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Via email

Francis J. Crosson, M.D.

Dear Dr. Crosson:

The Medicare Payment Advisory Commission (MedPAC, or the Commission) will vote next week on payment recommendations for fiscal year (FY) 2017. On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, the American Hospital Association (AHA) asks that commissioners consider the following issues that would have a significant impact on hospitals, health systems, other providers and Medicare beneficiaries before making final recommendations.

Our primary concern is MedPAC's draft recommendation to cut Medicare payments for hospitals participating in the 340B Drug Pricing Program. This recommendation is outside of the scope of MedPAC's mission, lacks a clear purpose and penalizes certain hospitals for their ability to obtain discounts on the items and services they purchase. The AHA strongly urges MedPAC to withdraw this draft recommendation and, instead, to undertake an analysis of the trend of rapidly increasing drug prices, which presents the Medicare program and its beneficiaries with remarkable challenges.

HOSPITAL INPATIENT AND OUTPATIENT UPDATE RECOMMENDATION

In December, the commissioners considered a package of draft recommendations related to the hospital inpatient and outpatient prospective payment systems (PPS). Specifically, the package included the following recommendations for FY 2017, each of which is addressed in detail below:

1. Update inpatient and outpatient payments by the amount specified in current law (projected to be 1.65 percent);
2. Reduce the payment rates for 340B hospitals' Part B drugs by 10 percent of the Average Sales Price (ASP) and direct the program savings from reducing Part B drug payment rates to the Medicare-funded uncompensated care pool; and
3. Distribute uncompensated care payments using data from the Medicare cost report's schedule S-10; this change would be phased in over three years.

Hospital Payment Update Recommendation. **The AHA agrees with MedPAC that positive updates for both the hospital inpatient and outpatient PPSs are necessary in FY 2017.** We appreciate the Commission's recognition that Medicare payments will remain below the cost of providing care – specifically, that, in FY 2016, the average hospital is projected to have an overall Medicare margin of *negative* 9.0 percent. Even when looking at MedPAC's analysis of "efficient" hospitals from the December meeting, overall Medicare margins were barely positive. AHA Annual Survey data illustrate the same trend – a staggering 64.8 percent, or 3,221 hospitals, were not adequately compensated for the cost of caring for Medicare patients in 2013. **Medicare payments are inadequate and a full market-basket increase for inpatient and outpatient hospital services is absolutely necessary.**

340B and Part B Drug Payment Recommendation. **The AHA strongly supports the 340B program's current intent and purpose. As such, we are concerned about MedPAC's draft recommendation, which is inappropriate, misguided and would penalize those hospitals caring for the most vulnerable patients. Reducing Part B payments for 340B hospitals would contribute to a lack of financial predictability and could have serious negative consequences for patients and communities.** The 340B program is crucial to helping provide low-cost pharmacy services to patients, and it remains a critical component of helping safety-net health care providers create healthier communities – especially in the face of rapidly increasing drug costs. Many 340B hospitals treat a high number of low-income patients, face cuts to disproportionate share hospital payments and have negative operating margins – for example, in 2013, one out of every three 340B hospitals had a negative operating margin.[1]

We are concerned that this draft recommendation is outside the scope of MedPAC's mission. Specifically, MedPAC is charged with providing Congress with analysis and policy advice on the *Medicare* program. In contrast, the 340B program is a *public health* program that is administered by the Health Resources and Services Administration (HRSA). It is not a Medicare program, and Medicare does not subsidize 340B hospitals or pay them different rates. Rather, Medicare pays 340B hospitals the same predetermined payment rates it pays to other inpatient PPS hospitals.

Thus, in venturing beyond its scope, MedPAC appears to call into question the wisdom of Congress in designing the 340B program – suggesting that MedPAC should step in and fix the intent of a congressionally-designed public health program. When Congress created the 340B program more than 20 years ago, it clearly and affirmatively stated that the purpose of the program was to permit providers that care for a high number of low-income and uninsured patients "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." As a result, the 340B program, through the provision of discounts on drugs purchased by hospitals, has a proven track record of enabling eligible entities, including certain hospitals, to expand and improve access to comprehensive health care services for low-income and uninsured patients. **It is a dangerous and slippery slope for the Commission to weigh in on issues that are beyond its expertise, question**

[1] American Hospital Association Annual Survey, data for 2013.

congressional intent and penalize hospitals for their ability to obtain discounts on the items and services they purchase.

