Via Electronic Submission (www.regulations.gov)

September 11, 2017

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

Re: CMS–1676–P, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program; Proposed Rule (Vol. 82, No. 139), July 21, 2017.

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) proposed rule for the calendar year (CY) 2018 physician fee schedule (PFS).

While NJHA supports a number of the proposals in this rule, we have serious concerns about other proposals. **In particular, NJHA is extremely concerned about the proposal to significantly reduce the payment rate for "nonexcepted" services provided in off-campus provider-based departments (PBDs) and strongly urges the agency to withdraw it.**

NJHA's detailed comments on the PFS proposed rule follow.

CY 2018 PFS Relativity Adjuster for Nonexcepted, Off-campus Provider-based Departments (PBDs)

Section 603 of the Bipartisan Budget Act of 2015 (BiBA) requires that, with the exception of emergency department (ED) services, services furnished in off-campus PBDs (PBDs) that began billing for services under the outpatient prospective payment system (OPPS) on or after Nov. 2, 2015 (referred to as "nonexcepted services") are no longer paid under the OPPS. Instead, these services are covered and paid under "another applicable Part B payment system." For CY 2017, CMS finalized the PFS as the applicable Part B payment system for most nonexcepted services and set the payment at 50 percent of the OPPS rate. CMS refers to this 50 percent rate as the "PFS Relativity Adjuster." It calculated this rate by comparing OPPS and PFS payment rates for certain services frequently reported in PBDs and described by the same codes under both the OPPS and PFS.

However, in the CY 2018 PFS proposed rule, CMS suggests significant reductions to the payment rate for nonexcepted service. Specifically, for CY 2018, the agency proposes to set the PFS Relatively

Adjuster to 25 percent, rather than 50 percent. It calculated this rate using a different methodology than it used for 2017 – basing it exclusively on only one service, which reflects the most commonly billed service in the off-campus provider-based department setting under the OPPS.

This proposal has a questionable legal and policy basis and threatens access to care for patients, including many in vulnerable communities without other sources of health care. The AHA strongly urges CMS to withdraw its proposed Relativity Adjuster of 25 percent. Making such an adjustment in CY 2018 would be arbitrary and capricious because it is unreasonable and unsupported by existing data, and therefore is in violation of the Administrative Procedure Act (APA).

Instead, the agency should retain its current methodology, which bases the Relativity Adjuster on a comparison of payment rates for the most frequently billed services in off-campus PBDs, and which resulted in the CY 2017 rate of 50 percent of the OPPS rate for nonexcepted services. NJHA agrees with the American Hospital Association's (AHA) recommendations on how CMS should improve its methodology to make it more accurate by better accounting for differences in packaging across the OPPS and the PFS. Based on AHA's updated analysis, doing so would result in a payment rate of 65 percent of the OPPS payment for nonexcepted services in 2018.

CMS'S PROPOSED REDUCTION WOULD BE ARBITRARY AND CAPRICIOUS BECAUSE IT IS UNREASONABLE AND UNSUPPORTED BY EXISTING DATA, AND THEREFORE IS IN VIOLATION OF THE APA

Regardless of setting, it is important for Medicare to make reasonable and adequate payment for the high-quality care that hospitals furnish to Medicare beneficiaries. Hospitals should not be penalized for providing services in locations like off-campus PBDs that may best meet the needs of patients and communities. However, the proposed reduction to the CY 2018 PFS Relativity Adjuster from 50 percent to 25 percent of the OPPS payment rate would do just this – create an inadequate payment rate and penalize hospitals for providing services in nonexcepted, off- campus PBDs. **We strongly urge CMS to wait for more precise data before making any significant changes affecting payments for services furnished at nonexcepted, off-campus PBDs such as those proposed. Indeed, it would be arbitrary and capricious to make the proposed reduction to the Relativity Adjuster now for at least three reasons:**

- **CMS does not address serious limitations and shortcomings of its proposed methodology, which violates the APA;**
- **The agency has completely failed to provide a sufficient explanation for its proposed reduction to the Relativity Adjuster; and**
- **The agency's proposal would make an arbitrary and unjustified reduction when its CY 2017 PFS Relativity Adjuster was already unreasonably low, as the AHA explained in its comments on the CY 2017 OPPS final rule with comment period and interim final rule with comment period.**

<u>CMS's Proposed Methodology Ignores Serious Limitations and Shortcomings of the Methodology</u>. Last year's 50 percent PFS Relativity Adjuster was adopted as part of an interim final rule that

contemplated refinement in response to stakeholder comments. CMS acknowledged that it "lack[ed] . . . data regarding the mix of services currently being furnished in nonexcepted off-campus" PBDs. But the agency nonetheless sought to estimate an appropriate CY 2017 PFS Relativity Adjuster by creating a weighted average based on the limited data available to it about PBDs' "most frequently billed [Healthcare Common Procedure Coding System (HCPCS)] codes." CMS recognized that it was relying on imperfect information and that there were "limitations to [its] data analysis" that necessitated, among other things, a need "to continue to study th[e] issue." The agency also suggested that "future refinements" would be needed to its CY 2017 methodology to promote greater accuracy and address the limitations that CMS acknowledged in its CY 2017 interim final rule.

