from CMS that provides a template on communication best practices could be a valuable resource for the provider community to promote more participation from patients. An additional consideration is providing easy access to the records for family caregivers. Perhaps a single, standard power of attorney for health information document that can be provided to all health professionals instead of the caregiver needing new documents with each health care provider or system. When signing up for an online EHR a patient should be able to designate all who are permitted access to this information. These tools are especially important when the person's cognitive function is impaired. One of the big challenges is working across EHR platforms – how can we more easily identify all providers involved in the care of the individual so we can achieve the goal of better integrated care and service delivery?

CMS can also play a significant role to help change the culture of distrust where receiving providers do not look at patient information and run their own assessments. One approach to this could be by CMS not reimbursing the costs of tests repeated by the receiving provider if they were communicated in a timely manner.

Finally, EHR should be expected to have the ability for key information to be "pinned" to the top of a record so critical care and treatment notes do not fall to the bottom of the virtual pile resulting in unnecessary tests, and suboptimal treatment. These items should be the first thing any provider looks at and may include patient preferences. Please see reference above to the suggestion about the SBAR-like summary document to be available especially during transitions.

Question 11: We have received stakeholder input through recent CMS Listening Sessions on the need to address health IT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and we would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

The concern should be for the adoption of a standardized vocabulary rather than the adoption of any specific technology. Standardized data sent by fax from an entity that has no certified HIT still has significant value and can be converted to electronically interoperable data by a receiver with certified HIT as long as the receiving party sees the data and incorporates processes ensuring that the information is considered and incorporated in decision-making, and even potentially in the certified HIT record. Non-standardized data has far less value. Electronic exchange of non-standardized data is what we do now.

However, non-incentivized providers are likely to lag behind their incentivized peers, in terms of both adoption of interoperable technology as well as engagement in information exchange. That is why over the past decade LeadingAge has called for considerations to provide incentives for these providers in one or more of the following ways:

- Establish initiatives to encourage and accelerate the adoption of interoperable EHRs, particularly among smaller, stand-alone, and rural LTPAC providers. Such initiatives might include state and federal legislation authorizing grants or low-interest loans to assist with initial health IT investments. Regulatory agencies should be encouraged to provide ongoing payment incentives to LTPAC providers that adopt these technologies and demonstrate that they meet certain quality and cost measures.
- Inclusion of LTPAC settings in national health IT initiatives, including the development, adoption and use of interoperability standards, the certification of IT products, receiving technical support, and the engagement of LTPAC providers in health information exchange activities. This exchange of health information would take place both directly and through health information exchange entities.
- Establish, test, and demonstrate incentives and payment models that encourage providers that were not eligible for HITECH funding, who may lack or lag behind in the adoption of HIT, to implement HIT solutions and effectively participate in the exchange of standardized information as previously mentioned. CMMI and PCORI could potentially lead such tests and demonstrations.