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June 10, 2024

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Hubert H. Humphrey Building 200 Independence Avenue, S.W., Room 445-G Washington, DC 20201

Submitted Electronically

RE: CMS-1808-P, Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes, (Vol. 89, No. 86), May 2, 2024.

Dear Administrator Brooks-LaSure,

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, 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 provide feedback on the proposed Transforming Episode Accountability Model (TEAM). We are submitting separate comments on the agency's proposed changes to the inpatient and long-term care hospital prospective payment system (PPS).

We are supportive of the Department of Health and Human Services (HHS) Secretary's goal of moving toward more accountable, coordinated care through new alternative payment models (APMs). However, we have deep concerns regarding TEAM. CMS is proposing to mandate a model that is has significant design flaws and, as proposed, places too much risk on providers with too little opportunity for reward in the form of shared savings, especially considering the significant upfront investments required. If CMS cannot make extensive changes to the model, it should not implement it at this time. To do so would make TEAM no more than a backdoor payment cut to hospitals, as it fails to provide hospitals a fair opportunity to achieve enough savings to garner a reconciliation payment.



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Additionally, the programmatic details of TEAM are almost identical to previous iterations of the CMS Innovation Center's (CMMI) episode-based APMs, including Bundled Payments for Care Improvement Advanced (BPCI-A), and Comprehensive Care for Joint Replacement (CJR). However, we are concerned that the programmatic details of TEAM are almost identical to previous iterations of bundled payment models like CJR and BPCI-A, which, according to CMMI's own report, have neither generated significant net savings nor met statutory criteria for expansion.¹ In particular, the relevant statute at 42 U.S.C. 1315a(b)(2)(A) directs the agency to "focus on models" expected to reduce program costs under the applicable subchapter." Yet, according to the most recent data from CMS, CJR reported cumulative losses of \$142.6 million to the Medicare program in its last year and may have widened disparities in lower extremity joint replacement (LEJR) rates for some populations.² BPCI-A generated a net loss of \$114 million in its third year, and beneficiaries reported unfavorable results for functional status and care experience measures.³ Thus, because TEAM is based on the extremely similar BPCI-A and CJR models, and because those prior models failed to meet statutory criteria for expansion as they failed to reduce program costs and generate net savings, we have serious concerns that the agency is stretching its legal authority. Moreover, in not accounting for lessons learned from previous models, we feel the agency has missed a critical opportunity to move bundled payment models forward in a meaningful way.

Moreover, the tremendous scope of this rule and its aggressive 60-day comment period has made it challenging for us to fully evaluate and analyze the proposal and its tremendous impact on hospitals and health systems. The five types of surgical procedures proposed for inclusion in TEAM comprise over 11% of inpatient PPS payments in 2023 – a staggering amount that does not even include the outpatient payments that would be at risk as part of the model. While we worked closely with our hospital and health system members to assess the potential impact of TEAM on the important work they do in caring for their patients and communities, the incredibly short comment period severely hampers our ability to provide comprehensive comments. That said, it is clear a number of changes need to occur to make this model feasible.

Make Participation Voluntary

The proposed rule would mandate TEAM participation for all acute care inpatient PPS hospitals in select geographies. However, mandatory participation is not practicable or advisable. Many organizations are neither of an adequate size nor in a financial position to support the investments necessary to transition to mandatory bundled payment models. Requiring hospitals to take on large, diverse bundles would require more risk than many can manage, threatening their ability to maintain access to quality care in their communities. **We strongly urge CMS to make model participation voluntary**

¹ https://www.cms.gov/priorities/innovation/data-and-reports/2022/rtc-2022

² https://www.cms.gov/priorities/innovation/data-and-reports/2023/cjr-py5-ar-findings-aag

³ https://www.cms.gov/priorities/innovation/data-and-reports/2023/bpci-adv-ar4-findings-aag

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and allow organizations to select the episodes for which they feel they can improve quality of care and best impact cost savings.

Lower the Discount Factor

The proposed rule includes a very aggressive 3% discount factor given the context of other TEAM design features. Indeed, based on our analysis, each of the five clinical episode categories would have most of the episode spending accounted for by the anchor hospitalization or outpatient procedure, with three of the five having at least three-quarters of spending accounted for by the anchor hospitalization or outpatient procedure for by the anchor hospitalization or outpatient procedure. This is extremely problematic as hospitals do not have an ability to decrease the anchor hospitalization payment amount, which leaves virtually no opportunity for them to achieve efficiencies and meet, let alone exceed, the proposed 3% discount factor. Thus, we recommend that a discount factor of no more than 1% be applied.

Modify Several Design Elements

The proposed rule has several problematic design elements delineated below and explained more thoroughly in the attached. If CMS cannot make significant changes to our concerns below, the agency should not implement TEAM. At the very minimum, CMS should:

- <u>Revise the risk adjustment factor</u>. We recommend that the risk adjustment factor capture complication or comorbidity/major complication or comorbidity (CC/MCC) flags from the anchor hospitalization and hierarchical condition codes (HCC) flags three years prior to the hospitalization.
- <u>Establish Longer Glidepath to Two-sided Risk</u>. We recommend extending the upside-only glidepath to a minimum of two years.
- <u>Revise the Low-volume Threshold</u>. We recommend CMS increase the lowvolume threshold to ensure statistical significance, establish separate thresholds within each episode category and fully exclude organizations not meeting those thresholds from participation.
- <u>Make Participation for Safety-net, Rural and Special Designation Hospitals</u> <u>Upside Only</u>. According to our analysis, these organizations are projected to have the most significant financial losses, and they already serve more complex patient populations often with lower margins.
- <u>Exclude Hospitals Participating in Other APMs</u>. CMS is creating "double jeopardy" for organizations participating in multiple APMs, and thus should exclude participants in accountable care organizations (ACOs), the States Advancing All-Payer Health Equity Approaches and Development (AHEAD) model, and the Increasing Organ Transplant Accountability model (IOTA).

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- <u>Revise Quality Measure Set</u>. At the very least, we recommend excluding the three measures CMS is considering for TEAM that have not yet even been adopted for the inpatient PPS quality reporting program.
- <u>Lower Composite Quality Score (CQS) Threshold.</u> Under the proposed approach, model participants would only receive a full reconciliation payment if their CQS is in 100th percentile nationally, essentially meaning that the CQS would serve only to decrease a participant's reconciliation payment.
- <u>Waive Applicable Fraud and Abuse Laws.</u> We recommend waiving physician self-referral laws and anti-kickback statutes so that organizations can form the financial arrangements necessary to implement the proposed rule.
- <u>Extend Certain Waivers to Support Care Delivery</u>. We urge CMS to give providers maximum flexibility to identify and place beneficiaries in the clinical setting that best serves their short- and long-term recovery goals.

The changes we recommend would help facilitate hospitals' success in providing quality care to Medicare beneficiaries, achieving savings for the Medicare program and having an opportunity for reward that is commensurate with the risk they are assuming. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Jennifer Holloman, AHA's senior associate director of policy, at <u>jholloman@aha.org</u>.

Sincerely,

/s/

Ashley Thompson Senior Vice President Public Policy Analysis and Development

Cc: Elizabeth Fowler, Director, Center for Medicare and Medicaid Innovation (CMMI)

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BACKGROUND

The proposed new mandatory TEAM payment model would bundle payment to acute care hospitals for five types of surgical episode categories: coronary artery bypass graft (CABG), LEJR, major bowel procedure, surgical hip/femur fracture treatment (SHFFT) and spinal fusion. It would make acute care hospitals responsible for the quality and cost of all services provided during select surgical episodes, from the date of inpatient admission or outpatient procedure through 30-days post-discharge. This includes services covered under both Medicare Part A and Part B, including physician, post-acute care, therapy, clinical laboratory, Part B drugs and biologicals, and other medical services and supports. It would run for five years and require participation for inpatient prospective payment system (PPS) hospitals in certain core-based statistical areas that would be selected at a later date.

Hospitals strongly support CMS' push for adoption of APMs and are working to help ensure these complex models benefit patients. However, CMS should both provide hospitals with the necessary tools to be successful under the program and appropriately balance the risk versus reward equation. Yet, as proposed, the rule places too much risk on providers with too little opportunity for reward in the form of shared savings. Moreover, in failing to account for lessons learned from previous models, the agency has missed a critical opportunity to move bundled payment models forward in a meaningful way. **Therefore, we urge CMS to make significant model design changes, including those identified below. If it cannot make these changes, it should not implement this model.**

PARTICIPATION AND MARKET SELECTION

Mandatory Participation

First and foremost, we oppose CMS' proposal to make participation in TEAM mandatory and instead urge it to allow voluntary participation. As proposed, CMS would require inpatient PPS hospitals in certain geographic regions to participate in TEAM as episode initiators. Specifically, it proposes that all inpatient PPS hospitals physically located in 25% of core-based statistical areas (CBSAs) be included in the model, with selection to be determined in the future based on a stratified random sampling method.

This mandatory requirement would require hospitals of many different sizes and types, and at very different points in the transformation process, to participate in the model. However, we again remind CMS that hospitals and health systems have built care processes and policies around the current regulatory payment structures, and these systems must be changed if they are to achieve success in these types of models. While some had already taken significant steps toward building their infrastructure and achieving alignment with physicians and post-acute care facilities, many are not as far down this path. The Honorable Chiquita Brooks-LaSure June 10, 2024 Page 7 of 46

We also have deep concerns that CMS is proposing to mandate this extremely financially challenging model for hospitals that have less flexibility in margins and infrastructure funding. Indeed, TEAM would run afoul of *CMS' own goals* of advancing health equity and reducing disparities in historically underserved and under-resourced communities. Specifically, as discussed below, the model would adversely impact underserved communities and organizations, like rural and safety-net hospitals, that CMS has pledged to support. The model could result in reduced access to services since the model would redirect critical resources; in addition, losses under downside risk could force hospitals to curtail services or even close. As such, we strongly urge CMS in not to require mandatory participation for TEAM.

Mandatory Participation Does Not Address the Model Design Flaws that Have <u>Historically Caused Organizations to Forego Voluntary Participation</u>. Much of CMS' justification for proposing mandatory participation is predicated on high rates of drop out from historical models. However, it does not propose commensurate changes that would make TEAM a more workable model for hospitals and patients. For example, we have previously commented on the necessity for waivers to support care coordination, more gradual glidepaths to two-sided risk, and reasonable discount factors to ensure financial viability. If anything, TEAM is a step backward with fewer waivers, shorter timelines to assume downside risk, and more aggressive discount factors that make cost savings more challenging. As such, instead of pursuing mandatory participation, we encourage CMS to address those model design features that led participants to withdraw from historical episode-based payment models in the first place. However, if CMS cannot make these changes, we recommend that it withdraw this model and not proceed at all.

<u>Mandatory Participation Can Negatively Impact Hospital Financial Stability and Patient</u> <u>Care</u>. We also urge CMS to pursue voluntary participation given the historic financial pressures that hospitals and health systems continue to face. Indeed, according to the Medicare Payment Advisory Commission (MedPAC's) March report to Congress, inpatient PPS hospitals' aggregate Medicare margins are projected to be a staggering *negative 13% in FY 2024*, and the median margins of even relatively efficient hospitals are projected to be negative 3%. Furthermore, MedPAC also reported that 18 hospitals closed last year, exceeding the number of hospital openings.⁴ Certain hospitals may not be in a position to make the infrastructure investments necessary to be successful in the model, nor absorb potential losses. If this model were to expand to all hospitals as was alluded to in the proposed rule, our analysis indicates that inpatient PPS hospitals would experience -\$3.8 billion to -\$2.7 billion in losses over five years.

