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September 20, 2018

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue S.W., Room 445-G  
Washington, DC 20201

**Ref: CMS-1695-P: RIN 0938-AT30**

**Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Mode**

Dear Ms. Verma:

On behalf of our 130-member hospitals and health systems in our state, the North Carolina Healthcare Association (NCHA) appreciates the opportunity to comment on Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Mode published in the *Federal Register* on July 31, 2018.

**Proposal to Limit Expansion of Services in Excepted Off-campus Provider-based Departments in Calendar Year 2019**

The Centers of Medicare & Medicaid Services (CMS) proposes to revise the definition of “excepted items and services” to apply only to those services from clinical families of services from which the excepted off-campus provider-based department (PBD) furnished a service (and subsequently billed for that item or service under the OPSS) during certain baseline periods (generally from November 1, 2014 through November 1, 2015). Thus, beginning January 1, 2019, excepted items and services would only include those services furnished and billed by an excepted off-campus PBD from the clinical families of service from which the excepted off-campus PBD furnished and billed (under the OPSS) at least one item or service during the baseline period. CMS also proposes that if an excepted off-campus PBD furnishes a new service from the same clinical family of services from which it furnished and billed a service during the baseline period, this would not be treated as a service expansion and would be paid under the OPSS.

NCHA is disappointed that CMS has revived the expansion of services proposal, which the agency had previously rejected. We are concerned that CMS did not share any claims-based or other evidence validating its premise that current policy incentivizes hospitals to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs, despite the fact that it had previously indicated that it would monitor service line expansion in excepted off-campus PBDs and share results. This policy will penalize hospital outpatient departments that expand the types of critical services they offer to their communities and prevent them from caring for the changing needs of their patients. **We believe that this proposed expansion of services proposal is inconsistent with CMS policy and does not comport with Congress’ intent to protect excepted off-campus PBDs from site-neutral cuts.** Off-campus PBDs must be able to expand the items and services that they offer in order to meet changes in clinical practice and the changing needs of their communities without losing



their ability to be reimbursed under the OPSS. Given the rapid pace of technological advances in medicine, the treatments and services offered by PBDs today will inevitably evolve into newer, innovative and more effective care in the future. CMS policy must not hamper access to innovative technologies and services. Nothing in Bipartisan Budget Act of 2015 (BiBA) requires that CMS treat expanded services in an excepted PBD in this way. In fact, the plain language does not address relocation or expansion at all. CMS must ensure that patients continue to have access to the services they need at the facilities where they seek treatment. **We strongly urge CMS to protect our hospitals' ability to offer an expanded range of needed services without experiencing a loss of reimbursement and to ensure that these facilities are treated as Congress intended.**

**Proposed Reduction in Payment for Hospital Outpatient Clinic Visit in Excepted Off-campus PBDs**

CMS proposes to pay for clinic visits (i.e., evaluation and management services) furnished in excepted off-campus PBDs at the same rate they are paid in non-excepted off-campus PBDs. In other words, all outpatient clinic visits would be reimbursed on a site-neutral basis, at equivalent rates to physician offices if furnished in an off-campus location. **NCHA believes that this proposed policy misinterprets Congressional intent by proposing to reduce payments for services in excepted off-campus PBDs that Congress explicitly protected from site-neutral cuts in Section 603 of the Bipartisan Budget Act of 2015 (BiBA).** If Congress had meant to apply site neutrality to excepted sites, it would have done so in Section 603. Instead, Congress established a compromise by identifying those off-campus PBDs that would be restricted in reimbursement (e.g., new off-campus PBDs established on or after November 2, 2018) and those that would not (e.g., off-campus PBDs that had been billing OPSS prior to November 2, 2015 – grandfathered facilities). Congress was very clear in its intentions regarding grandfathered facilities. **We are concerned that CMS is ignoring Congressional intent by erasing the benefits of the excepted (grandfathered) locations.**

Also, CMS is proposing to implement this rate adjustment in a nonbudget-neutral manner resulting in a reduction in hospital payments by \$760 million in calendar year 2019. By statute, Congress has made it clear that adjustments under the OPSS must be made in a budget neutral manner. NCHA disagrees with CMS' assertion that this proposal refers to a method for controlling volume increases in PBD. **There is no doubt that this proposal is a rate adjustment that should be subject to the budget neutrality provisions of the Social Security Act.**

**NCHA remains concerned that CMS's continued flawed site-neutral reimbursement policies will prevent North Carolina communities from having access to the most up-to-date services that they desperately need. These onerous site-neutral payment policies jeopardize access to care by making off-campus clinic expansion into North Carolina's underserved communities financially unsustainable.**

