

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 our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) physician fee schedule (PFS) proposed rule for calendar year (CY) 2018. The AHA supports a number of the proposals in this rule. **For example, we support the agency's proposal to add new codes to its list of approved Medicare telehealth services. In addition, we strongly support the proposal to delay the appropriate use criteria requirements.** However, this is an extraordinarily complex policy to implement and hospitals may need additional time to revise information systems to provide the necessary data. As such, we ask CMS to consider that it may need to further delay this policy in the future, such as to 2020 or beyond.

However, the AHA has serious concerns about other CMS proposals, including the proposal to significantly reduce the payment rate for “nonexcepted” services provided in off-campus provider-based departments (PBDs). Specifically, for CY 2018, the agency proposes to pay for these services at 25 percent of the outpatient prospective payment system (OPPS) rate, instead of its current rate of 50 percent. **The agency's 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 proposal. Making such an adjustment in CY 2018 would be arbitrary and capricious, unreasonable and unsupported by existing data, and in violation of the Administrative Procedure Act.

Instead, the agency should retain its current methodology, which bases the rate on a comparison of payment rates for the most frequently billed services in off-campus PBDs and physician offices, and resulted in the CY 2017 rate of 50 percent of the OPPS rate for nonexcepted services. The AHA also has 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 our updated analysis, doing so would result in a payment rate of 65 percent of the OPPS payment for nonexcepted services in 2018.

Finally, regarding CMS's initial data collection and reporting periods for the clinical lab fee schedule (CLFS), we have serious concerns that the data that CMS collected from laboratories is inaccurate, incomplete and unable to be validated, and, therefore, will result in payment rates that do not accurately reflect the broad spectrum of private payer payment rates as Congress intended. **Given the expected Jan. 1, 2018 timeframe for implementing the new CLFS payment rates, we urge the agency to take immediate steps, outlined in our detailed comments, to address these concerns.**

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Joanna Hiatt Kim, vice president of payment policy, at (202) 626-2340 or jkim@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy

Enclosure

American Hospital Association (AHA) Detailed Comments on the Physician Fee Schedule (PFS) Proposed Rule for Calendar Year (CY) 2018

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) services¹, 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 Relativity 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. The AHA also has 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 our updated analysis, doing so would result in a payment rate of 65 percent of the OPPS payment for nonexcepted services in 2018.

¹ As well as services in off-campus PBDs meeting the additional “under development” exception in the 21st Century Cures Act.

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.**

CMS’s Proposed Methodology Ignores Serious Limitations and Shortcomings of the Methodology. 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.² 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.”³ CMS recognized that it was relying on imperfect information and that there were “limitations to [its] data analysis”⁴ that necessitated, among other things, a need “to continue to study th[e] issue.”⁵ 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.⁶

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

² 81 Fed. Reg. 79,562, 79,726 (Nov. 14, 2016).

³ *Id.*

⁴ *Id.* at 79,725.

⁵ *Id.* at 79,726.

⁶ *Id.*

“more precise data.”⁷ 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.”⁸

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.⁹ 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 2017.¹⁰ 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.¹¹ 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 previously raised by the AHA](#) and others. Specifically, AHA and others identified serious problems in CMS’s CY 2017 analysis¹² and demonstrated that the 50 percent CY 2017 PFS Relativity Adjuster was already unreasonably low — even before CMS’s proposal to reduce it to 25 percent for CY 2018. CMS promised it would respond to comments on the CY 2017 interim final rule.¹³

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 the AHA and other 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.¹⁴

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

⁷ 82 Fed. Reg. at 33,982.

⁸ *Id.*

⁹ *See also Covad Comm’n Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006) (agencies “must respond in a reasoned manner to those [comments] that raise significant problems”).

¹⁰ 81 Fed. Reg. at 79,723.

¹¹ *See, e.g., Northern Spotted Owl v. Hodel*, 716 F. Supp. 479, 483 (W.D. Wash. 1988) (example where an agency arbitrarily ignored information that the agency itself put forward).

¹² *See, e.g., AHA, Comment Letter* at 3-5 (Dec. 21, 2016) (identifying unreasonable methodological assumptions in CMS’s CY 2017 analysis); *Ass’n of Community Cancer Ctrs., Comment Letter* at 4 (Jan. 3, 2017) (“Instead of being concerned that the 50 percent reduction ‘might be too small,’ CMS must recognize that it likely is too large.”).

¹³ *See* 81 Fed. Reg. at 79,729.

¹⁴ *Cf. Heartland Regional Medical Ctr. v. Sebelius*, 566 F.3d 193, 198 (D.C. Cir. 2009) (*vacatur* of a rule is appropriate if an agency cannot meaningfully cure legal defects through remand).