In addition, it is unclear exactly what problem the Commission is trying to address with this draft recommendation. Discussions on this point at the December meeting were wide ranging, moving from concerns about hospitals' use of 340B savings to determining how the Medicare program and its beneficiaries could capture some of the benefit of the 340B program. Even the basic rationale for the most recent recommendation was unclear, first stating that the goal was to "balance the beneficiaries' good access to care," but then concluding that "redirecting the 340B savings to hospitals providing uncompensated care is a more direct way to help hospitals that are serving the uninsured."[2] During the December discussion, commissioners expressed concern that "the use of 340B discounts was accelerating and that there was reason to believe that not all of that usage comported with the purposes of the 340B program."[3]

It appears the commissioners' motivation is also driven by a desire to reduce the Part B drug copayments of Medicare beneficiaries. However, we do not believe this recommendation would accomplish that goal. Specifically, many Medicare patients coming to 340B hospitals do not pay their own copayments. Rather, their copayments are made by either Medicaid (if they are dually eligible) or by their Medigap plan. MedPAC staff was asked how many Medicare 340B patients fall into these categories and, therefore, how Medicare beneficiaries would actually realize a reduction in their Part B drug copayments. However, MedPAC staff was unable to provide a clear analysis of beneficiary savings resulting from this draft recommendation, except to say that "...we're not mailing checks to people. We're talking about a beneficiary walks into a 340B hospital. The ASP price in that hospital would be ten percent, and, therefore, the beneficiary's copayment, whether it's gap or state or personally that they pay, would be lower by that amount. "[4] We believe this recommendation would not directly benefit many Medicare beneficiaries, dually eligible Medicare beneficiaries included, but would instead penalize 340B hospitals, including those serving high numbers of dually eligible beneficiaries.

If MedPAC's intent is for Medicare to access discounts on drugs, we strongly urge it to review alternatives that would allow Medicare to access those discounts directly through Part D. The 340B program accounts for only 2 percent – or $6.5 billion – of the $374 billion in annual drug purchases made in the U.S. In contrast, Part D drugs account for about 20 percent, or $70 billion. MedPAC's recommendation should not cut payments to hospitals as a back-door method of obtaining discounts on drugs. Indeed, we believe it would be prudent for the Commission to undertake an analysis of the trend of rapidly increasing drug prices, which presents the Medicare program and its beneficiaries with remarkable challenges. For example, critical oncology drugs have recently undergone extraordinary price increases. A recent study found that the average launch price of oncology drugs, adjusted for inflation and health benefits,

[2] MedPAC meeting transcript, December 10, 2015, pages 84-85.
[3] MedPAC meeting transcript, December 10, 2015, pages 122-123.
[4] MedPAC meeting transcript, December 10, 2015, pages 121

increased by 10 percent annually, or an average of $8,500 per year, for almost 20 consecutive years – from 1995 to 2013.[5]

At one point, concerns were raised about how hospitals are using the 340B program savings. Specifically, MedPAC staff indicated that the draft recommendation would more closely tie 340B savings to hospitals that provide more uncompensated care, and that doing so would be better than the current 340B program approach. However, they did not provide any analysis backing up this assertion, such as demonstrating that shifting 340B program savings would result in better or more care for Medicare beneficiaries. In reality, the savings created by the 340B program are used by hospitals to reinvest in patient care and health activities that benefit communities and save money for state and federal governments. 340B hospitals provide uncompensated care that is about 95 percent higher than other hospitals,[6] as a percent of their revenue. In fact, although they represent about one-third of hospitals, they provide 62 percent of uncompensated care.[7] **In total, 340B hospitals provided $28.6 billion in uncompensated care in 2013, which is four times the amount of drugs purchased through the 340B program.[8]**