⁴ https://www.medpac.gov/wpcontent/uploads/2024/03/Mar24_Ch3_MedPAC_Report_To_Congress_SEC.pdf

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In addition, a Government Accountability Office report found that mandatory participation could negatively impact patient care and financial sustainability if participants are not able to leave the model. ⁵ It also found that mandatory participation could impact organizations' ability to support other voluntary models for which they may be better equipped.

Further, the fact that participants would not only be required to participate but participate in all five episodes is also concerning. It is vitally important for participants to have the ability to select individual clinical episodes, as opposed to requiring participants to take on risk for large, diverse bundles of episodes. We recommend that CMS allow organizations to select the episodes where they can best impact patient care, quality and cost savings.

Finally, CMS states that although it proposes to start with five clinical episodes, it may add others (including medical episodes) in future years at its discretion. In a five-year proposed model, this is untenable, ill-advised and deeply troublesome. Participants must know up-front in which episodes they are participating. **As such, we urge the agency to rescind its ability to add additional episodes**.

<u>Mandatory Participation Does Not Provide Necessary Options for Those Hospitals that</u> <u>Previously Participated in Bundles</u>. CMS' proposal would require participation from hospitals in selected CBSAs even if they previously participated in CJR and BPCI and reasonably have little further cost savings to achieve. Specifically, due to the ratchet effect over time, some organizations have squeezed as much cost savings out of certain bundles that they can; thus, they would, in fact, now simply be taking a payment cut when participating in this model. Other organizations that wish to continue participation in bundles, but are not part of a selected market, would not have a pathway to continue.

Mandatory Participation Would Increase Disparities for Underserved Populations. Model design features that we describe below, like the inadequacy of CMS' proposed risk adjustment, would cause organizations like safety-net hospitals and those serving higher proportions of dual-eligible (DE) and low-income subsidy (LIS) beneficiaries to be penalized under this model simply because of the patient populations they serve. As such, mandatory participation would contribute to a downward financial spiral for these organizations, who would have even fewer funds to invest in APMs, let alone targeted interventions to benefit their patients and communities. This would in turn, lead to even larger losses under the model, eventually resulting in decreased access to care. This is all compounded by the fact that participation would implement the model across five service lines simultaneously without upfront infrastructure resources to support the implementation. It takes from these (and all) hospitals the ability to identify those

⁵ https://www.gao.gov/assets/gao-19-156.pdf

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bundles with the best opportunities for outcomes improvement, clinical standardization and cost savings for them and their communities.

Indeed, TEAM runs counter to CMS' own goals of advancing health equity and reducing disparities in under-resourced communities. This is evidenced by the fact that the historical models on which TEAM is based and extremely similar, like CJR, have contributed to disparities in certain procedures. Specifically, the most recent report from CMMI suggests that "[t]he CJR model did not impact the existing disparities between historically underserved populations and their reference populations in payments, utilization, and quality observed prior to the model. However, there was evidence suggesting that disparities in elective LEJR rates widened for some populations."6 Furthermore, an article from JAMA analyzing hospitals leaving the CJR program in 2018 found that the majority of those opting out served higher proportions of non-white and Medicaid patients.⁷ The article stated that these hospitals likely dropped out "since they were more likely to sustain financial losses by remaining in the program" due to higher prevalence of complications and post-acute care needs. This is of deep concern to us. By not addressing model design features that may have contributed to widening disparities, CMS actually risks expanding disparities to more populations and communities through TEAM.

Geographic Selection

CMS proposes to use a stratified random sampling method to select 25% of 803 eligible CBSAs for participation. Markets would be stratified based on four criteria: average historical episode spending, number of hospitals, number of safety-net hospitals and exposure to prior bundled payment models. Each market would be assigned a "high" or "low" value based on these four criteria. CMS proposes to oversample from strata with high numbers of safety-net hospitals and low participation in previous bundled payment models.

We are very concerned with CMS' proposal to oversample from markets with a high number of safety-net hospitals or low exposure to previous bundled payment models. In doing so, the agency has failed to recognize the very real barriers some providers face in building the technical and workforce infrastructure necessary to be successful or the limits posed by an inadequate population base. Indeed, our analysis shows that TEAM would adversely impact certain hospitals simply because of the patient populations they serve. This includes safety-net hospitals and organizations serving high volumes of DE and LIS populations.

In conducting this analysis, we divided eligible hospitals in eligible CBSAs into quintiles based on the difference between their regional target price and their payments per

⁶ https://www.cms.gov/priorities/innovation/data-and-reports/2023/cjr-py5-ar-findings-aag

⁷ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6342001/

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episode across all clinical episode categories (see Table 1). We found that hospitals in the highest spending quintiles included a disproportionate share of safety-net hospitals and served a disproportionate share of DE or LIS patients. This trend was consistent even when looking at individual clinical episode categories. As such, the very organizations that CMS proposes to oversample are the ones that would be hardest hit financially within the model. These organizations also are the ones that are less able to make infrastructure investments and to absorb financial losses due to existing financial challenges.

Table 1: Distribution of Hospital Characteristics for All TEAM Episodes by	
Quintile	

	Number of Hospitals	Average Number Episodes	Average Spending Per Episode	Avg. Target Price	Percent Difference Between Target and Spending	Percent Safety- net	Percent Patients DE	Percent Patients LIS
Highest								
Spending	580	465.6	\$37,316	\$32,813	-13.7%	56.6%	16.5%	17.8%
Quintile								
2 nd Quintile	581	800.6	\$31,808	\$29,721	-7.0%	34.4%	11.4%	12.5%
3 rd Quintile	580	989.7	\$28,604	\$27,807	-2.9%	28.8%	9.2%	10.1%
4 th Quintile	581	897.7	\$26,791	\$27,027	0.9%	28.1%	9.1%	10.0%
Lowest Spending Quintile	581	634.0	\$26,045	\$27,695	6.0%	34.3%	8.9%	9.9%
Total	2,903	757.6	\$29,493	\$28,623	-3.0%	36.4%	10.5%	11. <mark>5%</mark>

As such, it would be inappropriate for CMS to move forward with its proposal to oversample from markets with higher volumes of safety-net hospitals and hospitals that have not participated previously, knowing that the model does not provide adequate adjustments for their higher-risk patient populations. This further reinforces our position that CMS must implement TEAM on a voluntary basis.

Participant Definition

CMS proposes that, like CJR, inpatient PPS acute care hospitals would be TEAM participants and only entities able to initiate an episode. **The AHA supports CMS' proposal that hospitals serve as episode initiators.** We agree with the agency that utilizing hospitals as the episode initiators is a straightforward and reasonable approach.

Participant Exclusions

Because Maryland hospitals are not paid under the inpatient or outpatient PPSs, CMS proposes to exclude all CBSAs that are located entirely in the state of Maryland. It also would exclude those located partially in Maryland and in which more than 50% of the five episode categories were initiated in Maryland from Jan. 1, 2022, through June 30, 2030.

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<u>Exclude Hospitals Participating in Other APMs.</u> We agree that Maryland CBSAs should be excluded from participation. However, we also recommend excluding hospitals participating in any other advanced APMs. The staffing and resources required for one hospital to stand up multiple APMs is challenging, particularly when or if they are being implemented at the same time. There is also the potential for organizations to be penalized in multiple models for the same cases and measures. Model interactions are not accounted for in the proposal. Some examples are below.

Exclude AHEAD Hospital Participants. The proposed rule would not exclude hospitals participating in AHEAD. While states participating in AHEAD should still be eligible to participate in TEAM, individual hospitals that elect to participate in AHEAD should be excluded. These organizations will already be undergoing significant organizational change and redesign of care pathways for all their clinical areas. Conducting further redesign for TEAM clinical episodes is simply untenable. In addition, AHEAD and TEAM performance periods would overlap, and it would be difficult to discern which model interventions would be responsible for changes in outcomes.

Exclude IOTA Hospital Participants. Just four weeks after TEAM was proposed, CMS proposed another mandatory payment model for kidney transplants. IOTA is estimated to include transplant hospitals in 50% of donor service areas. Again, implementation of complex payment models requires significant time, resources and staffing on the part of hospital participants. The proposed start date for IOTA is 2025, meaning that some organizations may hypothetically be implementing multiple models at the same time (e.g., AHEAD, TEAM and IOTA, not to mention any other voluntary models that the organization may be better equipped to support). **CMS should exclude IOTA hospitals from TEAM participation.**

Exclude Accountable Care Organization (ACO) Participants. The proposal fails to account for interactions with ACO participants. Such total cost of care models are intended to hold organizations accountable for aggregate health care expenditures and population health outcomes for an attributed population. Requiring ACO participants to also participate in TEAM could result in duplication of effort, since ACOs already support episode management post-discharge, and redirecting of resources. The proposal also does not account for the financial implications since organizations could be penalized twice for the same patient and case.

<u>Allow Safety-net, Rural and Other Special Designated Hospitals to Opt-in.</u> As previously mentioned, these organizations have less infrastructure resources available to implement a mandatory bundled payment model. They would also be disproportionately negatively impacted because of the more medically complex patient populations they serve, as discussed further below. As such, these organizations should have the flexibility to opt-in to the model, but otherwise be excluded from participation.

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<u>Exclude Low-volume Hospitals.</u> In addition to protections for certain groups of hospitals that may have a lower risk tolerance and less infrastructure to achieve efficiencies, hospitals with a low volume of cases should be excluded from participation in TEAM. These organizations are inherently subject to volatility in cases that cannot be reduced simply by standardization in clinical process, as discussed further below in the Low-volume Threshold and Risk Adjustment sections. **As such, low-volume organizations should also be excluded from participation.**

Participation Tracks

The TEAM proposal includes three potential participation tracks, one of which is an optional year of upside-only risk (Track 1). The breakout of proposed participation tracks is below in Table 2.

Track	Eligible Hospitals	Performance Years (PY)	Type of Risk	Stop-gain	Stop-loss	Composite Quality Score Adj.
Track 1	All	PY1 Only	Upside Only	10%	N/A	10%
Track 2	 Safety-net Rural Medicare- dependent Sole community Essential access community 	PY2-PY5	Two- Sided	10%	10%	10% for positive adjustments 15% for negative adjustments
Track 3	All others outside Track 2	PY1-PY5	Two- Sided	20%	20%	10%

Table 2. TEAM Proposed Participation Tracks

More Gradual Introduction of Downside Risk is Necessary. We urge CMS to provide hospitals with at least one additional year before downside risk is implemented in TEAM. Specifically, the agency proposes to allow only one year of upside-only risk for all participants (Track 1). However, 12 months is not an adequate timeframe in which to effectively manage episodes subject to downside risk. This is particularly true for hospitals that do not have prior experience implementing bundled payment models, which is a population that CMS proposes to oversample from in its selection methodology.