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,¹⁵ 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.¹⁶ 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.”¹⁷ 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.¹⁸

CMS Arbitrarily and Unreasonably Failed to Provide a Sufficient Explanation for its Proposed Reductions. Although the AHA has numerous concerns about site neutrality,¹⁹ the AHA’s primary objection to CMS’s CY 2018 PFS Relativity Adjuster is even more basic. The AHA 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.²⁰ 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,²¹ and “[t]here is no consensus among stakeholders regarding the appropriate PFS Relativity Adjuster.”²² **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.**

¹⁵ See 82 Fed. Reg. at 33,983.

¹⁶ *Conn. Light & Power Co. v. Nuclear Reg. Comm’n*, 673 F.2d 525, 530–31 (D.C. Cir. 1982).

¹⁷ *Council of Southern Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981).

¹⁸ Cf. *United States Steel Corp. v. United States Environmental Protection Agency*, 595 F.2d 207, 213 (5th Cir. 1979) (the existence of a deadline is not good cause); *Natural Resources Defense Council, Inc. v. Abraham*, 355 F.3d 179, 205 (2d Cir. 2004) (the basis for good cause cannot be an exigent circumstance of the “agency’s own making”).

¹⁹ In addition, we continue to disagree with CMS’s view that a site-neutral payment policy reflects an appropriate interpretation of section 603 of the BiBA. See Pub. L. No. 114-67 § 603, 129 Stat. 584, 597.

²⁰ See 5 U.S.C. § 706(2)(A).

²¹ 82 Fed. Reg. at 33,982.

²² *Id.*

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."²³

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.²⁴ 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."²⁵

CMS cannot justify its proposed policy by relying on "conclusory statement[s]" grounded in the agency's speculation about data it has not reviewed.²⁶ It is well established under the APA that "[s]peculation is no substitute for evidence."²⁷ "[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."²⁸ 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.²⁹ CMS cannot simply assume that data will eventually become available that it "suspects" will support its current conclusions.³⁰

CMS Proposes an Arbitrary and Unjustified Reduction when the CY 2017 PFS Relativity Adjuster was *Already* Unreasonably Low. The AHA 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 OPSS incorporates vastly more packaging into its payments for services relative to the PFS. As a practical matter,

²³ *Id.* (emphasis added).

²⁴ *Id.* 33,981.

²⁵ *Id.* at 33,982.

²⁶ *Allied-Signal v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 136, 152 (D.C. Cir. 1993).

²⁷ *White ex rel. Smith v. Apfel*, 167 F.3d 369, 375 (7th Cir. 1999).

²⁸ *Safe Extensions, Inc. v. FAA*, 509 F.3d 593, 605 (D.C. Cir. 2007).

²⁹ *Humana of Aurora, Inc. v. Heckler*, 753 F.2d 1579, 1582–83 (10th Cir. 1985) ("[t]here are limits . . . to the degree of imperfection that is permissible" in data that an agency relies on); *see also Lloyd Noland Hosp. & Clinic v. Heckler*, 762 F.2d 1561, 1568 (D.C. Cir. 1985).

³⁰ CMS also says that the "differential between the OPSS and PFS payment update for CY 2018 . . . suggests that that the proposed PFS Relativity Adjuster may overestimate PFS nonfacility payment relative to OPSS payments." 82 Fed. Reg. at 33,983. CMS's reasoning is so opaque that it is not even clear whether the agency thinks the CY 2018 PFS Relativity Adjuster is too high or too low an estimate. But, to the extent this explanation is a tacit effort to shore up the agency's justification for its CY 2018 PFS Relativity Adjuster, CMS's reasoning falls flat. CMS provides no explanation for its apples to oranges comparison. CMS does not indicate that the differential between these two payment updates is significantly driven by payments to PBDs that are subject to the PFS Relativity Adjuster. *See Getty v. Fed. Sav. & Loan Ins. Corp.*, 805 F.2d 1050, 1055 (D.C. Cir. 1986) ("cryptic assertions" are not a substitute for reasoned explanation). Nor does CMS even purport to consider whether alternative explanations are available; such as the statutory differences in how payments under these two systems are actually calculated. *See Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 57 (1983) (agency action is arbitrary and capricious when the agency "fail[s] to consider" important aspects of the identified problem).