Further, the 340B program is currently under review by HRSA. Therefore, if the Commission is attempting to address what it believes are deficiencies in the 340B program, in addition to being beyond its scope, such efforts also are premature. Currently, 340B hospitals are subject to oversight by the HRSA Office of Pharmacy Affairs and must meet numerous program integrity requirements. These include yearly recertification, audits from HRSA and drug manufacturers, and maintaining auditable inventories of all 340B and non-340B prescription drugs. However, HRSA recently proposed comprehensive changes to its oversight of the program, including modifications to the definition of patient eligibility, contract pharmacy arrangements, and mechanisms to prevent ineligible patients from receiving the benefit and duplicate discounts for Medicaid patients. **MedPAC should refrain from considering any recommendations related to the 340B program until HRSA finalizes these programmatic changes.**

Finally, based on the discussion at the November and December MedPAC meetings, we question whether the data is sufficiently accurate and reliable to support the draft recommendation. Specifically, MedPAC based the 10 percent reduction in the draft recommendation on the fact that, in November, staff estimated that hospitals were saving 23 percent on their 340B program drug purchases. However, in December, staff revised this number to a 34 percent savings – a 50 percent change based on analysis from the Department of Health and Human Services Office of Inspector General (OIG). But the OIG acknowledges limitations in its own analysis through a footnote in its report that states: "Because there is no identifier on Part B claims indicating that a drug was purchased through the 340B Program, we could not confirm that claims submitted by covered entities were in fact for drugs purchased at or below

[5] David Howard, Peter Bach, Ernst Berndt, and Rena Conti, "Pricing in the Market for Anticancer Drugs," Journal of Economic Perspectives, vol. 29, no. 1 (Winter 2015): 139-162.
[6] GAO-15-442 340B Drug Pricing Program, page 12.
[7] AHA 340B Infographic 2015 http://www.aha.org/research/policy/infographics/pdf/340b.pdf
[8] Ibid.

the 340B discount price."[9] Because of this and other reasons, we do not have confidence in either MedPAC's figure or the underlying OIG analysis.

Thus, for the reasons listed above, we strongly urge MedPAC to withdraw its draft recommendation to reduce Part B drug payment rates to 340B hospitals.

Uncompensated Care Payment Recommendation. At the December meeting, Commissioners discussed a draft recommendation that would require CMS to distribute uncompensated care payments based on data hospitals report on Schedule S-10 of the cost report. Currently, for purposes of distributing uncompensated care payments to disproportionate share hospitals (DSH), CMS uses a formula based on inpatient days of Medicaid beneficiaries, plus inpatient days of Medicare supplemental security income (SSI) beneficiaries, as a proxy for measuring the amount of uncompensated care each hospital provides.

The AHA believes that if reported in an accurate and consistent manner, the S-10 data have the potential to serve as a more exact measure of the treatment costs of uninsured patients. We have communicated our major concerns and suggestions regarding the S-10 to the Centers for Medicare & Medicaid Services (CMS) on multiple previous occasions, including in a stakeholder discussion group lead by Dobson DaVanzo & Associates, LLC, in January 2014 and in our comments on the FY 2015 inpatient PPS proposed rule. Indeed, CMS has discussed the alternative of using Worksheet S-10 to determine the amount of uncompensated care for several years. Most recently, in the inpatient PPS final rule for FY 2016, CMS indicated that it intends to propose use of the Worksheet S-10 sometime in the future and that it intends to discuss its timeline for this transition in the FY 2017 inpatient PPS proposed rule, which will be released in April.

During the December meeting, MedPAC staff indicated that the S-10 data are not currently used to determine payment and, therefore, they are not accurate. To clarify, while the S-10 data are not currently used to determine DSH payments, they are used in other payment calculations, namely in determining a hospital's incentive payment under the Electronic Health Record Incentive Program. In addition, MedPAC staff indicated that, if uncompensated care payments were tied to the S-10, hospitals would more accurately fill out the forms, thereby improving the accuracy of the data. Unfortunately, it is not as simple as that – the S-10 form and instructions are confusing and require significant changes before hospitals may begin using the form in an accurate and consistent manner. Simply tying this form to payment and requiring its regular use will not improve its accuracy.

