North Carolina Healthcare Association

Uniting hospitals, health systems and care providers for healthier communities

September 27, 2019

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-1717-P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals.

Dear Ms. Verma:

On behalf of our 130-member hospitals and health systems, the North Carolina Healthcare Association (NCHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs proposed rule for fiscal year (FY) 2020.

Continuation to apply the 340B Drug Payment Policy:

CMS proposes to continue paying the average sales price (ASP) −22.5 percent for 340B-acquired drugs. This proposal continues the 27 percent reduction in Medicare reimbursement for 340B drugs that was originally enacted in 2018. In the proposal, CMS acknowledges the court's decision on December 27, 2018, in the case of American Hospital Association et al. v. Azar et al, 18-2084 (RC), where the court decided to reverse CMS' decision to cut 340B reimbursement. However, CMS discloses their commitment to appeal the U.S. District court's decision explaining why they will continue to reimburse hospitals at the preposterous rate of ASP −22.5 percent.

NCHA strongly disagrees with CMS' proposal and is disappointed that CMS continues to oppose, and plans to appeal, the U.S. District court's decision. NCHA disagrees with CMS' proposal as the 27 percent reduction is drastic, and negatively impacts safety-net hospitals that serve vulnerable communities. 340B hospitals rely on these funds to perform needed community benefits and to "stretch scarce federal resources to support care for the low-income and rural patients they treat." NCHA also believes the proposal further complicates and obscures the remedy process ordered by the U.S. District court. **As such, NCHA's 340B hospitals urge CMS to adhere to the U.S. District court decision and update the FY 2020 proposal to revert to paying 340B hospitals at 106 percent of ASP.**

CMS acknowledges they could lose their appeal of the U.S. District court decision which would result in them having to repay hospitals for 340B claims that were processed with the 27 percent reduction. CMS requests public comment on how to resolve 340B claims paid incorrectly in the event they lose their appeal. NCHA believes the remedy should be completed retrospectively on a claim-by-claim basis, rather than prospectively adjusting prior 340B claims with an arbitrary percentage. A retrospective claim-by-claim remedy is the most accurate way to ensure 340B hospitals are reimbursed the amount ordered by the court (ASP plus 6% methodology). The claim by claim analysis should follow the method outlined below:

1) Hospitals that have already received payment for 340B claims using the 2018 and 2019 OPPS methodology should receive a supplemental payment for those claims in an amount that equals the difference between the amount they received and the amount the district court decision has determined that they are entitled to (based on the ASP plus 6% methodology), plus interest.

2) Claims that have not yet been paid should be paid in the full amount (the amount they would have received under the statutory default, ASP plus 6%, which is the rate set forth in the 2017 OPPS rule).

Lastly, the remedy should be made without consideration of budget neutrality since 340B funds are not taxpayer funded and are derived solely from private transactions. Further, statutes do not give CMS the authority to require hospitals to pay back money they have already been paid as a result of CMS' erroneous reimbursement reductions, such as the 340B reduction.

Disclosure of Standard Charges and Negotiated Rates:

CMS proposes expanding title 45 of the Code of Federal Regulations (CFR), adding a new Part 180 – Hospital Price Transparency. The proposal requires hospitals to release a machine-readable list of all of their standard charges, both gross charges and rates negotiated with private payers, for all items and services on their websites. In addition to the posting of a machine-readable list, CMS proposes requiring hospitals to post negotiated rates for 300 "shoppable" services in a consumer-friendly way that is both easily understood and searchable. Shoppable services are typically those that are routinely provided in non-urgent situations that do not require immediate action or attention to the patient, thus allowing patients to price shop and schedule a service at a time that is convenient for them. CMS requires the charges for the shoppable services be displayed along with charges for ancillary items and services. CMS is proposing that hospitals make public the payer-specific negotiated charge for a shoppable service that is grouped together with charges for associated ancillary services because they believe the charge information should be displayed in such a way that is consumer-friendly and patient-focused.