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,"³¹ but took no steps to correct it in setting the CY 2017 PFS Relativity Adjuster. In its comments on CMS's CY 2017 interim final rule, the AHA explained that it undertook the analysis needed to correct for this limitation. The AHA evaluated the relevant claims data that CMS had previously relied on, and calculated the packaging percentages for all of the HCPCS codes that CMS used under its CY 2017 methodology.³² In addition, the AHA accounted for other limitations in CMS's analysis, such as the agency's failure to use the full amount that Medicare pays under the PFS for practice expenses for comparison against the OPPS rate.³³ Based on this analysis, the AHA concluded that the CY 2017 PFS Relativity Adjuster was significantly too low. If CMS had used more reasonable assumptions that better reflected the real world reimbursement differences between the PFS and OPPS, the agency would have adopted a PFS Relativity Adjuster of 64 percent rather than 50 percent.³⁴

For CY 2018, CMS not only ignores the analysis and objections of the AHA (and others) about its CY 2017 methodology, but also compounds its error by simply assuming the CY 2017 PFS Relativity Adjuster was too low and reducing it by half to 25 percent, despite effectively acknowledging that the agency lacks the data needed to support a robust and "precise" analysis in support of its proposal.³⁵

The AHA also believes that CMS arbitrarily fails to justify the new methodology it proposes for calculating the CY 2018 PFS Relativity Adjuster. In last year's rulemaking, CMS estimated the CY 2017 PFS Relativity Adjuster 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. CMS compared 22 of the most frequently billed major codes and created an average, which CMS weighted based on volume and adjusted further based on the payment rate differential between OPPS and PFS evaluation and management services.

As discussed above, CMS's CY 2017 methodology failed to account for packaging differences between OPPS and PFS codes and relied on other unrealistic or unreasonable assumptions that led to an unduly low CY 2017 Relativity Adjuster.³⁶ Nonetheless, given the information CMS said was available, the AHA understands why CMS elected to base its CY 2017 PFS Relativity Adjuster on a subset of the most frequently billed codes that would be subject to that adjuster. The AHA believes CMS should continue to rely on its basic CY 2017 approach – at least, until more robust data eventually become available to support a more complete analysis.³⁷

³¹ 81 Fed. Reg. at 79,725.

³² AHA, Comment Letter at 3 (Dec. 21, 2016).

³³ *Id.* at 4.

³⁴ *Id.*

³⁵ 82 Fed. Reg. at 33,982.

³⁶ *See* AHA, Comment Letter at 4 (Dec. 21, 2016).

³⁷ *See* Part X.1, *supra* (describing appropriate corrections to CMS's 2017 methodology).

But CMS's CY 2018 proposal does not seek to refine or improve the agency's CY 2017 methodology. Rather, CMS abandons the CY 2017 methodology entirely. For CY 2018, CMS says it will base its PFS Relativity Adjuster exclusively on one code, which reflects the service most commonly billed in the off-campus provider-based department setting under the OPSS: HCPCS code G0463.³⁸

CMS says that its CY 2018 methodology will "ensure that payment made to nonexcepted [PBDs] better aligns with the services that are most frequently furnished in this setting."³⁹ But that does not explain why CMS will no longer give *any* consideration to the 22 other most frequently billed codes that the agency previously considered under its CY 2017 methodology.⁴⁰

Agencies are required to give due consideration to alternatives clearly supported by the record.⁴¹ But CMS does not explain how looking at a single code could possibly be a "better proxy" for the difference between PFS and OPSS payments than looking at that code *plus* the other 22 most frequently billed codes that CMS relied on in last year's rulemaking.⁴²

CMS's view that relying on *less* information, rather than *more*, is the best proxy for accurately calculating payment "runs counter to the evidence before the agency."⁴³ It also defies common sense. Examining the single most frequently billed code in off-campus, PBDs could not possibly reflect a "better align[ment] with the services that are the most frequently furnished in" such settings relative to examining all 23 of the most commonly billed codes.⁴⁴ This is especially true here, given CMS's acknowledgment that "the comparison between the OPSS and PFS rates for [different] services varies greatly."⁴⁵ Moreover, CMS has already demonstrated that it is able to consider the other 22 most frequently billed codes: It did so in last year's rulemaking. CMS's conclusion that its CY 2018 PFS Relativity Adjuster reflects the best available proxy is, on its face, "so implausible that it does not represent reasonable administration of the Medicare program."⁴⁶

The AHA further notes that CMS has not supplied all the data it relied upon in arriving at its proposed 25 percent reduction of the PFS Relativity Adjuster. "An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary."⁴⁷ "[I]t is especially important for the agency to identify and make available. . . [the] data that it has employed in reaching [its]

³⁸ Although CMS completely abandons the CY 2017 *methodology*, CMS's CY 2018 approach is obviously designed to "back-end" into a 50% reduction in the *rate* set in CY 2017.

³⁹ 82 Fed. Reg. at 33,982.

⁴⁰ See *Puerto Rico Sun Oil Co. v. EPA.*, 8 F.3d 73, 77, 79–80 (1st Cir. 1993) ("Perhaps there is some explanation for [the agency's] action other than a mechanical desire to reach a rapid conclusion without regard to whether the result is sound. . . . [But an agency must] explain why it[s] . . . [proposal] makes sense.").