Thus, we urge MedPAC to recommend that action be taken to not only use but also revise and improve both the Worksheet S-10 and its instructions. Further, we urge it to recommend that, once stakeholders have had an opportunity to weigh in on the proposed changes, CMS conduct extensive education of both the field and CMS's contractors about the worksheet so that these data could potentially be used as soon as possible. MedPAC also

[9] Office of Inspector General: Part B Payments for 340B-Purchased Drugs (OEI-12-14-00030), Nov. 2015, page 6

should consider requiring that additional steps be taken to verify the accuracy of these data given the concerns about their current validity and completeness.

INPATIENT REHABILITATION FACILITIES UPDATE RECOMMENDATION

In its December meeting, MedPAC put forth a draft recommendation to eliminate the Inpatient rehabilitation facility (IRF) PPS market-basket update in FY 2017, as well as a call for further study of concerns related to IRF case selection and coding practices. IRFs provide hospital-level treatment in combination with intensive rehabilitation services. The IRF field, as a whole, has experienced significant change over the past 10 years, which has resulted in a major volume reduction – 122,000 fewer cases per year. Indeed, during the December meeting, Commission staff noted that IRF volume has stabilized in recent years at a very low 64 percent occupancy rate, which is consistent with this volume reduction. The dramatic decrease is due to strict enforcement and regulatory tightening of the "60 Percent Rule," more stringent admission criteria since 2010 that further distinguished IRFs from skilled nursing facilities (SNFs), and aggressive medical necessity audits that require IRFs to undertake costly appeals to recover funding. These challenges affect the entire IRF field.

In addition, during the December meeting, Commission staff noted impressive IRF quality outcomes. Specifically, IRFs have a community discharge rate of 76.1 percent, which is highly favorable to the SNF rate of 37.6 percent. In addition, IRF readmission rates within 30 days of discharge are 4.5 percent, compared to the 5.6 percent SNF rate.

With regard to the Commission's research on IRF Medicare margins, we urge mindfulness on the following points:

- When comparing certain metrics between IRFs with the highest Medicare margins (5th quintile) to those with the lowest margins (1st quintile), MedPAC staff has not provided sufficient detail on the metrics used, or shown whether the differences are not only statistically significant but also "substantively" significant. For example, slide 14 in the Dec. 11, 2015 presentation, "Assessing payment adequacy and updating payments: Inpatient rehabilitation facility services," states that patients in the high-margin IRFs are, during the preceding ACH stay, "less likely to spend time in ICU/CCU," "less likely to be high-cost outliers in ACH," etc. than patients in the low-margin IRFs. We would appreciate an elaboration on the degree of difference found by these analyses, prior to the formal March report, if possible. In addition, we encourage a discussion of how these differences affect patient care and outcomes.

- The MS-DRGs are based on ICD diagnoses and other factors that do not capture functional levels. As such, this metric offers some insight on the severity level of a patient, but does not provide a comprehensive assessment of the severity of IRF patients, who are, in part, admitted to address functional deficiencies.

- The research shared in December was presented as preliminary work that would continue through the spring. The AHA has great interest in following this effort. While we would like to duplicate some of the analyses, our efforts to study the work shared so far are limited by the dearth of details on the methodologies being used. In particular, we seek the following:

    - clarification of the specific parameters used to select cases in the comparative analysis on margins for stoke and neurological disorder cases. In particular, specify the rationale for the length of the 30-day window used to define the sample size and note whether staff included cases that, during this window between general acute-care hospital discharge and IRF admission, received other services;
    - specifications for the metrics used to analyze patients' prior stays in general acute-care hospitals, along with the relevant test statistics;
    - the definition of "ACH severity," as used in slide 14. Further, please share the data that supports the finding that high-margin IRFs consistently code higher impairment than low-margin IRFs.
    - information on how the motor scores per quintile differ for the stroke MS-DRGs (slide 15). We also request the sample sizes and standard deviations for this analysis.
    - clarification on whether data for low-volume IRFs were included in these analysis, which, if included, could yield unreliable results; and
    - clarification on which revenue codes were used for the analysis on time spent in prior hospital ICU/CCU.