NCHA understands and appreciates CMS' efforts to promote healthcare transparency on price and quality to ensure patients can afford healthcare. 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 strongly supports a patient-focused approach where patients are equipped with the information they need regarding healthcare and its cost. **However, NCHA strongly disagrees with CMS' proposal as releasing privately negotiated rates would undermine the competitive forces in the private market and result in increased prices.** The Federal Trade Commission (FTC) has warned numerous times against the disclosure of competitively sensitive information, such as payer-negotiated prices. Such disclosure can "facilitate collusion, raise prices and harm…patients…."[1] That warning extends explicitly to contract terms with health plans.[2] The FTC has urged that transparency be limited to out-of-pocket expenses, co-pays, and quality and performance comparisons of plans or providers. In addition, 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. **NCHA believes that CMS imposing on the private healthcare market is unlawful, exceeding the administration's legal authority. Therefore, 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.**

[1] FTC Letter to the Hon. Nellie Pou, April 17, 2001.
[2] FTC Letter to Hons Joe Hoppe and Melissa Hortman, June 29, 2015.

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.
- Patients may receive additional services not included in the initial estimate or providers may render, code and bill for a service different from the service for which the patient sought an estimate. Thus, price information will likely take the form of an estimate or price range, given that unexpected complications may affect the price of care.
- 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 to define and provide 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 benefit designs, networks, and real time out of pocket balances 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.**

NCHA also believes the proposed approach does not accomplish CMS' intent to be consumer-friendly and patient-focused. Patients want to know the total price of the service, their estimated out-of-pocket responsibility, along with other available provider and service-specific information such as quality ratings, clinical outcomes, patient safety, and satisfaction scores. Rather than helping patients, CMS' proposal complicates getting patients the information they truly desire and instead, increases healthcare costs, burdens providers, and confuses patients with unnecessary information. **In order for patients to obtain the information they truly desire, allowing them to shop for healthcare in an acceptable manner, CMS should develop a committee of healthcare stakeholders and use these subject matter experts to develop a viable solution.**

Site-Neutral Payment Policies for Off-Campus PDBs:

CMS proposes to complete the phase-in of the reduction in payment for the clinic visit services furnished in grandfathered (expected) off-campus provider-based departments (PBD). This proposal will pay for hospital outpatient clinic visit services in grandfathered (expected) PBDs at a payment rate of 40 percent of the OPPS payment amount.

NCHA urges CMS to remove this proposal for FY 2020 in accordance with the ruling in the U.S. District court case of the American Hospital Association et al. v. Azar et al, 18-2841 (RMC), where the court decided CMS exceeded their statutory authority when it cut the payment rate for clinic services at off- campus provider-based clinics. As stated by the court, CMS was not authorized to ignore the statutory process for setting payment rates in the OPPS. Congress established an elaborate statutory scheme which spelled out each step for determining the amount of payment for services under the Outpatient Prospective Payment System. NCHA agrees with the court that CMS' proposal clearly undermines congressional intent.

In addition, NCHA wants CMS to recognize that the 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 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. CMS needs to be aware that 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. **For these reasons, NCHA urges CMS to develop a remedy to issue payments to hospitals for the improperly withheld payments associated with the 2019 Final Rule.**

The remedy should be completed at a hospital specific level, on a claim by claim basis, to ensure hospitals are adequality reimbursed for these needed services. The remedy should be completed as follows:

1) Hospitals that have already received payment for OPPS claims using the 2019 OPPS methodology should receive a supplemental payment for those claims in an amount that equals the difference between the amount they received and the amount the they are entitled to (100% of OPPS methodology), plus interest.
2) Claims that have not yet been paid should be paid in the full amount (the amount they would have received under the default OPPS methodology).

Level of Supervision of Outpatient Therapeutic Services:

CMS proposes to change the minimum required level of supervision from direct supervision to general supervision for all hospital outpatient therapeutic service provided by all hospitals and critical access hospitals (CAH). General supervision means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure. **NCHA strongly supports this proposal as the direct supervision requirements for hospital outpatient therapeutic services places an additional burden on providers, particularly CAHs and small rural hospitals.** NCHA supports the general supervision for all outpatient therapeutic services as providers will use their own discretion to determine if direct supervision is needed for medical procedures.

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

Sincerely,

Stephen J. Lawler
President
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