In the CY 2018 proposed rule, CMS continues to emphasize that its proposal is a transitional one: CMS says that, before it can adopt anything other than a "transitional policy," it needs "more precise data." In the absence of such data, the agency recognizes there is not enough information available to "identify and value [all of the] nonexcepted items and services furnished by nonexcepted off-campus [PBDs] and billed by hospitals."

Yet in the face of these statements and absence of data, CMS does not propose to refrain from making further changes until more information is available. Nor does the agency respond to stakeholder comments on the CY 2017 interim final rule that questioned numerous assumptions and decisions made in setting the CY 2017 Relativity Adjuster at 50 percent. Rather, with little explanation, CMS proposes that the CY 2018 PFS Relativity Adjuster for nonexcepted, off-campus PBDs be reduced from 50 percent to 25 percent of the OPPS payment rate. In doing so, CMS relies on an entirely new transitional methodology that ignores the already "limited information available to" the agency in CY 2017. Presumably, CMS does so because reliance on all of the data it had examined in CY 2017 would have necessitated a higher adjuster in CY 2018. Yet, CMS is not permitted simply to blind itself to the information before it. Nor can the agency wholly disregard the comments it solicited in its 2017 interim final rulemaking and propose dramatic reductions to the CY 2018 Relativity Adjuster without even purporting to respond to the concerns raised by AHA and others.

This guarantee has been rendered almost meaningless because CMS's CY 2018 Relativity Adjuster proposal would alter the methodology used by CMS for CY 2017 without ever addressing the problems and concerns raised by commenters about the CY 2017 methodology. CMS's failure to respond to the CY 2017 interim final rule comments can therefore no longer be cured by responding at a later date; the time for consideration of these comments passed when CMS completely abandoned the CY 2017 methodology to which commenters were responding.

CMS's Failure to Respond Timely to Methodological Problems Previously Identified is an APA Violation. Even more importantly, CMS's failure to respond timely to the comments subverts the APA itself. Many, if not all, of the central defects in the CY 2017 PFS Relativity Adjuster have carried over to and been exacerbated by the methodology proposed for CY 2018. In saying that it will defer responding to comments on the CY 2017 PFS Relativity Adjuster until some unspecified "future" rulemaking, CMS has effectively shielded itself from the need to respond promptly to commenter objections addressing those defects. This insulation from criticism has allowed CMS to perpetuate "one-sided" views, which has fostered even more arbitrary and unreasonable approaches, such as the proposed CY 2018 methodology. Moreover, CMS's actions fundamentally misapprehend how interim final rules operate under the APA. An interim final rule is a brief deferral of the

necessary responses to comments, which is restricted to good cause, 5 U.S.C. § 553(b), (d), based on "exceptional circumstances. Otherwise, an agency. . . could simply . . . raise up the 'good cause' banner and promulgate rules without following APA procedures." Even through an interim final rule, an agency cannot adopt rules while deferring responses to comments until a later date *simply because, sometime in the future, it plans to change the rules it is now adopting.* Postponing responding to comments across *entire rulemaking cycles* where the agency implements policies directly related to commenter statements is tantamount to conceding that good cause does not support the agency's ongoing failure to respond to comments.

CMS Arbitrarily and Unreasonably Failed to Provide a Sufficient Explanation for its Proposed Reductions. Although NJHA has numerous concerns about site neutrality, our primary objection to CMS's CY 2018 PFS Relativity Adjuster is even more basic. NJHA strongly believes it is appropriate for CMS to change hospital payment policies only when CMS's proposals are based on reasonable assumptions and sufficiently precise information to support the agency's considered reasoning. The proposed reduction to the CY 2018 Relativity Adjuster fails on all counts.