- The possibility of expanding the IRF PPS outlier pool also was discussed as a short-term fix to help address margin disparities among IRFs. Since outlier payments are complex and IRF practice patterns are expected to change in 2016 due to implementation of mandatory bundled payment for selected joint replacements, it may be difficult to project how any outlier changes would mesh with the impact of bundled payment. Therefore, we encourage caution and comprehensive study of any potential outlier change to avoid unanticipated impacts on the field as a whole.

LONG-TERM CARE HOSPITALS UPDATE RECOMMENDATION

Long-term care hospitals (LTCHs) treat high-acuity patients who need hospital care for extended periods of time. For example, AHA claims analysis shows that 86 percent of LTCH patients have an extreme or major severity of illness (the two highest levels on the four-tiered scale from the APR-DRG classification system), which is a far greater than the proportions treated in general acute-care hospitals, their ICU units or other post-acute care settings.

The statutorily mandated implementation of site-neutral payment for LTCHs, which affects one out of two LTCH cases with an average payment reduction of 73 percent, began in October 2015. Under this system, site-neutral cases will no longer be paid under the LTCH PPS, but will

instead by paid inpatient PPS-level rates. During the December meeting, Commission staff acknowledged the magnitude of this change, and the resulting instability to the field. Given the challenge of modeling this complex and transformative change, Commission staff provided projected 2017 margin data for only non-site neutral LTCH cases. These data show a stark downward trajectory from a 7.5 percent margin in FY 2014 to a range of 3.2 to 5.8 percent projected for FY 2016.

The magnitude of the payment cut for site-neutral cases, together with the already decreasing margins for LTCH PPS cases, supports a full market-basket increase for LTCHs in FY 2017, rather than the draft recommendation to eliminate the market basket. A full market-basket update will help ensure that adequate resources are available for LTCH cases – the highest-acuity subset of Medicare beneficiaries – during this period of great regulatory instability.

PAYMENTS TO HOSPITAL-BASED SNFS

The AHA supports MedPAC's recommendations to improve payment accuracy for SNFs, which were discussed both in the December 2015 Commission meeting and recent years: revise and rebase the SNF PPS, add an outlier policy to the SNF PPS, and establish a separate payment for non-therapy ancillary services, which are often required by medically complex patients and lead to reduced access to care. Over the years, MedPAC has recognized that the care provided by hospital-based SNFs is unique compared to that of freestanding SNFs. As noted in its March 2015 report to Congress, while the shortcomings of the SNF payment system continue to result in favorable selection of higher-margin rehabilitation patients over medically complex patients, hospital-based facilities are disproportionately represented among those SNFs with the highest shares of medically complex patients. In addition, despite targeted payment interventions to encourage more resources for medically complex patients, the treatment of intensive therapy patients has continued to grow. However, hospital-based facilities had notably lower shares of intensive therapy days (54 percent) compared with freestanding facilities (79 percent). Hospital-based SNFs also showed better quality outcomes than their freestanding counterparts, with higher community discharge rates (by 6.6 percentage points) and lower readmission rates (by 2.1 percentage points).

While only a small segment of the SNF field, hospital-based SNFs already have the case-mix being targeted by policymakers for the overall field, and this unique role should be supported. Therefore, in addition to the other positive payment recommendations, we also support a full market-basket update for FY 2017. We note that while the extremely negative Medicare margins of hospital-based SNFs (-70 percent in FY 2013) are partly due to the higher cost, hospital-based setting, these margins are also caused by hospital-based SNFs' desirable, but low-margin, case mix. **If policymakers want hospital-based SNFs to continue treating higher proportions of medically complex patients, in lieu of higher-margin intensive therapy patients, then a positive market-basket update is needed in FY 2017 to support the greater and higher-skilled staffing needed to treat this sicker population.**

We appreciate your consideration of these issues. Safeguarding adequate payment for hospital services will ensure Medicare beneficiaries continue to have access to high-quality, innovative and effective care in their communities. If you have any questions, please feel free to contact me or Priya Bathija, senior associate director of policy, at (202) 626-2678 or pbathija@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development

Cc: Mark Miller, Ph.D.
MedPAC Commissioners