⁴¹ *Motor Vehicles Mfrs. Ass'n*, 463 U.S. at 51 (agency action is arbitrary where the agency fails to consider a clear alternative presented in the record before it).

⁴² 82 Fed. Reg. at 33,983.

⁴³ *Motor Vehicles Mfrs. Ass'n*, 463 U.S. at 43.

⁴⁴ 82 Fed. Reg. at 33,983.

⁴⁵ *Id.* at 33,982–83.

⁴⁶ *Bedford Cty. Mem'l Hosp. v. Health & Human Servs.*, 769 F.2d 1017, 1022 (4th Cir. 1985).

⁴⁷ *Conn. Light & Power Co.*, 673 F.2d at 530–31.

decision to propose particular rules.”⁴⁸ Failing to do so contravenes the purpose of the APA’s notice-and-comment requirement because it limits the ability of the rulemaking process to support a “genuine interchange” of “useful criticism.”⁴⁹ As a consequence, “the agency may operate with a one-sided or mistaken picture of the issue at stake in the rulemaking,” while insulating itself from “useful criticism” if it “play[s] hunt the peanut with technical information” that it does not make freely available to interested stakeholders during the comment process.⁵⁰

As shown, the CY 2018 PFS Relativity Adjuster departs from basic principles of reasoned decision-making, which are mandatory under the APA.⁵¹ Therefore, as the AHA discusses further below, it recommends that CMS withdraw its proposed CY 2018 PFS Relativity Adjuster for nonexcepted services payment.

Adopting an Alternative PFS Relativity Adjuster would be Premature and in Violation of the APA. Finally, the AHA believes it would be premature to adopt a “different PFS Relativity Adjuster, such as 40 percent,” for CY 2018, as CMS sets forth in the rule.⁵² Adopting such a hypothetical alternative would violate the APA because the agency has failed to supply a reasoned basis for it.

As a threshold matter, we note that a “reviewing court ‘may not supply a reasoned basis for the agency’s action that the agency itself has not given,’”⁵³ and CMS has not explained why it might be appropriate to adopt a “middle ground” like 40 percent, except for stating that it is between the 50 percent CY 2017 PFS Relativity Adjuster and CMS’s (arbitrary and unreasonable) proposal to adopt a 25 percent adjuster for CY 2018.⁵⁴ The mere fact that a position is “in-between” two alternatives does not render the middle position non-arbitrary. CMS must *actually supply* a reasoned explanation as to why the “middle-ground option could pass muster under the statute” and otherwise satisfy all of the APA’s requirements of reasoned decision-making.⁵⁵ And CMS must ordinarily do so *before* finalizing its rule, so that all interested stakeholders have the opportunity to participate in the rulemaking process through commenting and are not left to guess at the reasoning CMS ultimately chooses to adopt.⁵⁶

⁴⁸ *Id.* at 530.

⁴⁹ *Id.*; see also 5 U.S.C. § 553(b)–(c).

⁵⁰ *Conn. Light & Power Co.*, 673 F.2d at 530.

⁵¹ Even where judicial review is precluded, CMS’s longstanding position has been to comply with the APA. In addition, here, judicial review *is* available: The PFS Relativity Adjuster is not subject to the OPPS provision precluding judicial review of payment adjustments because payment of the PFS relativity adjustment is not made under the OPPS. See 42 U.S.C. § 1395l(t)(21)(A)–(B). The PFS Relativity Adjuster is also not subject to any other provision that would preclude judicial review to enforce the APA’s requirements against an arbitrary, capricious, or otherwise unreasonable agency action. See *id.* § 1395l(t)(21)(E); cf. *Marble Mountain Audubon Soc. v. Rice*, 914 F.2d 179, 181 (9th Cir. 1990).

⁵² 82 Fed. Reg. at 33,983.

⁵³ *Bowman Transp., Inc. v. Ark-Best Freight Sys., Inc.*, 419 U.S. 281, 285–86 (1974).

⁵⁴ 82 Fed. Reg. at 33,983.

⁵⁵ *Ctr. For Biological Diversity v. EPA*, 722 F.3d 401, 411 (D.C. Cir. 2013) (requiring EPA to *consider* a proposed middle-ground option, but declining to opine on whether the middle-ground option was *actually* legally viable).

⁵⁶ Cf. *Nat’l Elec. Mfrs. Ass’n v. EPA*, 99 F.3d 1170, 1172 (D.C. Cir. 1996) (“An agency ‘must provide sufficient . . . rationale . . . to permit interested parties to comment meaningfully.’”).