Moreover, CMS itself says that "claims data from CY 2017, which are not yet available, are needed to guide potential changes to [CMS's] general approach, and "[t]here is no consensus among stakeholders regarding the appropriate PFS Relativity Adjuster." **Given that CMS believes there are neither sufficient data for precise estimates nor broad public consensus as to what constitutes an appropriate PFS Relativity Adjuster, CMS should, at a minimum, defer any changes to its transitional adjuster until next year's rulemaking when CMS expects to have studied all of the claims data necessary to make a fully informed judgment.**

CMS's CY 2018 proposal presumes that last year's PFS Relativity Adjuster dramatically over-inflated payments to nonexcepted, off-campus PBDs, such that an additional 50 percent reduction from the CY 2017 rate is supported. CMS justifies this dramatic reduction by speculating that "the [CY 2017] PFS Relativity Adjuster *might* [have] be[en] too small."

CMS supplies virtually no explanation or support for why it thinks this is the case. CMS notes that, when it promulgated its CY 2017 methodology, it said that, if it "were able . . . to sufficiently estimate" various factors under its CY 2017 methodology, it "suspected" that a 50 percent adjuster would have been too high. But CMS's current proposal is not based on an evaluation of all of the data that CMS lacked at the time of its CY 2017 rulemaking. Those "claims data . . . are [still] not yet available."

CMS cannot justify its proposed policy by relying on "conclusory statement[s]" grounded in the agency's speculation about data it has not reviewed. It is well established under the APA that "[s]peculation is no substitute for evidence." "[A]n agency's 'declaration of fact that is capable of exact proof but is unsupported by any evidence' is insufficient to make the agency's decision non-arbitrary." The rulemaking record must contain the specific evidence needed to support a rational nexus between specific facts found and an agency's proposed course of action. CMS cannot simply assume that data will eventually become available that it "suspects" will support its current conclusions.

CMS Proposes an Arbitrary and Unjustified Reduction when the CY 2017 PFS Relativity Adjuster was *Already* Unreasonably Low. NJHA is especially troubled because there is strong reason to think that last year's PFS Relativity Adjuster was actually too low, rather too high. CMS's CY 2017 methodology did not account for the fact that the OPPS incorporates vastly more packaging into its payments for services relative to the PFS. As a practical matter, this means that CMS's CY 2017 methodology did not account for a significant variable affecting the real world reimbursement actually received by providers billing under the OPPS, which would be necessary to consider in order to accurately compare the OPPS and PFS rates. In last year's rulemaking, CMS acknowledged this "limitation to [its] data analysis," but took no steps to correct it in setting the CY 2017 PFS Relativity Adjuster.

CMS SHOULD RETAIN ITS CURRENT METHODOLOGY BUT INCORPORATE METHODOLOGICAL IMPROVEMENTS TO ACCOUNT FOR DIFFERENCES IN PACKAGING ACROSS THE OPPS AND PFS

We urge CMS to retain its CY 2017 methodology for determining the Relativity Adjuster, which resulted in a CY 2017 rate of 50 percent of the OPPS rate for nonexcepted services. However, we also urge CMS to improve the accuracy of this methodology to account for differences in packaging across the OPPS and the PFS and to ensure that it accounts for both direct and indirect practice expense.

Expansion of Services and Relocation Policies for CY 2018. NJHA appreciates that for CY 2018, CMS has not proposed any changes its policy that allows existing off-campus PBDs to expand their services, without penalty, to meet the changing needs of their patients and communities. However, we remain concerned that CMS has not proposed to reverse its CY 2017 policy prohibiting the relocation of an excepted off-campus PBD, which penalizes hospitals that must relocate their PBDs. The agency should recognize the need for hospitals to modernize existing facilities so that they can provide the most up-to-date, high-quality services to patients in locations that best meet patients' needs.

MEDICARE TELEHEALTH SERVICES

NJHA supports the agency's proposal to add new Current Procedural Terminology (CPT) codes to its list of approved Medicare telehealth services. Covering these telehealth services will expand access to care for Medicare beneficiaries in rural areas. Specifically, CMS proposes to add two new services to the list of Medicare-payable telehealth services:

- Counseling visit to determine low-dose computed tomography (LDCT) eligibility (G0296); and
- Psychotherapy for crisis (90839, first 60 minutes; 90840, each additional 30 minutes).

Comment Solicitation on Telehealth and Remote Patient Monitoring. CMS solicits comment on ways it might expand access to telehealth within its statutory authority. We note that limited Medicare

coverage and payment for telehealth services remains a major obstacle for providers seeking to improve patient care. We acknowledge that many of the limitations to expanding Medicare coverage for telehealth are statutory. However, CMS should use its own authority to identify services that could be effectively and efficiently furnished using telehealth and add those to the list of approved Medicare telehealth services. Currently, the agency approves new telehealth services on a case-by-case basis, with the result that Medicare pays for only a small percentage of services when they are delivered via telehealth. However, this process should be simplified, such as by a presumption that Medicare-covered services also are covered when delivered via telehealth, unless CMS determines on a case-by-case basis that such coverage is inappropriate.