Only one year of upside-only risk would not allow hospitals to learn from their first year in the model and adjust their approaches going into downside risk. Hospitals would not know their first-year performance until at least six months into their second year due to the six-month claims run out necessary for calculating performance. In other words, hospitals would be well into their second year and subject to six months of downside risk while still not sure of their first-year performance. The Honorable Chiquita Brooks-LaSure June 10, 2024 Page 13 of 46

In addition, hospitals need adequate time to prepare for downside risk, including time to incorporate adjustments to their practices as necessary. For example, they need to be able to:

- Educate staff and physicians on the TEAM program.
- Analyze claims data to understand episode spending.
- Build relationships with physicians and post-acute care providers.
- Negotiate and execute cardiac sharing arrangements with physicians and post-acute care providers.
- Develop and implement use of documents to meet CMS' proposed beneficiary notification requirements.
- Create protocols to identify TEAM patients upon admission.
- Create protocols to determine if potential TEAM patients meet all of CMS' inclusion criteria (e.g., ensure they are not eligible for Medicare based on end-stage renal disease).
- Create protocols to identify cancelled episodes (e.g., change in Medicare status).
- Create protocols to ensure notification materials are shared with appropriate beneficiaries.
- Examine and modify discharge planning protocols.
- Create a system to meet the proposed requirement to provide beneficiaries with a complete list of all post-acute care options in the service area, including cost-sharing and quality information.
- Create systems to track and monitor beneficiaries throughout the episode.

We cannot emphasize enough that hospitals want and need to adequately prepare because they want to be successful throughout the duration of the program. They also want and need to be afforded the opportunity to take full advantage of the transition to downside risk, especially for those that have little bundled payment experience.

Participation for Safety-net and Rural Hospitals Should Be Upside Only. The TEAM model also includes a participation track (Track 2) specifically for certain hospital types, including safety-net hospitals, rural hospitals, Medicare-dependent hospitals, sole community hospitals and essential access community hospitals. Eligible participants would be able to opt-in to Track 2 beginning in their second year, where they would be subject to slightly smaller stop-gain and stop-loss limits (10%) and lower CQS thresholds.

We appreciate the establishment of a separate track for these organizations. However, they should not be subject to two-sided risk at all. Indeed, even accounting for maximum quality adjustments and stop-gain/stop-loss adjustments,

Track 2 is projected to substantially perform worse than Track 3 in terms of potential losses (see Table 3.)

	Number of Hospitals	Number of Episodes	Avg. Episode Spending	Avg. Target Price	Difference Between Target and Spending	Difference Between Target and Spending with Max Quality Adjustment	Difference Between Target and Spending with Max Quality and Stop Loss/Gain
Track 2	1,964	1,318,273	\$30,395	\$29,334	-\$1,060	-\$855	-\$734
Track 3	939	880,912	\$28,143	\$27,558	-\$585	-\$488	-\$466

Table 3. Tracks 2 and 3 Episode Performance Across TEAM Episode Categories

Safety-net hospitals in particular could be subject to higher losses as shown below in Table 4. When breaking safety-net and non-safety-net hospitals into deciles based on volume, safety-net hospitals consistently had larger losses even with maximum quality adjustments and stop-losses applied. This implies that the stop-loss percentages as proposed are ineffective in mitigating disproportionate losses to these hospitals.

Table 4. Safety-net Hospital versus Non-Safety-net Hospital Performance AcrossTEAM Episode Categories

		Safety-r	net Hospitals		Non-Safety-net Hospitals			
Decile Rank on Volume	Number of Hospitals	Mean episode Count	Weighted Mean NPRA	Weighted Mean NPRA with Max Quality and Stop Loss	Number of Hospitals	Mean episode Count	Weighted Mean NPRA	Weighted Mean NPRA with Max Quality and Stop Loss
1	105	7.5	-\$2,162	-\$489	184	33.9	-\$1,031	-\$163
2	106	30.8	-\$2,454	-\$1,130	185	148.8	-\$985	-\$684
3	106	65.8	-\$2,381	-\$1,248	184	272.5	-\$798	-\$601
4	105	117.2	-\$2,344	-\$1,138	185	418.5	-\$905	-\$578
5	106	174.0	-\$1,935	-\$1,166	184	570.4	-\$1,337	-\$983
6	106	250.2	-\$1,959	-\$1,062	185	755.9	-\$870	-\$615
7	105	365.1	-\$2,106	-\$1,395	185	1,005.2	-\$940	-\$707
8	106	551.3	-\$1,727	-\$1,129	184	1,326.9	-\$761	-\$592
9	106	839.0	-\$1,690	-\$1,170	185	1,803.9	-\$404	-\$295
10	106	1,762.2	-\$1,053	-\$806	185	3,180.8	-\$579	-\$458
Total	1,057	417.0	-\$1,523	-\$1,022	1,846	952.5	-\$706	-\$528

This difference in performance can be attributed to the differences in patient complexity and social risk factors that CMS' risk adjustment fails to account for, as discussed below in the Risk Adjustment section. It also serves as conclusive evidence of our assertion that TEAM stands to adversely impact organizations that treat underserved and medically complex populations. We cannot emphasize enough that if the CMS does not allow voluntary participation with upside-only risk for these hospitals, it will run afoul of *its own goals* of advancing health equity and reducing disparities in historically underserved and under-resourced communities. The Honorable Chiquita Brooks-LaSure June 10, 2024 Page 15 of 46

Definition of Safety-net Hospital

CMS proposes three possible ways to define a safety-net hospitals within TEAM.⁸ We support the CMMI Strategy Refresh definition over the two other definitions of safety-net that CMS is considering (MedPAC's safety-net index (SNI) and the area deprivation index). As the AHA has previously <u>commented</u> to MedPAC, we have concerns over the use of the SNI, and recommended an alternative approach to supporting safety-net providers.

EPISODES OF CARE

Initiating Episodes

CMS proposes to begin episodes on the date of admission for an anchor hospitalization or date of procedure for outpatient surgery, as identified based on the MS-DRG or Healthcare Common Procedure Coding System (HCPCS) code on the claim. Episode categories would include five surgical episode categories: CABG, LEJR, major bowel procedure, SHFFT and spinal fusion. We agree that episodes should be initiated by an anchor admission or procedure. However, if both inpatient and outpatient procedures are included, CMS' risk adjustment and target price methodologies must be modified further to better account for the anchor setting. As discussed further in the Risk Adjustment section below, the setting is heavily correlated with patient complexity and acuity, and as such, generates substantial differences in spending.

Episode Duration

The TEAM proposal includes a proposed episode duration of the anchor hospitalization/outpatient procedure and 30 days. This narrow window does not account for clinical complexity of cases, and combined with other model design features (like the 3% discount factor), it makes cost savings unattainable. More importantly, an arbitrary window of 30 days ignores what is clinically appropriate based on the specific clinical episode, complexity of the patient and individual patient needs. Bundle duration should be based on clinical appropriateness.

Included and Excluded Services

CMS proposes that episodes would include the surgical procedure and inpatient and/or outpatient stay, as well as all related care covered under Medicare Parts A and B within 30 days of discharge, including physician, inpatient hospital, inpatient psychiatric facility, long-term care hospital (LTCH), inpatient rehabilitation facility, skilled-nursing facility (SNF), home health (HH) agency, hospital outpatient, outpatient therapy, clinical

⁸ https://www.cms.gov/priorities/innovation/data-and-reports/2022/cmmi-strategy-refresh-imp-tech-report

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laboratory, durable medical equipment, Part B drugs and biologicals (with exceptions), and hospice services. There are exceptions included in the proposed rule such as:

- Categories of diagnoses such as oncology, trauma medical admissions, organ transplant and ventricular shunts, as determined by MS-DRGs.
- Certain Major Diagnostic Categories (MDCs) including MDC 02 (Diseases and Disorders of the Eye), MDC 14 (Pregnancy, Childbirth, and Puerperium), MDC 15 (Newborns), and MDC 25 (Human Immunodeficiency Virus).
- Drugs paid outside of the MS-DRG, such as hemophilia clotting factors.
- Inpatient PPS new-technology payments (identified under value code 77).
- Part B payments for certain high-cost drugs and biologicals, low volume drugs and blood clotting factors for hemophilia patients.
- Outpatient PPS transitional pass-through payments for devices.

<u>Clarification Is Needed on What Constitutes Unrelated Services.</u> While the proposed rule states that certain categories of diagnoses and MDCs would be excluded, additional clarification is needed. For example, the proposed rule states oncology, trauma medical admissions, organ transplant and ventricular shunts, as determined by MS-DRGs, would be excluded, but these are very broad categories. **We urge the agency to delineate specific diagnoses for exclusion.** We also continue to urge CMS to conduct additional research on the list of services to be excluded from bundles. In doing so, we urge the agency to consider taking a different approach to included and excluded services. That is, instead of delineating services that should be excluded, CMS should focus on what services should be included. There are infinite permutations of unrelated services a patient can have in an episode; if the agency instead focused on procedures and complications that could arise from the procedure itself as a starting point, it would arrive at a more appropriate list.

Additionally, certain services were not addressed in the proposed rule. These include, but are not limited to, pre-scheduled inpatient/outpatient services (e.g., glaucoma surgery) and critical care transport. For example, for rural and geographically remote areas, critical care transport often requires high-cost air ambulance services, which may inappropriately and adversely impact hospitals' episode spending if included. CMS also should exclude these services.

Further, we urge CMS to explore revised outlier methodologies to account for patients with unforeseen conditions, such as high-cost trauma or emergent services, or complications from unrelated comorbidities, as described further in the Risk Adjustment section below.

Transfers

Under TEAM, CMS proposes to view hospitalizations for hospital-to-hospital transfers discretely; that is, they may result in an episode depending on each hospitals'

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participation and the MS-DRGs involved.

We appreciate that like CJR, if both hospitals are in TEAM and treat the same patient for a TEAM condition then the anchor hospitalization would be linked to the initial hospitalization (i.e., a separate anchor hospitalization would not be initiated at the receiving hospital). However, we urge CMS to ensure that, like previous models, if the patient's discharge MS-DRG from the receiving hospital is not one of the eligible model MS-DRGs, the episode should be cancelled. These episodes are atypical but can adversely impact spending in a significant way.

We also have concerns that the transfer policy does not account for the fact that transfer episodes will inherently be extremely costly and may affect hospitals differently due solely to their capabilities and patient populations. For example, smaller community hospitals may transfer cases more frequently to allow their most complicated patients to receive the most appropriate care at larger, tertiary hospitals. They should not be penalized for doing so. Therefore, to avoid inappropriately penalizing hospitals for transferring patients, we recommend that CMS exclude the amount paid to the initially admitting hospital when calculating target prices and actual episode spending. Doing so would help put all hospitals on a more level playing field and encourage the best provision of care.

Cancelling Episodes

As with CJR, CMS proposes that, once an episode begins, it would continue to the end unless the beneficiary no longer meets the inclusion criteria, in which case the episode would be cancelled. Proposed criteria include:

- The beneficiary ceases to meet beneficiary inclusion criteria (the beneficiary must be enrolled in Medicare Parts A and B, must not be eligible for Medicare on based on end-stage renal disease, must not be enrolled in any managed care plan such as Medicare Advantage, must not be covered under a United Mine Workers of America health plan and must have Medicare as their primary payer).
- The beneficiary dies during the anchor hospitalization or anchor procedure (however, the episode would not be cancelled if the beneficiary dies at any other point during the post-discharge period).
- The participating hospital is subject to Extreme and Uncontrollable Circumstances policy associated with natural disasters such as hurricanes, flooding and wildfires and would apply to participants located in counties where both a major disaster has been declared under the Stafford Act and Section 1135 waivers have been issued.