In addition, if CMS adopts an entirely different PFS Relativity Adjuster, commenters — including the AHA — will not have been given any meaningful opportunity to address the methodology underlying that alternative. This would circumvent an essential guarantee assured by notice-and-comment: that an agency will “reveal the portions of the technical basis for a proposed rule in time to allow for meaningful commentary” from interested stakeholders.⁵⁷ If CMS believes that a 40 percent PFS Relativity Adjuster may be appropriate, the agency should have expressly proposed such an adjuster in the alternative and offered an explanation as to why it is appropriate and methodologically defensible (as well as a reasoned explanation for why CMS nonetheless believes a 25 percent proposal is still preferable).⁵⁸ A contrary approach risks reducing the rulemaking process to “mere bureaucratic sport” and is counter to the requirement that agencies “provide an accurate picture of the reasoning that led the agency to [its] proposed rule,” so that “interested parties . . . [are] able to comment meaningfully upon the agency’s proposals.”⁵⁹

CMS SHOULD RETAIN ITS CURRENT METHODOLOGY BUT INCORPORATE METHODOLOGICAL IMPROVEMENTS TO ACCOUNT FOR DIFFERENCES IN PACKAGING ACROSS THE OPPTS 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 OPPTS rate for nonexcepted services. However, we also urge CMS to improve the accuracy of this methodology to account for differences in packaging across the OPPTS and the PFS and to ensure that it accounts for both direct and indirect practice expense. Based on an updated AHA analysis, as described below, this improved methodology would result in a payment rate of 65 percent of the OPPTS payment for nonexcepted services in CY 2018.

In the CY 2017 OPPTS interim final rule, CMS established the Medicare PFS as the “applicable payment system” for most nonexcepted items and services furnished in an off-campus PBD. The agency also set payment at 50 percent of the OPPTS payment rate (i.e., a PFS Relativity Adjuster of 50 percent), inclusive of packaging. CMS arrived at the 50 percent adjuster by comparing: (1) the weighted average payment differential for overall payment under OPPTS and the agency’s determination of the “equivalent” practice expense amount under the PFS for the 22 most frequently billed services reported with the PO modifier (indicating items and services furnished in off-campus PBDs), arriving at 45 percent; and (2) the payment differential between the OPPTS and the ambulatory surgical center (ASC) payment rates, noting that covered surgical procedures in ASCs are paid at 55 percent of the rate under the OPPTS.

⁵⁷ *Am. Radio Relay Leage, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008).

⁵⁸ *See, e.g.*, 81 Fed. Reg. at 19,992–93 (example from the CY 2018 IPPS proposed rule where CMS proposed a both primary approach and a possible alternative approach regarding the timing of an extension to the Rural Community Hospital Demonstration Project. In the proposed rule, CMS provided reasoned explanations in support of *both* approaches. This allowed CMS to switch to and finalize the *alternative* proposal in the CY 2018 IPPS final rule, while still satisfying the APA’s requirements of notice-and-comment).

⁵⁹ *Conn. Light & Power Co.*, 673 F.2d at 530.

In AHA's CY 2017 interim final rule comments, we noted that, while we supported CMS's intent to continue to gather more precise data in order to fine-tune its payment rate in future years, the PFS Relativity Adjuster should not be moved below 50 percent; instead, we stated that a higher adjuster would be appropriate considering that the agency has instituted the interim final rule payment policy for nonexcepted items and services, *inclusive of packaging*. That is, while CMS's analysis compared the OPPS rate to a rate that CMS determined physicians would have been paid for their practice expense under the PFS for each of the 22 HCPCS codes evaluated, the agency's analysis did not explicitly account for the fact that the OPPS incorporates far more packaging into its payments for services than does the PFS. CMS even acknowledged this limitation in the CY 2017 interim final rule. Therefore, to make its analysis truly equivalent and accurate, we recommended that the agency remove packaged costs that are incorporated in the OPPS rates, but not in the PFS practice expense rates.

Furthermore, the AHA also recommended that, when making the comparison between payment for a service at the OPPS versus the PFS rate, CMS should always use the full PFS payment for practice expenses in a nonfacility setting because a hospital continues to incur indirect costs, as well as direct costs, when a service is provided in the off-campus PBD. **When we took this factor into consideration, in addition to the packaging correction above, it resulted in a ratio of PFS payment to OPPS payment of 64 percent; as such, we [recommended](#) a PFS Relativity Adjuster of 64 percent for CY 2017.**

Recommended PFS Relativity Adjuster for CY 2018. Because we believe that the agency's CY 2017 methodology is preferable to the agency's (arbitrary and unreasonable) CY 2018 proposals, we repeated our CY 2017 analysis, using updated claims data. Specifically, we used the CY 2018 OPPS proposed rule rate-setting methodology and data for our analysis to again estimate the amount of packaging included in the 22 most frequently billed services reported with the PO modifier. Based on this analysis, we estimated that, on average, the amount of packaging in these codes is slightly higher than the amount we calculated for CY 2017. That is, we estimated that packaging represents approximately 22 percent of the cost for these services. Table 1, attached, shows our calculations of the packaging percentages for single claims used in rate setting for the CY 2018 OPPS proposed rule. Accordingly, we adjusted the OPPS denominator to be 78 percent of the value we calculated.