These proposed site-neutral reimbursement cuts will result in hospitals' re-evaluating decisions to develop new off-campus PBDs in underserved areas. The cuts will also undermine the ability of hospitals to develop and/or integrate lower-cost ambulatory facilities at locations that would better serve the patient's needs and increase access to much needed care in these rural and underserved areas. The cost structures of hospitals and their hospital-based ambulatory care facilities are much different than for freestanding physician offices and freestanding ambulatory surgery centers. Hospitals have greater investment in information systems, equipment technology, facilities, quality and safety systems, and other human and technology resources. Without adequate and appropriate reimbursement from Medicare and other payers for off-campus hospital departments, hospitals will not have the financial resources to develop such sites in rural and underserved communities. These communities have not been adequately served by other health care stakeholders, such as freestanding physician offices and freestanding ambulatory surgery centers, because of their challenging economic profiles. Furthermore, such changes undermine our hospitals' efforts to integrate and coordinate care between ambulatory, acute, and post-acute care sites at the same time that CMS and others are promoting accountable care, Triple Aim, and population health management.

**We ask you to also note that, as NCHA drafts these comments, hospitals and other providers in eastern North Carolina are reporting to us daily that clinics, physician practices, dialysis centers and other care providers are not operational due to the winds and floods from Hurricane Florence. Although our member hospitals were also significantly impacted by the storm, they are providing these much needed services in their main facilities and PBDs until these other community based services can re-open.**

**Proposal to Apply the 340B Drug Payment Policy to Non-excepted Off-campus PBDs**

For calendar year 2019, CMS proposes to pay for separately payable drugs in biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program at a rate of Average Sales Price (ASP) minus 22.5 percent when they are furnished by non-excepted off-campus PBDs. CMS is continuing its assault on 340B hospitals that serve vulnerable communities by expanding the nearly 30% cut to outpatient drug payments to a significant number of additional PBDs. **NCHA recommends that CMS withdraw its proposal to reduce payment for separately-payable drugs purchased through the 340B program because it is inconsistent with the agency's statutory authority under the Social Security Act.**

**Decoupling the IPPS and OPSS Wage Index for the Rural Floor Calculation**

NCHA continues to oppose the continued application of the nationwide rural floor budget neutrality adjustment. NCHA recognizes that the impetus for the policy is a federal statute, not regulation. A one-sentence section of law enacted in the Patient Protection and Affordable Care Act (PPACA) of 2010 established a policy of national budget neutrality for Medicare wage index changes. Coupled with the orchestrated conversion of a single facility in Massachusetts – Nantucket Cottage Hospital – from a critical access hospital to an IPPS hospital, this law unfairly manipulates the Medicare payment system to reward hospitals in Massachusetts and a few other states at the expense of most other hospitals across the nation.

CMS, the Medicare Payment Advisory Commission (MedPAC) and many others have commented over the past several years on the adverse consequences of the nationwide rural floor budget neutrality adjustment, yet no action has been taken to correct it. Until this policy is corrected, the Medicare wage index system cannot accomplish its objective of ensuring that payments for the wage component of labor accurately reflects actual wage costs.

CMS has taken positive steps to create fairness in the wage index for the skilled nursing facility PPS by excluding the effects of reclassifications and the application of the national rural floor adjustment. We also agree with CMS's assertion that it has the legal authority to decouple the wage index used for IPPS and the wage index used the OPSS.

**Given the actions taken relative to the skilled nursing facility wage index and recent initiatives by CMS in the IPPS rule to restore accuracy and fairness to the wage index, NCHA encourages CMS to explore those options which would permit CMS to decouple PPACA Section 3141 from the OPSS wage index. NCHA also encourages CMS to continue publishing the state-specific impact table as displayed in the IPPS rule and requests a similar state-specific impact table in the 2019 final OPSS rule.**

**Rural Adjustment for Sole Community Hospitals**

**NCHA supports the continued payment adjustment to rural sole-community hospitals, including essential access community hospitals, by 7.1 percent for all services paid under the OPSS.** NCHA is appreciative of CMS's consideration of access to care in rural areas as part of the proposed OPSS rule.

**Request for Information on Price Transparency**

Under current law, hospitals are required to establish and make public a list of their standard charges. However, CMS is creating more specific guidelines, effective January 1, 2019, that would require hospitals to make available a list of their current standard charges via the internet in a machine-

readable format and to update this information at least annually, or more often, as appropriate. This could be in the form of the charge master itself or another form of the hospital's choice, as long as the information is in machine-readable format.

CMS also is considering initiatives to promote hospitals' consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain at the hospital. These actions also would enable patients to compare charges for similar services across hospitals. Therefore, it is seeking information regarding barriers that prevent providers from informing patients of their out-of-pocket costs; changes that are needed to support greater transparency around patient obligations for their out-of-pocket costs; what can be done to better inform patients of these obligations; and what role providers should play in this initiative. It also is considering making information regarding hospital non-compliance with the requirements public and intends to consider additional enforcement mechanisms in future rulemaking.