However, whereas one reason that CMS would cancel a CJR episode is if the beneficiary dies at any time during the episode, it proposes to cancel a TEAM episode only if the beneficiary dies during the anchor hospitalization. We disagree with this approach. Specifically, episodes during which a beneficiary dies usually include atypical

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courses of care, such as end-of-life care. Failing to cancel such episodes penalizes hospitals for providing care such as this. Therefore, the AHA urges CMS to cancel all episodes in which the beneficiary dies either during the anchor hospitalization or during the 30 days post discharge.

PRICING AND PAYMENT METHODOLOGY

Under TEAM, CMS proposes to use three years of baseline data trended forward prospectively to the performance year to calculate target prices by episode type (at the MS-DRG/HCPCS level) and region. Episodes would be capped at the 99th percentile for each episode type and across nine regions (identified by U.S. census divisions) to exclude outlier spending. Average standardized spending for each episode type in each region would be used as the benchmark price.

Baseline Period for Benchmarking

Under the proposed rule, three years of baseline spending data would be used to calculate target prices each performance year, with annual rebasing. In addition, CMS proposes to weight more recent baseline years more heavily, with baseline year one representing 17%, baseline year two representing 33% and baseline year three representing 50% of the benchmark price.

While we appreciate that CMS has incorporated feedback to have a longer baseline period for calculating target prices, we are concerned that there is still potential for the ratchet effect for participating hospitals. Notably by rebasing the target price annually and weighting the most recent baseline year more heavily, hospitals are more likely to be subject to diminishing returns over time and must compete against their own best performance. We urge CMS to use equal weighting for baseline years and to extend rebasing timelines.

Outlier Spending

The proposed rule would cap spending at the 99th percentile for each MS-DRG for each region. While we agree that high-cost spending caps are necessary to protect hospitals from incurring undue penalties from unexpected and severe complications, the 99th percentile is not sufficient to appropriately include outliers. The CJR model originally capped individual episode costs at two standard deviations above the mean. However, CMS later changed the cap to the 99th percentile, which was too high and did not capture the prevalence of severe complications. We urge CMS to use its initial CJR policy and set outlier spending thresholds at two standard deviations above the mean.

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Regional Target Prices

Like the later years of CJR, CMS proposes to provide target prices for each proposed MS-DRG/HCPCS and region based on 100% regional data for all TEAM participants.

While we appreciate that this was intended to mitigate hospitals competing against their own best performance, we recommend additional protections to accomplish this and to support organizations serving disproportionately medically complex populations (like safety-net hospitals).

First, hospitals that generate savings should not be penalized in subsequent performance years by having their success make future savings more difficult to achieve. To be clear, no matter the adjustments CMS makes, programs that are designed to achieve savings for the Medicare program year after year will see diminishing returns over time. Providers in low-spending areas will first begin to encounter such limited opportunities for additional gains in efficiency, but eventually, the agency will no longer be able to continue decreasing target prices for any providers without putting quality of care at risk.

We are particularly concerned that high performing hospitals that previously participated in BPCI-A and CJR may be particularly impacted by diminishing returns, as in many cases, they have achieved as much cost savings as they could, and TEAM target prices would include these savings from previous models.

Therefore, we urge the agency to instead use the higher of national or regional historical episode payments in calculating the target price. Doing so would help ensure that appropriate incentives are provided to participants in both high- and low-spending areas. This would help mitigate the impacts of regional variation that have been seen in other models.

We also urge CMS to further stratify target prices beyond the MS-DRG to account for clinical complexity, as discussed below in the Risk Adjustment section. For example, at a minimum, target prices should be separated based on whether the procedure was inpatient or outpatient, whether the case was elective or emergent, and based on fracture status where applicable. In addition, as also discussed below, there are other factors outside the control of hospitals that impact spending that relate to clinical complexity and social risk. Without an adequate risk adjustment to account for these factors, separate target prices should be pursued.

Finally, safety-net hospitals and other hospitals serving a higher proportion of underserved beneficiaries also should have a separate target price methodology. We echo the concerns expressed in the proposed rule that regional target prices inclusive of all provider types would adversely impact these organizations. Indeed, by lumping all provider types together, the model as proposed ignores the complexity of patients served by organizations like rural and safety-net hospitals.

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Prospective Trend Factor

CMS proposes to use a prospective trend factor to calculate target prices updated from baseline data. This factor would be the percent difference between the average regional MS-DRG/HCPCS episode expenditures computed using the most recent year of the applicable baseline period and the comparison average regional MS-DRG/HCPCS episode type expenditures during the first year of the baseline.

The proposal did not include any guardrails for the prospective trend factor. We appreciate that such a factor can help mitigate the significant deltas between initial target prices and target prices at reconciliation. However, we encourage CMS to establish guardrails to prevent significant reductions in the target prices from the initial target price to target price at reconciliation.

Discount Factor

CMS proposes a discount factor of 3%. However, 3% is too aggressive, especially in the context of other TEAM model design features. The opportunity to achieve savings under TEAM is not the same as previous models; rather, it is much less. Indeed, based on our analysis, each of the five clinical episode categories would have most episode spending accounted for by the anchor hospitalization or outpatient procedure, with three of the five having at least three-quarters of spending accounted for by the anchor hospitalization or outpatient procedure. For example, over 83% of CABG episode spending is tied to the anchor hospitalization, 81% of spinal fusion episode spending is tied to the anchor procedure, and over 75% of major bowel episode spending is tied to the anchor procedure.

This is extremely problematic. Hospitals do not have an ability to decrease the anchor hospitalization payment amount, leaving virtually no opportunity for them to achieve efficiencies and meet, let alone exceed, the proposed 3% discount factor. For example, it is unclear to us how CMS could reasonably expect them to meet or exceed the proposed discount factor by achieving efficiencies in the 17% of spending that occurs outside the initial hospitalization CABG episodes. To avoid turning TEAM into a thinly disguised payment cut, we urge CMS to provide hospitals with a fair opportunity to achieve enough cost savings to garner a reconciliation payment.

Specifically, we recommend that the discount factor be reduced to 1%.

Low-volume Thresholds.

The proposed rule includes a low-volume threshold. Specifically, if a participant does not meet a threshold of 31 total episodes across the baseline period in the first year of the model, then they would be subject to Track 1 for that year. If a participant does not

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meet a threshold of 31 total episodes across the baseline period for other years of the model, they would be subject to Track 2 for those years.

A low-volume threshold of 31 cases across five episode categories across three baseline years is unreasonable. This is especially true considering that hospitals meeting this threshold would still be required to participate in TEAM. The purpose of a low-volume threshold is multi-faceted, it should ensure that hospitals have enough cases to integrate changes in care delivery and determine if they had an impact based on statistical significance. Additionally, it should ensure that the costs associated with standing-up infrastructure for model participation (like analytics infrastructure and staffing) can be offset by potential gains in the model. Financially, it also should provide protection against outliers and volatility inherent with small sample sizes. A set threshold of 31 cases across five surgical episode categories and three baseline years would not accomplish any of these objectives.

Our analysis further clarifies this point. In analyzing the average gains and losses per episode (i.e., spending below or more than the regional price), we found that high losses and high variation was experienced in hospitals with up to 461 episodes per year (see Table 5). This is almost 45 times as high as CMS' proposed threshold. Hospitals with 39 to 111 cases per year had the widest range in gains and losses and the highest projected losses. Even these figures are still over 10 times as high as CMS' proposed threshold.

	-			-		Gain/Loss	per Episode	e
Decile by Episode Volume	Number of Hospitals	Avg. Number of Episodes	Min Number of Episodes	Max Number of Episodes	Weighted Average	Min	Max	Range
1	290	15		38	-\$1,722	-\$33,445	\$21,709	\$55,154
2	290	72	39	111	-\$1,957	-\$57,041	\$14,607	\$71,649
3	290	155	111	195	-\$1,469	-\$30,345	\$4,501	\$34,846
4	291	252	196	312	-\$1,222	-\$11,139	\$4,675	\$15,813
5	290	386	312	461	-\$1,490	-\$22,180	\$3,466	\$25,646
6	290	549	461	639	-\$1,340	-\$16,354	\$3,427	\$19,781
7	291	754	639	886	-\$1,107	-\$12,698	\$2,841	\$15,540
8	290	1,050	887	1,226	-\$995	-\$7,948	\$4,393	\$12,341
9	290	1,520	1,228	1,843	-\$712	-\$6,896	\$3,757	\$10,653
10	291	2,818	1,854	13,375	-\$573	-\$6,507	\$5,552	\$12,058
Total	2,903	758		13,375	-\$870	-\$57,041	\$21,709	\$78,750

 Table 5. Gain/Loss Values Across Episode Categories for Hospitals Before

 Application of Stop-loss and Stop-gain Limits

Even when adjusting for the application of proposed stop-gain and stop-loss limits, high average losses coupled with high variation were still experienced well beyond 31 cases

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(see Table 6). Again, the starkest losses and most significant variation were between 39 and 111 cases.

						Gain/Loss	s per Episod	le
Decile by Episode Volume	Number of Hospitals	Avg. Number of Episodes	Min Number of Episodes	Max Number of Episodes	Weighted Average	Min	Мах	Range
1	290	15		38	-\$674	-\$5,696	\$4,028	\$9,724
2	290	72	39	111	-\$962	-\$9,806	\$7,301	\$17,108
3	290	155	111	195	-\$852	-\$6,528	\$3,582	\$10,111
4	291	252	196	312	-\$756	-\$5,993	\$4,675	\$10,667
5	290	386	312	461	-\$997	-\$6,679	\$3,466	\$10,145
6	290	549	461	639	-\$943	-\$6,049	\$3,427	\$9,476
7	291	754	639	886	-\$750	-\$4,690	\$2,841	\$7,531
8	290	1,050	887	1,226	-\$746	-\$6,433	\$4,393	\$10,826
9	290	1,520	1,228	1,843	-\$547	-\$6,062	\$3,757	\$9,819
10	291	2,818	1,854	13,375	-\$448	-\$3,882	\$3,814	\$7,696
Total	2,903	758		13,375	-\$627	-\$9,806	\$7,301	\$17,108

Table 6. Gain/Loss Values Across Episode Categories for Hospitals After Application of Stop-loss and Stop-gain Limits

In addition, we are concerned that CMS has proposed only one, overarching lowvolume threshold and not individual thresholds for each clinical episode category. For example, under the proposed rule, a hospital could have 28 LEJR cases and one for each other clinical episode category and still exceed the low-volume threshold. This violates the principles of statistical significance with only one case, a hospital has no opportunity for regression to the mean. If that one case is a complicated major bowel case, for example, which requires significant post-acute care, then they would be penalized even though the circumstances are beyond their control. As noted in Table 7, it is easy to see how this could impact performance given the stark difference in spending based on post-acute needs.