In addition, for services where Medicare's PFS payment is not differentiated by facility and nonfacility locations, the full PFS payment for practice expenses was used in this comparison. However, where the PFS payment is differentiated by facility and nonfacility locations, we used the full amount Medicare pays under the PFS for practice expenses for the comparison to the OPPS rate in order to account for the indirect practice expense costs that a hospital continues to incur when a service is provided in the hospital outpatient department. **When this is done, in addition to using a denominator of 78 percent as described above, our analysis shows that the resulting ratio of PFS payment to OPPS payment for CY 2018 is 65 percent.**

Therefore, AHA recommends that, for the purposes of the CY 2018 payments for nonexcepted services, CMS continue to rely on its basic CY 2017 approach. Furthermore, we again recommend that CMS improve its methodology to account for differences in

packaging across the OPPS and the PFS and to adjust for both direct and indirect practice expense, which would result in a PFS Relativity Adjuster of 65 percent for 2018.

Expansion of Services and Relocation Policies for CY 2018. The AHA 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. We refer the agency to our CY 2017 interim final rule [comments](#) for more on these specific concerns.

Continued Use of the Institutional Bill. **The AHA continues to strongly support CMS's decision to allow hospitals to bill for items and services furnished in nonexcepted PBDs using the institutional bill (UB04/837I). As it has noted, there also would be a significant advantage of continuing to use this payment approach for future years.** Continued use of the institutional bill will allow for these PBDs to properly use cost reporting procedures and to accurately reconcile the cost report to hospital ledgers for all services and departments and to correctly allow revenue for nonexcepted PBDs to flow through the Provider Statistical and Reimbursement (PS&R) report. Thus, hospitals will be able to continue to track their costs and charges for cost-reporting purposes and for certain important programs.

MEDICARE TELEHEALTH SERVICES

The AHA 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.

The AHA 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.

APPROPRIATE USE CRITERIA (AUC) FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

The Protecting Access to Medicare Act (PAMA) requires CMS to establish a program that promotes AUC for advanced diagnostic imaging. The statute requires that, beginning Jan. 1, 2017, payment may be made to the furnishing professional for an applicable advanced diagnostic imaging service only if the claim indicates that the ordering professional consulted with a qualified clinical decision support mechanism (CDSM) as to whether the ordered service adheres to applicable AUC. This policy applies only when applicable imaging services are provided in specific settings – a physician’s office, hospital outpatient department (including an ED), an ASC, and any other provider-led outpatient setting as determined by CMS.

CMS [released](#) the first qualified CDSMs on July 13 and proposes that AUC consultation and reporting requirements would begin on Jan. 1, 2019. However, 2019 would be considered an “educational and operations testing year,” and CMS would pay claims regardless of whether they contain information on the required AUC consultation. CMS states that this would allow time for needed education and outreach efforts, for practitioners and stakeholders to prepare, and for CDSMs to become more user-friendly and less burdensome. **The AHA had urged CMS to allow providers adequate time to implement the AUC requirements before they begin impacting payment, and strongly supports the proposal to delay the requirements.**

However, this is an extraordinarily complex policy to implement and hospitals may need additional time to revise information systems to provide the necessary data. Specifically, CMS states that CDSMs may be modules within or available through certified electronic health records (EHRs) or private sector mechanisms independent from certified EHRs technology. Certified EHRs are widely used to enable electronic documentation and review of clinical care provided, tests and medications ordered and information exchanged with others on the care team. Users of EHRs rely on vocabulary, content and transport standards in the EHRs to enable the understanding and exchange of electronic health information. Progress has been made to support clinical workflow by integrating disparate information into an EHR without the need for manual data entry or including information more than once in the EHR to support multiple uses. At this time, barriers remain that prevent this integration of data from being quick, efficient and affordable. Interfaces (software programs that allow the import or export of data) allow an EHR to receive and understand data from picture archive communication systems, medical devices and other systems that support care, such as CDSMs modules or CDSMs independent from certified EHRs. Currently, new requirements for information exchange require a new interface or set of interfaces, as each interface is created to meet specific data exchange requirements and cannot be reused.

As noted above, in July, CMS announced seven organizations approved to be a qualified provider-led entity (PLE) to offer CDSMs. This initiated a process to review and update EHR standards to determine how the CDSMs and the EHRs will support electronic orders that capture AUC-related data for advanced imaging. In addition, radiology information system (RIS)-to-claims system exchange of AUC-related data is not defined in a standard at this time.