NJHA will continue to urge Congress to remove the statutory barriers to increased Medicare coverage of telehealth services, including the geographic and practice setting limitations on where Medicare beneficiaries may receive telehealth services and the limitations on the types of technology that providers may use to deliver services via telehealth.

PHYSICIAN QUALITY MEASUREMENT

As required by the Medicare Access & CHIP Reauthorization Act (MACRA), CY 2018 is the final year for payment adjustments under both the Physician Quality Reporting System (PQRS) and the Value Modifier (VM). The new two-track physician Quality Payment Program (QPP), which includes the Merit-based Incentive Payment System (MIPS), will supplant the PQRS and VM beginning with CY 2019 payments.

NJHA applauds and supports CMS's proposals to streamline the requirements of its two legacy physician quality measurement programs, and to align them more closely with the MIPS. Specifically, we support CMS's proposal to lower retroactively the number of measures required for the CY 2018 PQRS program. While the data submission for the CY 2018 PQRS has passed, CMS would lower the number of required measures from nine measures to six measures, the same number of measures required under the MIPS. Those clinicians that did not meet the previous PQRS standard of nine measures, but did report at least six measures, would therefore not be subject to the PQRS non-reporting penalty of 2.0 percent in CY 2018.

NJHA also supports CMS's proposals to reduce the maximum VM penalties for CY 2018. CMS previously finalized maximum negative payment adjustments for CY 2018 of -2.0 percent for individual clinicians and groups of 10 or fewer clinicians, and -4.0 percent for groups of 10 or more clinicians. CMS proposes to lower the VM's CY 2018 maximum negative adjustment to -1.0 percent for individual clinicians and groups under 10 clinicians, and -2.0 percent for groups of 10 or more clinicians. Moreover, no clinicians and groups successfully reporting PQRS data would be subject to any negative adjustments under the VM. Taken together, CMS's proposals for the PQRS and VM would mean that the maximum negative adjustment for quality in CY 2018 would be -4.0 percent, the same as the CY 2019 MIPS program.

MEDICARE SHARED SAVINGS PROGRAM (MSSP)

Accounting for Primary Care Services. **NJHA supports CMS's proposals to better account for primary care services when assigning beneficiaries to an accountable care organization (ACO).** Specifically, CMS would treat all services provided by a rural health clinic (RHC) or federally-qualified health center (FQHC) in the same way as a primary care service provided by a primary care physician, and would no longer require RHCs and FQHCs to attest to which physicians provided primary care services. CMS also would add to its definition of primary care services the new codes for chronic care management and behavioral health integration that it adopted in the CY 2017 PFS final rule. Taken together, we believe these proposals will reduce burden and enable ACOs to capture a wider range of primary care services.

MSSP Quality Measure Validation. **NJHA supports CMS's proposal to lower the data "match rate" required for MSSP quality measures from 90 percent to 80 percent.** In previous rulemaking, CMS adopted a validation process for MSSP quality measures in which it lowers an ACO's quality score if there is a less than 90 percent match between an ACO's medical records and the quality data it reports. However, a recent CMS analysis showed that the average match rate for 2016 MSSP data was 72 percent, and the median was 80 percent.

Furthermore, we agree with the agency's suggestion that there remain challenges with the clarity of the MSSP program's measure specifications, and with coordinating data collection across the entities participating in an ACO. As a result, we believe an 80 percent match rate is a more reasonable standard and is consistent with the standard used in other CMS quality programs. For example, the hospital inpatient and outpatient quality reporting programs validation standards require a 75 percent match.

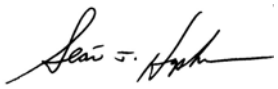
MEDICARE EHR INCENTIVE PROGRAM

CMS proposes to align the reporting requirements for physicians and groups that chose to electronically report clinical quality measures through the PQRS portal for the EHR Incentive Program for 2016. Specifically, CMS proposes that reporting six electronic clinical quality measures (eCQMs) for the EHR Incentive Program without a domain requirement will meet the 2016 PQRS reporting requirement as well as the transition year of the MACRA QPP reporting requirement. **NJHA supports the proposed alignment of Medicare EHR Incentive Program and QPP reporting requirements.** This proposed change would maintain alignment with PQRS while minimizing redundant reporting.

The New Jersey Hospital Association appreciates the opportunity to share our comments with CMS on the physician fee schedule proposed rule for CY 2018.

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,



Sean J. Hopkins
Senior Vice President, Federal Relations & Health Economics
New Jersey Hospital Association

760 Alexander Road, PO Box 1, Princeton, New Jersey 08543
Tel 609-275-4000