Discharge Destination	Number of Hospitals	Number of TEAM Episodes	Avg. Episode Spending	Avg. Target Price	Difference Between Target and Spending Before CQS and Stop Loss/Gain
Home Health	2,483	51,080	\$30,608	\$32,196	\$1,588
Home	2,680	128,688	\$23,964	\$26,334	\$2,370
Hospice	1,509	3,723	\$43,043	\$45,146	\$2,103
IRF	1,400	7,850	\$63,789	\$40,222	-\$23,567
LTH	936	2,252	\$94,638	\$46,981	-\$47,657
Other Inpatient	59	60	\$51,183	\$39,512	-\$11,671
SNF	2,414	28,252	\$50,374	\$39,394	-\$10,980

Table 7. Major Bowel Episode Spending Based on Discharge Destination

Therefore, we urge CMS to increase the low-volume threshold to ensure statistical significance and effectively mitigate potential impacts of outliers and volatility in cases. Low-volume thresholds also should be developed within each individual episode category as opposed to across episode categories. Finally, hospitals not meeting the low-volume thresholds should be excluded from participation in the model so they are not unnecessarily exposed to financial risk for factors beyond their control.

Risk Adjustment

CMS' proposed risk adjustment for TEAM episodes is wholly inadequate. Specifically, the agency proposes to include adjustments for age, HCCs and social risk, in addition to MS-DRG-specific target pricing. However, this is not sufficient to account for patients' clinical factors that lead to spending variation. This lack of a robust risk-adjustment methodology penalizes hospitals treating the sickest, most complicated and historically marginalized patients, as we demonstrate in detail below. Indeed, researchers have recently confirmed that this is occurring in CMS' other bundled payment models, which, as we have stated, are almost identical in design to TEAM. For example, they found that CJR may penalize hospitals that treat medically complex patients.⁹ Indeed, the agency's own recent findings identified that CJR may in fact exacerbate disparities in elective LEJR for non-white beneficiaries.¹⁰

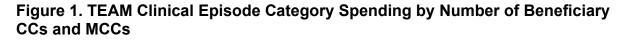
⁹ Ellimoottil C, Ryan AM, Hou H, Dupree J, Hallstrom B, Miller DC. Medicare's New Bundled Payment for Joint Replacement May Penalize Hospitals That Treat Medically Complex Patients. Health Aff (Millwood). 2016; 35(9):1651–7.

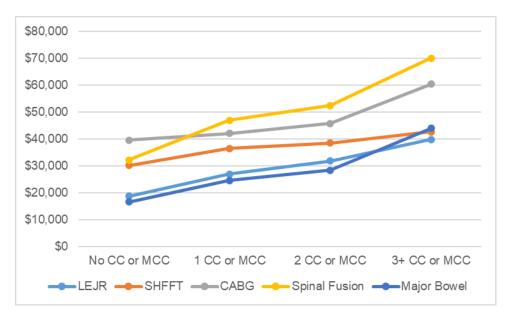
¹⁰ https://www.cms.gov/priorities/innovation/data-and-reports/2023/cjr-py5-ar-findings-aag

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In examining the adequacy of the TEAM risk adjustment methodology, we conducted analyses of certain patient factors and their effect on episode spending. They demonstrate that relying on MS-DRGs, age, a 90-day lookback for HCC flags and social risk does not fully account for numerous other factors that affect spending beyond hospitals' control. Based on our analysis, the variables of age, HCC count, social risk (as defined by DE and LIS) and DRG combined explain over 73% of spending variation. However, the explanatory power of the DRGs alone is 72%. Including age, HCC count and social risk provided less than 3% incremental explanatory power. This suggests that the DRG is the primary adjustment driver, and the variables currently included in the risk adjustment are not sufficient in accounting for clinical complexity and social risk that may contribute to episode spending. As detailed further below, we urge CMS to apply a more robust risk adjustment methodology to TEAM episodes.

<u>Risk Adjustment Should Include Consideration of Additional Conditions</u>. The proposed rule specifies that the risk adjustment would only include HCC flags from the 90 days prior to the anchor hospitalization. Any CC or major CC (MCC) flags from the actual anchor hospitalization would not be included. However, we found that for each of the five clinical episode categories, spending increases almost linearly by the number of beneficiary CCs and MCCs (see Figure 1). Therefore, the risk adjustment should also include CCs and MCCs from the anchor hospitalization.





In addition, the lookback period for HCCs is not sufficient. Specifically, CMS proposes a 90-day lookback, which is counter to its own standards in other programs. For example, BPCI-A as well as other models, CMS uses a 12-month lookback. We actually

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recommend even longer for TEAM – a multi-year lookback – as even 12 months misses patients with certain chronic conditions.

<u>Risk Adjustment Should Include Other Factors that Delineate Clinical Complexity</u>. At a high level, the episode categories and individual MS-DRGs/HCPCS are too broad to serve as the primary variable for target prices and risk adjustments. For example, while we agree that inpatient admissions should serve as the episode initiator, the team model includes outpatient procedures in the same episode categories for purposes of calculating target prices. Risk adjustments and target prices must account for clinical complexity within episode categories, including, but not limited to factors like inpatient versus outpatient episode initiators, fracture versus non-fracture status, and emergent versus elective procedures. Other variables like frailty should also be evaluated (see Table 8 below).

	Number of Hospitals	Avg. Number Episodes	Avg. Spending Per Episode	Avg. Target Price	Percent Difference Between Target and Spending	Average Patient Frailty Score
Highest Spending Quintile	580	465.6	\$37,316	\$32,813	-13.7%	0.2444
2 nd Quintile	581	800.6	\$31,808	\$29,721	-7.0%	0.2310
3 rd Quintile	580	989.7	\$28,604	\$27,807	-2.9%	0.2196
4 th Quintile	581	897.7	\$26,791	\$27,027	0.9%	0.2155
Lowest Spending Quintile	581	634.0	\$26,045	\$27,695	6.0%	0.2138
Total	2,903	757.6	\$29,493	\$28,623	-3.0%	0.2231

Table 8. Distribution of Frailty Score for TEAM Episodes by Quintile

CABG. Our analysis highlights that CMS' lack of a robust risk adjustment means that hospitals treating higher complexity and underserved patient populations within the CABG episode category systematically perform worse under TEAM, as shown in Table 9. Specifically, when we divided hospitals into quintiles based on the difference between their regional target price and their payments, we found that hospitals in the highest spending quintiles included a disproportionate share of safety-net hospitals and served a disproportionate share of DE or LIS patients. These hospitals also had a higher proportion of patients admitted through the emergency department (ED) or for trauma.

	Number of Hospital s	Avg. Number Episodes	Avg. Spending Per Episode	Avg. Target Price	Percent Difference Between Target and Spending	Percent Safety- net	Percent of episodes with patients admitted through ER or trauma	Percent of patients who are DE	Percent of patients who are LIS eligible
Highest Spending Quintile	214	60.0	\$62,333	\$51,928	-20.0%	47.7%	27.9%	11.8%	13.1%
2 nd Quintile	215	100.0	\$54,950	\$50,763	-8.2%	30.2%	25.7%	9.8%	11.0%
3 rd Quintile	214	127.1	\$51,704	\$50,305	-2.8%	28.0%	23.3%	9.0%	10.0%
4 th Quintile	215	134.4	\$49,480	\$50,044	1.1%	24.2%	23.2%	8.2%	9.4%
Lowest Spending Quintile	215	98.2	\$48,772	\$52,116	6.4%	29.8%	23.1%	9.3%	10.3%
Total	1,073	104.0	\$52,421	\$50,855	-3.1%	32.0%	24.2%	9.3%	10.5%

Table 9. Distribution of Hospital Characteristics for CABG Episodes by Quintile

We looked further into episodes where patients were admitted through the ED or for trauma. In the proposed rule, CABG episodes would include any coronary revascularization procedure paid under MS-DRGs 231-236 whether the patient was receiving an emergent or elective CABG. This means that this episode category includes, for example, patients who are transported to an ED experiencing a ST elevation (STEMI) myocardial infarction, necessitating an immediate CABG or other cardiac intervention. STEMI patients often have an increased potential for comorbidities (anemia, renal failure and stress hyperglycemia) compared to more stable patients who schedule a CABG ahead of time to address more chronic type coronary artery disease. **Yet, episode spending for these two types of cases varies to a staggering degree and must be accounted for in CMS' risk adjustment methodology (see Table 10).**

 Table 10. Episode Spending for CABG Based on Admission Source

Admission Source	Number of Hospitals	Number of Episodes	Avg. Episode Spending	Avg. Target Price	Difference Between Target and Spending (before CQS and stop loss/gain)
ED/Trauma	1,044	27,006	\$62,764	\$58,592	-\$4,172
Other	1,035	84,536	\$49,117	\$48,383	-\$733

In addition, the lack of a robust risk adjustment plays into and may exacerbate physician-owned hospitals' (POHs') practices of cherry-picking patients (see Table 11).

	Number of Hospitals	Avg. Number of Episodes	Avg. Episode Spending	Avg. Target Price	Difference Between Target and Spending (before CQS and stop loss/gain)	Percent Difference between Target and Spending
POH Hospitals	26	159.6	\$48,000	\$48,667	\$667	1.4%
Non-POH Hospitals	1,047	102.6	\$52,592	\$50,939	-\$1,652	-3.2%
All Hospitals	1,073	104.0	\$52,421	\$50,855	-\$1,566	-3.1%

Table 11. CABG Episode Spending for POHs compared to Non-POHs

Indeed, historical analysis has shown that POHs select the healthiest and most profitable patients, and subsequently treat fewer DE and LIS patients than full-service acute care hospitals.¹¹ CMS' lack of a robust risk adjustment plays to this practice at the expense of full-service hospitals and may exacerbate inequities for underserved populations (see Table 12).

Table 12. Descriptive Hospital Characteristics for POH and non-POH Hospitals forCABG Episodes

	Number of Hospitals	Avg. Number of Episodes	Percent Difference between Target and Spending	Percent of episodes with patients admitted through ER or trauma	Percent of patients who are DE	Percent of patients who are LIS eligible
POH Hospitals	26	159.6	1.4%	10.6%	6.4%	7.7%
Non-POH Hospitals	1,047	102.6	-3.2%	24.7%	9.4%	10.6%
All Hospitals	1,073	104.0	-3.1%	24.2%	9.3%	10.5%

LEJR. Our analysis again highlights that CMS' lack of a robust risk adjustment means that hospitals treating higher complexity and underserved patient populations within the LEJR episode category systematically perform worse under TEAM, as shown in Table 13. We again divided eligible hospitals in eligible CBSAs into quintiles based on the difference between their regional target price and their payments for LEJR. We again found that hospitals in the highest spending quintiles included a disproportionate share of safety-net hospitals and served a disproportionate share of DE or LIS patients. In addition, hospitals with a higher proportion of outpatient anchor procedures consistently performed better, highlighting yet another failure of the risk adjustment methodology.