Experience to date indicates that 24-36 months is the time required for new or revised standards, implementation guidance for standards, interfaces that support information exchange and education and practitioner readiness that result in successful use of new electronic functionality. Readiness for January 2019 use of CDSMs for AUC reporting would have necessitated CDSM modules readiness to have interfaces with certified EHRs in January 2017. **As such, we ask CMS to consider that it may need to further delay this policy in the future, such as to 2020 or beyond.**

In addition, hospitals are concerned about the regulatory burden the AUC requirements impose on them. Obtaining and reporting information from the ordering professionals on whether they consulted a qualified CDSM could be very difficult at times; yet, all of the burden and payment fall to the furnishing professional. As such, we believe CMS should explore alternative methods of implementing this proposal that do not require reporting by the furnishing professional, such as a yearly attestation by ordering professionals that they consult CDSMs. At a minimum, we urge the agency to include clear instructions in the final rule and in the Medicare Manuals that the ordering professional needs to include the necessary information on their orders.

Lastly, there are many unanswered questions about this policy. For example, CMS has yet to clarify what recourse the furnishing professional has if CDSM information is not included on the order – should the furnishing professional not provide the service, inconveniencing the patient, or should they assume that AUC was not consulted and report as such? Therefore, we urge CMS to provide more detailed information in the final rule on its expectations for this policy.

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.

The AHA 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.

The AHA 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.

MACRA PATIENT RELATIONSHIP CODES

The AHA supports CMS’s proposal to allow the voluntary reporting of patient relationship codes starting Jan. 1, 2018. We strongly urge CMS to use the results of voluntary reporting to inform its policy approach before it mandates the reporting of the codes in the future. The MACRA requires CMS to develop a set of “patient relationship categories and codes” that specify the relationship between clinicians and patients at the time a service is furnished. The purpose of these codes is to facilitate the attribution of patients and episodes of care to clinicians according to the varying roles in which clinicians serve patients. CMS has the option of mandating the reporting of such codes starting in 2018.

The AHA agrees that patient relationship codes could be useful in improving the reliability and accuracy of cost and resource use measures. However, CMS has not yet tested the implementation of the codes, and there likely will be significant variation in how clinicians report them. Therefore, the gradual, voluntary approach CMS has proposed will afford both CMS and the field time to understand and more consistently implement code reporting.

MEDICARE SHARED SAVINGS PROGRAM (MSSP)

Accounting for Primary Care Services. **The AHA 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. **The AHA 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. **AHA 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.

SOLICITATION OF PUBLIC COMMENTS ON INITIAL DATA COLLECTION AND REPORTING PERIODS FOR CLINICAL LAB FEE SCHEDULE (CLFS)

In the proposed rule, CMS requests comments about the experience that certain "applicable laboratories" had in collecting and reporting private payer laboratory test payment data, as required by the June 23, 2016 final rule implementing a new "market-based" payment system for clinical diagnostic laboratory tests paid under the CLFS. This new payment methodology, enacted under a provision of the PAMA, is intended to ensure that the Medicare CLFS rates are based on the rates paid by private payers for laboratory tests. Under the CLFS final rule, certain applicable laboratories were required to collect, and then report to CMS, certain private payer laboratory test payment information. In general, the payment amount for a test on the CLFS furnished on or after Jan. 1, 2018, will be equal to the weighted median of private payer rates determined for each test collected during a data collection period and reported during a data reporting period. CMS established the first data collection period as Jan. 1, 2016 through June 30, 2016. The first data reporting period was Jan. 1, 2017 through May 31, 2017.

The AHA has serious concerns that the data that CMS collected from laboratories is inaccurate, incomplete and unable to be validated, and, therefore, will result in payment rates that do not accurately reflect the broad spectrum of private payer payment rates as Congress intended. This is of great import to hospitals that offer testing through community outreach laboratories and to the patients they serve. While most hospital laboratory services are packaged and paid through the inpatient and outpatient prospective payment systems, hospital outreach laboratories are currently paid through the CLFS, and these laboratories furnish critical

laboratory testing for patients in physician offices and nursing homes. **The significant payment reductions expected to result from the flawed PAMA process will place hospital outreach laboratories in an untenable situation and could have serious consequences for patient access to care.**

We have learned from our members and other laboratory stakeholders about difficulties encountered during the data reporting period, including problems with laboratories accurately and completely reporting their private payer data and in CMS accepting the data. Notwithstanding CMS's final regulation and other PAMA-related resources, we understand that applicable laboratories used a range of approaches in determining which private payer rates and volumes to report. These data reporting problems largely resulted from CMS's decision to impose a retrospective data collection period for applicable laboratories. For instance, there are reports that some laboratories erroneously reported partial payments due to the inability to accurately match primary insurer payments with related patient copayments and third-party insurer payments. **As a result, we are concerned that the data CMS will use to calculate 2018 CLFS payment rates are unreliable and incomplete.**