Patients are assuming greater financial responsibility for their healthcare needs and thus, need enhanced information that will allow them to make informed healthcare decisions. NCHA and its members support providing high-quality information to patients through well-designed tools, as well as other resources to help them understand and interpret that information and believe that this approach will enable patients to make better choices.

Price transparency and quality ratings are critical if patients are to be empowered to make meaningful decisions prior to receiving care. Patients want and need cost, quality, and treatment information that is highly personalized to their situations and preferences and delivered at the point of decision-making. Patients want to know the total price of the service, the provider's network status, and their estimated out-of-pocket responsibility, along with other available provider and service-specific information such as quality ratings, clinical outcomes, patient safety, satisfaction scores, etc. In addition, patients want to know the total price and out-of-pocket costs for a given episode of care, not just the price for a discrete procedure. For example, a patient undergoing a total knee replacement would like to understand the costs of the entire episode, from preparation for surgery through rehabilitation, rather than just the costs of the surgery. Ideally, the price would reflect the negotiated reimbursement rates between the insurance carrier and the providers as well as the patient's specific out-of-pocket responsibility. Thus, we do not believe that requiring hospitals to make available and update a list of their current standard charges via the internet in a machine-readable format would provide patients with the information needed to make informed decisions. This could be confusing since patients generally do not know all the services that they will receive prior to a given encounter, and the standard charge amounts are not the amounts that the insurance carrier will reimburse the provider on the patient's behalf.

The healthcare payment system is very complex, and these complexities create numerous challenges when addressing price transparency and quality ratings as illustrated below:

- There are many different sources of price and quality information, many different benefit designs for patients with insurance coverage, and an increasing variety of payment models and quality indicators.
- Patients may receive services from numerous independent providers as part of their treatment for a specific condition. They may also need to pay separately for pharmaceuticals or medical devices. As a result, it can be difficult for patients to obtain price estimates for everything that will be needed as part of the treatment or procedure.
- Unexpected complications may result in the patient receiving additional care or treatment that was not part of the original price or cost estimate. As a result, providers may only be able to provide a reliable estimate in advance.
- The rates negotiated between in-network providers and insurance companies are subject to the confidentiality clauses included in managed care contracts and in most cases, cannot be shared

with patients and others without breaching the terms of the contract. Transparency in the private insurance market should (i) focus on out-of-pocket costs in lieu of negotiated rates or (ii) mask provider-specific negotiated rates by reporting total episodic costs.

- Patients may also receive services from out-of-network providers, making it virtually impossible to obtain the total price of the service and the patient's out-of-pocket cost until after the insurance carrier processes the claim.

Given these complexities, payers, providers, and patients will need to work together on the price and quality information that patients need to make informed decisions. In today's healthcare environment, health plans have the most comprehensive understanding of their benefit designs, networks, and negotiated prices and thus, are in the best position to provide this information to their members. Providers must also be highly engaged in helping patients weigh treatment options, understanding total costs of treatment, and evaluating options to address their out-of-pocket liability.

Many health plans as well as the North Carolina Department of Health and Human Services (NCDHHS) have already developed or are in the process of developing web-based transparency tools. The NCDHHS tool, which was mandated by the North Carolina legislature in 2013 and requires reporting of insurer payments on select procedures, has been of little value to consumers. The complexities of reporting the required data categories in a logical format that is also acceptable to payers are enormous, and the result is an annual report that is costly to produce and of little benefit to patients. Public awareness and use of these tools are low, in part because these tools are difficult to use and sometimes the information lacks relevance. Quality ranking tools are also not being used as the information is not presented in a consumer-friendly manner. For example, very few tools provide quality data on providers at the procedure level and some pricing tools only present charge data. These existing tools must be improved by providing information that is tailored to a patient's specific conditions, needs, and insurance coverage, that is easy to understand and is made available at the point of decision-making. Providers, insurance carriers and other stakeholders must work to improve the accuracy, ease of use, and accessibility of information and must increase patient awareness of the new tools and resources. Transparency tools must be flexible to adapt to changing healthcare payment and delivery models. Public policy should support these goals by providing financial resources for development and implementation of new tools and resources.

Thank you for your consideration of our comments. If you have any questions, please contact me ([slawler@ncha.org](mailto:slawler@ncha.org), 919-677-4229), Jeff Weegar, Vice President Financial Policy ([jweegar@ncha.org](mailto:jweegar@ncha.org), 919-677-4231) or Ronnie Cook, Finance and Managed Care Consultant ([rcook@ncha.org](mailto:rcook@ncha.org), 919-677-4225).

Sincerely,



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President  
North Carolina Healthcare Association