¹¹ https://www.aha.org/fact-sheets/2023-03-28-select-financial-operating-and-patient-characteristics-pohs-compared-non-pohs-fact-sheet

	Number of Hospitals	Avg. Number Episodes	Avg. Spending Per Episode	Avg. Target Price	Percent Difference Between Target and Spending	Percent Safety- net	Percent of patients who are DE	Percent of patients who are LIS	Percent of episodes with an OP anchor procedure
Highest Spending	556	167.8	\$27,933	\$23.697	-17.9%	55.9%	14.3%	15.4%	46.2%
Quintile			<i> </i>	<i><i><i></i></i></i>		001070			
2 nd Quintile	557	420.6	\$23,372	\$21,405	-9.2%	33.0%	8.8%	9.7%	59.3%
3 rd Quintile	556	532.3	\$21,398	\$20,532	-4.2%	30.0%	7.8%	8.6%	68.5%
4 th Quintile	557	630.6	\$20,106	\$20,165	0.3%	28.4%	6.4%	7.2%	71.0%
Lowest Spending Quintile	557	484.5	\$19,221	\$20,378	5.7%	30.7%	6.2%	7.1%	71.9%
Total	2,783	447.2	\$21,423	\$20,796	-3.0%	35.6%	7.7%	8.6%	66.5%

Table 13. Distribution of Hospital Characteristics for LEJR Episodes by Quintile

In addition, we found that, again the lack of a robust risk adjustment plays into and may exacerbate POHs' practices of cherry-picking patients (see Table 14 and 15).

Table 14. LEJR Episode Spending for POHs compared to Non-POHs

	Number of Hospitals	Avg. Number of Episodes	Avg. Episode Spending	Avg.Target Price	Difference Between Target and Spending (before CQS and stop loss/gain)	Percent Difference between Target and Spending
POH Hospitals	135	776.2	\$18,472	\$18,569	\$97	0.5%
Non-POH Hospitals	2,648	430.5	\$21,694	\$21,001	-\$693	-3.3%
All Hospitals	2,783	447.2	\$21,423	\$20,796	-\$626	-3.0%

Table 15. Descriptive Hospital Characteristics for POH and non-POH Hospitals for LEJR Episodes

	Number of Hospitals	Avg. Number of Episodes	Percent Difference between Target and Spending	Percent of episodes with patients admitted through ER or trauma	Percent of patients who are DE	Percent of patients who are LIS eligible
POH Hospitals	135	776.2	0.5%	1.0%	4.0%	4.7%
Non-POH Hospitals	2,648	430.5	-3.3%	11.5%	8.1%	8.9%
All Hospitals	2,783	447.2	-3.0%	10.7%	7.7%	8.6%

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Spinal Fusion. CMS proposes to include any cervical, thoracic or lumbar spinal fusion procedure in the spinal fusion episode category. This would include MS-DRGs 453-455, 459-460 or 471-473 or HCPCS codes 22551, 22554, 22612, 22630 or 22633. However, these do not include all current version spinal fusion MS-DRGs. Specifically, CMS omits MS-DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curve, Malignancy, Infection or Extensive fusion with MCC, CC and without MCC/CC, respectively).

Additionally, as specified in the inpatient PPS proposed rule (specifically Section II Proposed Changes to MS-DRG Classifications and Recalibrations of Relative Weights), MS-DRGs 453-455 are proposed for deletion and would potentially be replaced by eight new MS-DRGs. This would be a major change to the logic that would add single and multiple levels to the MS-DRG consideration. There is not a direct mapping between MS-DRGs and HCPCS codes with these revisions. We urge CMS to consider excluding this clinical episode category from the model altogether due to its significant potential MS-DRG structural changes, with their unknown impacts. At a minimum, we urge CMS to postpone including spinal fusion in TEAM model until the MS-DRG change proposal comments are reviewed and any MS-DRG changes are finalized. Specifically, if the MS-DRG change proposals are finalized for FY 2025, CMS should allow two fiscal years of meaningful data review prior to reconsidering the inclusion of spinal fusion. Additionally, we urge CMS to consider that the HCPCS codes may not be a 1:1 match for the MS-DRGs proposed for the TEAM model when comparing the equivalent outpatient procedure to the inpatient procedure performed.

In addition, we again found that CMS' lack of a robust risk adjustment means that hospitals treating higher complexity and underserved patient populations within the spinal fusion episode category systematically perform worse under TEAM, as shown in Table 16. Specifically, hospitals in the highest spending quintiles included a disproportionate share of safety-net hospitals and served a disproportionate share of DE or LIS patients. Lowest spending quintiles included a disproportionate share of patients with an outpatient anchor procedure.

	Number of Hospitals	Avg. Number Episod es	Avg. Spending Per Episode	Avg. Target Price	Percent Difference Between Target and Spending	Percent Safety- net	Percent of patients who are DE	Percent of patients who are LIS eligible	Percent of episodes with an OP anchor procedure
Highest Spending Quintile	401	140.5	\$54,681	\$45,841	-19.3%	47.6%	14.2%	15.5%	11.0%
2 nd Quintile	401	204.0	\$45,441	\$42,289	-7.5%	28.7%	11.0%	12.4%	16.3%
3 rd Quintile	401	202.8	\$41,628	\$41,231	-1.0%	25.2%	10.7%	12.0%	19.4%
4 th Quintile	401	176.0	\$38,164	\$40,108	4.8%	26.2%	10.2%	11.5%	27.9%
Lowest Spending Quintile	402	103.7	\$33,019	\$38,734	14.8%	31.3%	10.4%	11.7%	44.7%
Total	2,006	165.4	\$42,966	\$41,722	-3.0%	31.8%	11.2%	12.6%	22.2%

Table 16. Distribution of Hospital Characteristics for Spinal Fusion Episodes byQuintile

Additionally, as with the other clinical episode categories, we are concerned that the lack of delineation between inpatient and outpatient procedures as well as variables to fully capture clinical complexity and social risk may exacerbate cherry-picking practices on the part of POHs (see Table 17 and 18 below).

	Number of Hospitals	Avg. Number of Episodes	Avg. Episode Spending	Avg. Target Price	Difference Between Target and Spending (before CQS and stop loss/gain)	Percent Difference between Target and Spending
POH Hospitals	133	241.7	\$39,245	\$39,236	-\$10	0.0%
Non-POH Hospitals	1,873	160.0	\$43,365	\$41,989	-\$1,376	-3.3%
All Hospitals	2,006	165.4	\$42,966	\$41,722	-\$1,244	-3.0%

Table 18. Descriptive Hospital Characteristics for POH and non-POH Hospitals forSpinal Fusion Episodes

	Number of Hospitals	Avg. Number of Episodes	Percent Difference between Target and Spending	Percent of episodes with patients admitted through ER or trauma	Percent of patients who are DE	Percent of patients who are LIS eligible
POH Hospitals	133	241.7	0.0%	0.5%	7.5%	8.9%
Non-POH Hospitals	1,873	160.0	-3.3%	6.8%	11.6%	13.0%
All Hospitals	2,006	165.4	-3.0%	6.2%	11.2%	12.6%

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Major Bowel. Under the proposal, any small or large bowel procedure under MS–DRGs 329-331 would be included in the major bowel episode category. **This is an overly broad clinical category that could include, for example, a patient undergoing emergency surgery, a cancer patient getting a tumor removed, a patient with colitis, or a patient with a minor blockage removal.**

In addition, we again found that CMS' lack of a robust risk adjustment means that hospitals treating higher complexity and underserved patient populations within the major bowel episode category systematically perform worse under TEAM, as shown in Table 19. Hospitals in the highest spending quintiles included a disproportionate share of safety-net hospitals and served a disproportionate share of DE or LIS patients (see Table 19). Highest spending quintiles also included a disproportionate share of patients admitted through an ED or trauma.

Table 19. Distribution of Hospital Characteristics for Major Bowel Episodes byQuintile

	Number of Hospitals	Avg. Number Episodes	Avg. Spending Per Episode	Avg. Target Price	Percent Differenc e Between Target and Spending	Perce nt Safety -net	Percent of episodes with patients admitted through ED or trauma	Percent of patients who are DE	Percent of patients who are LIS eligible
Highest Spending Quintile	546	38.8	\$37,866	\$31,985	-18.4%	57.5%	42.1%	21.3%	22.6%
2 nd Quintile	547	97.7	\$33,021	\$30,600	-7.9%	34.2%	34.6%	15.7%	17.0%
3 rd Quintile	547	122.3	\$30,926	\$30,129	-2.6%	27.4%	34.1%	14.0%	15.3%
4 th Quintile	547	101.4	\$29,109	\$29,750	2.2%	29.3%	31.5%	13.7%	15.0%
Lowest Spending Quintile	547	45.5	\$27,990	\$30,497	8.2%	37.7%	34.2%	14.5%	15.8%
Total	2,734	81.2	\$31,310	\$30,366	-3.1%	37.2%	34.4%	15.1%	16.4%

Differences in episode spending based on source of admission were also in stark contrast as shown in Table 20.

Table 20. Episode Spending for Major Bowel Based on Admission Source

Admission Source	Number of Hospitals	Number of Episodes	Avg. Episode Spending	Avg. Target Price	Difference Between Target and Spending (before CQS and stop loss/gain)
ED/Trauma	2,591	76,248	\$40,908	\$37,679	-\$3,229
Other	2,641	145,657	\$26,285	\$26,538	\$253

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SHFFT. This proposed episode category would include hip fixation procedure, with or without hip fracture reduction, but excluding major joint replacement under MS-DRGs 480-482.

When evaluating episode spending, again safety-net hospitals and DE and LIS patients represented the highest quintile of spending (see Table 21).

	Number of Hospitals	Avg. Number Episodes	Avg. Spendin g Per Episode	Avg. Target Price	Percent Difference Between Target and Spending	Percent Safety- net	Percent of patients who are DE	Percent of patients who are LIS eligible
Highest		a= 1	* / * * *	* • - • - •		/	aa 464	.
Spending Quintile	539	97.1	\$43,970	\$37,351	-17.7%	45.5%	20.1%	21.4%
2 nd Quintile	540	131.2	\$40,254	\$37,523	-7.3%	37.6%	18.9%	20.0%
3 rd Quintile	540	130.3	\$37,634	\$37,206	-1.2%	35.4%	19.1%	19.9%
4 th Quintile	540	120.6	\$35,813	\$37,342	4.1%	30.0%	16.7%	17.6%
Lowest Spending Quintile	541	56.7	\$33,066	\$37,421	11.6%	30.3%	16.5%	17.6%
Total	2,700	107.2	\$38,528	\$37,363	-3.1%	35.7%	18.4%	19.4%

Table 21. Distribution of Hospital Characteristics for SHFFT Episodes by Quintile

Normalization Factor

CMS also is proposing a prospective normalization factor with preliminary target prices. This would be subject to an adjustment at reconciliation based on observed case mix up to +/- 5%.

The normalization factor has the potential to negate the risk adjustment and in fact exceed the risk adjustment, as has been the case in previous iterations of bundled payment models. As such, we recommend that CMS cap the adjustment factor to, at a minimum, not exceed the risk adjustment. Additionally, because CMS proposes to incorporate a normalization factor adjustment at reconciliation, this may exacerbate issues where the target price at the start of the fiscal year differs significantly from the target price at reconciliation. We recommend CMS not pursue an adjustment at reconciliation.