Further, CMS has not clearly described how it will aggregate reported payment data for each clinical test or a way that it, or its stakeholders, can validate the accuracy of the final payment rates. **This lack of transparency and inability to validate the payment rates calls into question the integrity of the rates that CMS will publish for CY 2018.**

Addressing these concerns will certainly require a delay in implementing the new CLFS rates; however, we urge the agency to take such steps immediately. As a first step, the agency should publish preliminary information to improve transparency for impacted laboratories. We recommend that CMS release, as soon as possible, the number of clinical laboratories that reported private payer data, based on market segment and geographic locations. This should allow the agency as well as stakeholders to better understand whether reporting was truly representative of the wide spectrum of laboratories providing services under the CLFS. In addition, we urge CMS to publish its preliminary CLFS rates for CY 2018 to allow laboratories time to prepare for any potential disruptions to care delivery resulting from potential significant reductions in payments.

Second, given the serious concerns that the AHA and many other laboratory stakeholders have regarding the integrity and validity of the data that is to be used to set payment rates, we urge CMS to consider ways that it can address these shortfalls. For instance, one option would be to issue an interim final rule that modifies its existing regulations so as to allow for the agency to conduct a limited market segment survey of the full range of laboratories. Doing so would allow CMS to validate and adjust, as necessary, the PAMA-derived CLFS rates using the survey data in order to ensure that the final CLFS rates meet congressional intent that payments reflect private market payments.

Finally, we believe that one part of the PAMA-derived CLFS rates can move forward on Jan. 1, 2018, as planned. That is, the rates that CMS calculates for clinical laboratory tests that are only offered by one laboratory can be presumed to be accurate since these laboratories

typically offer only a limited test menu and the final payment amounts calculated for these laboratories should be easily validated by the performing laboratory itself.

Table 1 – Packaging Percentages

HCPCS	Short Descriptor	Mean Costs Based on Singles Used in Rate-setting			Percentage packaging
		Procedure	Packaging	Procedure plus packaging	
	Total: Top 22	\$ 172.73	\$ 49.71	\$ 222.44	22%
96372	Ther/proph/diag inj sc/im	\$ 50.18	\$ 79.76	\$ 129.95	61%
71020	Chest x-ray 2vw frontal&latl	\$ 64.84	\$ 19.29	\$ 84.13	23%
93005	Electrocardiogram tracing	\$ 34.72	\$ 146.35	\$ 181.07	81%
96413	Chemo iv infusion 1 hr	\$ 181.97	\$ 191.42	\$ 373.39	51%
93798	Cardiac rehab/monitor	\$ 207.96	\$ 0.05	\$ 208.01	0%
96375	Tx/pro/dx inj new drug addon	\$ 52.11	\$ 0.04	\$ 52.15	0%
93306	Tte w/doppler complete	\$ 508.76	\$ 13.53	\$ 522.30	3%
77080	Dxa bone density axial	\$ 99.11	\$ 27.71	\$ 126.82	22%
77412	Radiation treatment delivery	\$ 215.72	\$ 39.11	\$ 254.83	15%
90853	Group psychotherapy	\$ 115.59	\$ 0.52	\$ 116.11	0%
96365	Ther/proph/diag iv inf init	\$ 145.91	\$ 117.57	\$ 263.48	45%
20610	Drain/inj joint/bursa w/o us	\$ 272.52	\$ 96.75	\$ 369.27	26%
11042	Deb subq tissue 20 sq cm/<	\$ 450.70	\$ 99.97	\$ 550.67	18%
96367	Tx/proph/dg addl seq iv inf	\$ 71.05	\$ 0.19	\$ 71.23	0%
93017	Cardiovascular stress test	\$ 229.44	\$ 78.39	\$ 307.83	25%
77386	Ntsty modul rad tx dlvr cplx	\$ 603.76	\$ 9.09	\$ 612.84	1%
78452	Ht muscle image spect mult	\$ 769.34	\$ 555.53	\$ 1,324.87	42%
74177	Ct abd & pelv w/contrast	\$ 288.25	\$ 110.40	\$ 398.65	28%
71260	Ct thorax w/dye	\$ 175.14	\$ 91.39	\$ 266.53	34%
71250	Ct thorax w/o dye	\$ 131.93	\$ 15.72	\$ 147.65	11%
73030	X-ray exam of shoulder	\$ 72.42	\$ 43.43	\$ 115.85	37%
90834	Psytx pt&/family 45 minutes	\$ 156.38	\$ 0.93	\$ 157.31	1%

Notes:

- Calculations based on CY 2016 data used in CY 2018 rate-setting.
- CY 2018 Proposed Rule data and policies followed.
- Based on costs with singles.
- Costs have been standardized to account for wage index.
- Means are arithmetic.