Reconciliation

Similar to other bundled payment models, TEAM participants would reconcile performance year spending against their target price to determine if they receive a reconciliation payment or make a repayment. However, unlike previous models, for repayments, financial guarantees would not be required. Yet these financial guarantees provided reinsurance policies for participants if they could not pay back debts as a result of performance. CMS acknowledged in the proposed rule that some TEAM participants The Honorable Chiquita Brooks-LaSure June 10, 2024 Page 33 of 46

may be unable to cover upfront capital required to qualify for financial guarantees, which is why CMS proposed not to require insurance policies as a prerequisite and instead made this portion voluntary.

Again, this reinforces why participation should be voluntary in the full model. If an organization does not have capital resources available to acquire insurance to protect them from financial losses for repayment, they should not be forced to participate in the model. Although they are separate measures, a reasonable person could assume that these organizations also would not have the cash flow, volume and/or revenue to support repayment outright. Therefore, they shouldn't be required to assume unnecessary financial risk for repayments when they do not have capital to adequately insure them from potential losses.

Participant Responsibility for Increased Post-episode Payments

As with the CJR model, CMS proposes that TEAM participants would be financially accountable for certain post-episode payments occurring in the 30 days after conclusion of the episode. Specifically, it would calculate 30-day post-episode spending to determine if TEAM participants have spending three standard deviations above the regional average. If a participant does exceed this threshold, it would account for this amount in the reconciliation or repayment amount for the following year. This amount would not be subject to stop-loss limits. While we certainly agree with the intent of this proposed process to ensure services are not withheld or delayed until after an episode concludes, this does reinforce why episode duration should be instead based on clinical appropriateness rather than the set 30 days. We are concerned that certain complex cases requiring substantial post-acute care may exceed this threshold, resulting in penalties (not subject to stop-loss) for care that is clinically appropriate.

USE OF QUALITY MEASURES IN PAYMENT DETERMINATION

Quality Measure Set

CMS proposes to assess TEAM model participants' quality performance using three measures that are part of the CMS IQR program, hybrid hospital-wide all-cause 30-day readmissions, CMS' composite patient safety indicator (PSI 90) and a patient-reported outcome-based performance measure (PRO-PM) for THA and TKAs. The THA/TKA PRO-PM would only apply to LEJR episodes. CMS further proposes that hospitals would use existing hospital IQR reporting processes to submit measure data.

The AHA appreciates that CMS has proposed quality measures and reporting processes that already are part of the IQR program, thereby reducing data collection and reporting burden. Yet, none of the three measures is well-aligned to the structure of the payment model, and all three measures have notable

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implementation and methodological challenges. We urge CMS to be mindful of these limitations in tying quality performance to payment in this model.

Indeed, two of the three proposed measures, hybrid hospital-wide readmissions and the THA/TKA PRO-PM, are required for reporting in the hospital IQR program for the first time this year. Furthermore, those hospitals that participated in the voluntary reporting process for these measures encountered significant challenges that raise questions about the measures' readiness for the IQR program, let alone the TEAM model. On the hybrid hospital-wide readmissions measure, hospitals have not received enough information from CMS on the accuracy of the vital signs, labs and linking variables that they submitted to the agency. These data are essential because the measure relies on a matching process between data hospitals submit from their electronic health records (EHRs) and Medicare claims data. Furthermore, based on the information they have received from CMS, it appears some patients may have been included or excluded from the measure calculation inappropriately.

On the THA/TKA PRO-PM measure, the AHA appreciates CMS' goal of adopting measures that assess whether patients regain day-to-day function in their lives following their procedures. At the same time, hospitals participating in voluntary reporting have reported significant concerns about the level of administrative complexity required to administer the survey. The measure requires data collection in both the pre- and post-operative time periods, and patients may not respond to the post-operative survey. CMS has set a pre-post "match" rate that likely is unrealistic for hospitals.

The AHA also has repeatedly urged CMS to phase out PSI 90 from all its quality measurement and value programs. PSI 90's reliance on billing data has given the measure poor reliability and sometimes profound disconnects between performance captured in billing data and clinical reality. This is because billing data simply cannot and do not fully capture the full course of care and relevant risk factors that can impact outcomes.

Lastly, CMS indicates it is also considering three other measures for the TEAM model that the agency is proposing for the IQR program this year, two hospital harm-related electronic clinical quality measures, and a claims-based failure to rescue measure. CMS has not even adopted these measures for the IQR or implemented them in hospitals, providing us with no insight into their suitability for the TEAM model. We urge CMS not to adopt these three additional measures in the TEAM model currently.

Composite Quality Score

CMS proposes to calculate a composite quality score using the three proposed measures. For each applicable measure, CMS would covert the raw score into a scaled score of zero to 100 by using the national performance percentiles of the hospitals included in the model. The percentiles would be determined using a fixed baseline period of calendar year (CY) 2025. CMS would weight measures that apply to more

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episode categories more heavily based on volume. In turn, CMS would tie the composite quality score to reconciliation payments. However, composite quality scores of less than the 100th percentile would reduce positive reconciliation amounts.

The AHA urges CMS to provide greater opportunity for model participants to receive an upside from their quality performance. A threshold of 100 is unrealistically high and simply serves to penalize TEAM participants who otherwise have exceptional quality performance. This is especially true given that TEAM's three measures are not well-aligned to the episodes of care included in the model. We urge CMS to lower the CQS threshold for receiving full positive reconciliation payments to a more realistic level.

HEALTH EQUITY REQUIREMENTS

The TEAM model includes a number of proposals intended to advance health equity for the Medicare beneficiaries included in the model. Hospitals and health systems share CMS' deep commitment to advancing health equity within their organizations and in the communities they serve. Our members are eager to engage with CMS as it develops health equity policy approaches across its programs, including in CMMI models such as TEAM. The AHA supports many of CMS' proposals, but believes others are not well coordinated with other CMS policies or lack important details to help hospitals and health systems understand and plan their implementation.

Health Equity Plan

The AHA supports CMS' proposal to require TEAM model participants to submit a health equity plan starting in PY 2. Elements of the health equity plan would include identification of health disparities within the TEAM beneficiary population, health equity goals, intervention strategies and performance measures. Hospitals tell us that the type, prevalence and underlying causes of inequities can differ across the communities they serve. The development of a hospital-specific health equity plan can help ensure the solutions they employ are most relevant to the communities they serve.

We also recommend that CMS allow hospitals participating in multiple CMMI models that require health equity plans to submit a single plan applicable to all models. Given the potential overlaps between CMMI models, hospitals likely would use similar approaches to stratify their data, monitor performance and engage with their communities. If hospitals can describe how their plans are relevant to the CMMI models in which they participate, we believe a single plan would both suffice and promote a coordinated approach to health equity. The Honorable Chiquita Brooks-LaSure June 10, 2024 Page 36 of 46

Demographic Data Reporting.

In addition to health equity plans, CMS would require participants to report demographic data of TEAM beneficiaries to CMS beginning in PY 2. Data would need to conform to United States Core Data for Interoperability (USCDI) version 2 data standards developed by the Office of the National Coordinator for Health IT (ONC). The proposed rule indicates that hospitals would be required to report the data in a "form and manner and by a date specified by CMS" but does not provide details on the level of completeness that CMS would require for such data, or what mechanisms CMS would use to collect and protect the confidentiality of the data.

The AHA recommends that CMS not make the reporting of demographic data mandatory until it can provide more details in rulemaking and has gained experience with accepting the data from hospitals. As a general matter, the AHA appreciates the importance of demographic data in identifying inequities and providing a basis to track improvements. However, we are not confident the USCDI demographic standard is as ready to support reporting as CMS appears to assume. Furthermore, CMS' proposal lacks important details that would help hospitals plan for these requirements and ensure they could meet CMS' expectations. We believe these details should be subject to notice and comment rulemaking, and not left for CMS to determine unilaterally and without adequate stakeholder input.

CMS and ONC have worked to include USCDI version 2 standards in the certification criteria for EHRs. Yet, certification standards are effective only when they are adopted consistently across EHR vendors. The AHA has long been concerned that the testing requirements for certified EHRs are not sufficient to ensuring the USCDI standards can support hospitals in the collection, reporting and exchange of data, including demographic data. Furthermore, while the majority of EHR vendors may have already implemented more advanced versions of the USCDI, we are concerned about whether smaller vendors, especially those that may be in use in some safety facilities, have successfully pushed out versions of their software that meet USCDI version 2. Any hospitals whose EHRs do not support the USCDI version 2 standard currently would be required to undertake significant upgrades, raising guestions about disruption to operations, vendor availability and costs. Additionally, there are currently 44 EHRs on the ONC's corrective action list (Product List-Corrective Action), many of which are commonly used by providers operating in a private practice. If a patient comes from a practice that is using an EHR that is not USCDI version 2 compliant, the patient's data will be incomplete when the patient first enters the health system, forcing the hospital or health system to manually input that information, which shifts this burden to the hospital and runs contrary to the objectives of interoperability.

Furthermore, we note that the USCDI's version 2 definitions of race and ethnicity may not fully align with the latest standards from the Office of Management and Budget (OMB). On March 28, OMB issued an updated Statistical Policy Directive 15 that governs how federal agencies collect and use race and ethnicity data in their programs, The Honorable Chiquita Brooks-LaSure June 10, 2024 Page 37 of 46

the first update since 1997. OMB made several groundbreaking changes to the guidance such as consolidating race/ethnicity into a single question, adding a new category for Middle Eastern and North African individuals to identify themselves, and establishing new minimum and detailed categories for each race/ethnicity field. It does not appear that the USCDI version 2 aligns to this requirement currently.

Lastly, CMS' proposal leaves out critical details that the AHA strongly believes should be subject to further notice and comment rulemaking to ensure the expectations are clear, transparent and subject to stakeholder feedback. For example, the USCDI version 2 includes race, ethnicity, sexual orientation and gender identity. Yet, some patients may prefer not to report that information to hospitals, even when they are asked. CMS does not articulate in the proposed rule an approach for honoring the choices of patients who may choose not to share these data while also not penalizing hospitals for not reporting "complete" data.

Furthermore, it is not clear what level of data CMS is seeking. For example, is the agency seeking *aggregate* demographic data or *patient-level* data? If it is aggregate-level data, CMS would need to consider how to protect patient confidentiality in hospitals where there may be small numbers of a particular demographic variable. If CMS is considering the reporting of patient-level data, such reporting would introduce even more questions about how to protect and de-identify patient data, as well as whether CMS reporting systems have the capacity to securely accept such data. This is especially true because the USCDI asks for other potentially identifying information such as name, address, date of birth, phone and email.

Health-related Social Needs

Participants would be required to screen TEAM beneficiaries for health-related social needs (HRSN) across four domains starting in PY 1: food insecurity, housing instability, transportation needs and utility difficulties. Additionally, CMS proposes that participants would need to aggregate screening data for each domain and report on referral policies to community-based organizations.

The AHA supports the concept of screening TEAM model participants for HRSNs but believes existing reporting requirements may achieve the same goal. We recommend that CMS defer finalizing this proposal until the agency has clarified its approach to HRSN screening measures across its hospital quality measurement programs. We are concerned that CMS' proposal may duplicate other HRSN measurement requirements in both the IQR and Hospital Outpatient Quality Reporting (OQR) programs. The two IQR HRSN screening measures assess hospitals on the percentage of all adult inpatient admissions screened for the same HRSNs included in the proposed TEAM model screening requirements. In December 2023, CMS also included two measures assessing whether hospitals screen outpatients for HRSNs on its pre-rulemaking Measures Under Consideration list for the OQR program. As a result, CMS could propose the HRSN screening measures for the OQR as soon as The Honorable Chiquita Brooks-LaSure June 10, 2024 Page 38 of 46

the CY 2025 outpatient PPS rule this summer. The adoption of the measures in the OQR would ensure that all inpatient and outpatient episodes of care include an assessment for HRSN screenings. Thus, a separate reporting requirement for the TEAM model could lead to unhelpful administrative burden and inconsistency between CMS' measurement programs and the TEAM model.

Ultimately, hospitals and health systems want to use HRSN data to inform their efforts to address inequities, rather than diverting resources to decipher differing reporting requirements across CMS programs. We urge CMS to carefully coordinate any HRSN reporting requirements across its programs and ensure they use a consistent set of data definitions.

WAIVERS OF MEDICARE PROGRAM RULES

The waiver of certain Medicare program regulations is essential so that hospitals and health systems may coordinate care and ensure that it is provided in the right place at the right time. We urge CMS to provide hospital participants with additional and maximum flexibility to identify and place beneficiaries in the clinical setting that best serves their short- and long-term recovery goals. First, we have concerns over certain proposed waivers, namely those related to SNF three-day rule. Second, we recommend that the agency consider additional waivers, outlined below, that would provide our members with valuable tools to increase quality and reduce unnecessary costs. These waivers are commensurate with the level of risk and accountability that CMS is asking hospitals to assume as it shifts the burden of risk further away from the Medicare program onto providers.

Post-discharge Home Visits and Homebound Requirement

In the proposed rule, CMS indicated that it had considered whether to waive the "incident to" rule, which would allow a model beneficiary to receive post-discharge visits in their home or place of residence any time during the episode but found that there was very low uptake in prior models, such as those in BPCI-A and CJR. The agency believes that there has been a greater shift towards telemedicine as a modality for post-discharge follow up and therefore did not propose to waive the "incident to" rule. The AHA strongly urges CMS to waive the "incident to" rule as this allows the greatest flexibility for providers, whether through telehealth services or through home post-discharge visits. We believe that it is a clinical judgement as to what entails most appropriate care, and the agency should allow for the greatest flexibility in the delivery of that care.

Similarly, the agency considered waiving the "home-bound" rule for HH services but believed that many beneficiaries would meet the requirement and would receive medically necessary HH services under existing program rules. Therefore, the agency is not proposing to waive the rule. **However, the AHA urges CMS to waive the requirement that a beneficiary is "home-bound" to receive HH services.** CMS The Honorable Chiquita Brooks-LaSure June 10, 2024 Page 39 of 46

states that this requirement provides a way to help differentiate between patients who require medical care at home versus patients who could more appropriately receive care in a less costly outpatient setting. However, hospitals would not have an incentive to direct patients to HH when a less costly option, such as outpatient therapy, also would be clinically appropriate. In contrast, they may find good clinical rationale for utilizing HH services for non-homebound patients. In fact, CMS itself acknowledges in the rule that waiving the homebound requirement could result in lower episode spending in some instances, such as helping a non-homebound beneficiary avoid a hospital readmission. Again, CMS should allow physicians, working together with participating hospitals, to determine the most clinically appropriate plan for a patient's post-acute care, unimpeded by regulatory barriers.

Telehealth

The AHA supports CMS' proposed telehealth waivers. Specifically, the agency would waive the geographic site requirements that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of Dec. 31, 2000. In addition, CMS would waive the originating site requirements that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system, but only when telehealth services are being furnished in the beneficiary's home or place of residence during the episode.

In addition, the agency proposes to create a specific set of nine HCPCS G-codes to describe the evaluation and management (E/M) services furnished to TEAM beneficiaries in their homes via telehealth like those in the BPCI-A and CJR models. In general, we recommend CMS leverage existing coding practices to delineate telehealth visits as opposed to creating new codes. The G-codes proposed do not appear to differ clinically with existing E/M codes and are the same E/M codes in the list of current telehealth codes covered by Medicare; as such, it is unclear why separate codes would be necessary, especially considering there is already guidance on leveraging Place of Service (POS) codes for professional telehealth services to the provided to the patient's home.

SNF Three-day Rule

CMS proposes to waive the SNF three-day rule for discharges to SNFs with at least a three-star rating in the Five-Star Quality Rating System for SNFs on the Nursing Home Compare website. We are concerned about CMS' proposal to limit the waiver to SNFs with at least a three-star rating given their limited availability in certain markets. **Specifically, we are concerned the structure of CMS' proposed waiver would lead to two separate and unequal tiers of care: a more flexible, patient-centered level for patients in markets with an adequate supply of three-star SNFs and a more restrictive, regulation-driven level of care for patients in markets with an inadequate supply of three-star SNFs.**

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We also have concerns about the star rating methodology itself. For example, the biggest part of a SNF's star rating is the facility inspections conducted by CMS or, most likely, state surveyors. While surveys are an important activity for assuring compliance with regulations, there is significant state-to-state and surveyor-to-surveyor variation in how survey standards and guidance are applied. As a result, the findings from surveys can be highly subjective. Although CMS has attempted to account for the variation in survey practices by creating a distribution of star ratings on inspection data based on the relative performance of facilities within a state, we have concerns about the extent to which this adequately addresses the problem. Since CMS proposes to hold participating hospitals financially accountable for the quality and costs of the entire episode of care, the decision to admit a patient to a setting of care should be at the discretion of the patient's physician working together with the beneficiary and the participating hospital.

CMS also recognized that there may be instances where a TEAM participant would like to use the three-day SNF rule waiver, but the TEAM beneficiary receives inpatient postacute care through swing bed arrangements in a hospital or critical access hospital (CAH), which is not subject to the Five-Star Quality Rating System. CMS believes that allowing TEAM participants to use the three-day SNF rule waiver for hospitals and CAHs operating under swing bed agreements may support beneficiary freedom of choice and provide greater flexibility to TEAM participants for their care coordination efforts. We agree and urge CMS to allow TEAM participants to use hospitals and CAHs operating under swing bed agreements for the three-day SNF rule waiver.

Hospital Discharge Planning Requirements

The AHA strongly urges CMS to waive hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the information provided on post-hospital services. Such regulations inhibit the efficient coordination of care. When a patient elects to receive a bundle of services from a provider, that patient also is electing to receive a carefully prescribed course of treatment which can span multiple provider settings. CMS proposes to hold participating hospitals financially accountable for quality and costs for the entire episode of care. The agency also must provide them with the flexibility to direct patients to the most clinically appropriate, high-quality next setting of care.

Inpatient Rehabilitation Facility "60% Rule"

We urge CMS to waive the Inpatient Rehabilitation Facility (IRF) 60% Rule that requires that at least 60% of an IRF's patients have one of 13 clinical conditions. Hospital participants would have no incentive to over-utilize or inappropriately direct patients to IRFs. In contrast, they may find good clinical rationale for IRF stays for some patients, such as allowing beneficiaries to more quickly return to their communities. Further, as a matter of principle, since CMS proposes to hold participating hospitals

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financially accountable for the quality and costs of the entire episode of care, the agency also must provide them with the flexibility to direct patients to the most clinically appropriate next setting of care.

IRF "Three-hour Rule"

Medicare has a long-standing requirement that IRF patients require and receive at least three hours of therapy a day, the "preponderance" of which must be provided one-onone. **We urge CMS to waive the "preponderance" requirement under the TEAM program.** Medicare has stated that, for IRFs, the "standard of care is individualized (i.e., one-on-one) therapy." However, each mode of therapy is carefully selected by the therapist based on the individual needs of the patient, and hospital participants have every incentive to work with IRFs to obtain the best possible treatment for their patients. And for many patients, such as those for whom medical improvement, restoration of functional independence and the achievement of patient education goals are advanced through the social interaction and motivation gained through the group dynamic, concurrent or group therapy are often preferred treatment methods. Allowing more flexibility on the type of therapy an IRF provides would serve as a valuable tool for participants to increase quality and reduce unnecessary costs.

FINANCIAL ARRANGEMENTS AND BENEFICIARY INCENTIVES

Fraud and Abuse Waiver and Office of Inspector General Safe Harbor Authority

Prior to issuance of a final rule, the AHA urges the secretary to use the full scope of the combined authority granted by Congress under Section 1115A(d)(1) of the Affordable Care Act to issue waivers of the potentially applicable fraud and abuse laws to enable participating hospitals to form the financial relationships necessary to succeed in TEAM. Specifically, to the extent these arrangements are not already captured within the valuebased care and CMS sponsored payment model exceptions, the secretary should waive the Physician Self-Referral Law, the Anti-Kickback Statute, and the Beneficiary Inducement CMP Law (the "fraud and abuse laws") with respect to financial arrangements formed by hospitals participating in TEAM that comply with the requirements in the proposed rule. The secretary ultimately recognized the necessity of these waivers to the success of the CJR, issuing them in conjunction with the rule finalizing that program. We urge the same to occur for this proposed TEAM model. These waivers are consistent with HHS's efforts to broaden the use of value-based payment models and essential to enable hospitals to form financial arrangements with other providers collaborating in the model, without which hospitals have no real ability to make sure those providers for whose outcomes hospitals would be held accountable have a real stake in achieving the model's goals.

As proposed, any financial arrangement or agreement under TEAM that implicates fraud and abuse laws would not be protected unless it falls under an existing exception or safe harbor. Although AHA takes the position that the value-based exceptions to the

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fraud and abuse laws and the CMS sponsored model arrangement safe harbor to the Anti-Kickback Statute should cover many scenarios, it is critical that HHS fully mitigate the risk for hospitals, whose participation in this program would be mandatory. They should not have to spend hundreds of hours or thousands of dollars in hopes of stringing together components from the existing exceptions and safe harbors or developing inefficient workarounds to meet the demands of this new program and avoid running afoul of the fraud and abuse laws. **Hospitals must have needed, explicit protections in place and adequate time to form the necessary financial arrangements. As the Administration is aware, such programs cannot be successful for Medicare and its beneficiaries without these protections.**

Under TEAM, hospitals would bear responsibility for the financial and quality outcomes of other providers who provide care to Medicare beneficiaries during qualifying episodes. In the proposed rule, CMS notes that participating hospitals may rely on financial arrangements with those providers which CMS refers to as "TEAM collaborators" to share the program's potential risks and rewards. Indeed, our members report that such financial arrangements are not just a desirable but rather an essential component of successful participation in TEAM. CMS itself acknowledges in the proposed rule that the financial relationships between hospitals and TEAM collaborators may implicate fraud and abuse laws. Despite this recognition, the proposed rule does not include waivers of any of the potentially applicable fraud and abuse laws. CMS indicated that it expects to make a determination that the Anti-Kickback Statute safe harbor for CMS-sponsored model arrangements is available to protect certain remuneration when arrangements with eligible providers and suppliers are in compliance, but there is no parallel exception to the Physician Self-Referral Law.

Sharing Arrangements

CMS has proposed a very detailed regulatory structure that would govern any TEAM financial arrangements, and which would also serve as a built-in safeguard against fraud and abuse concerns. Hospitals, for example, would be required to set forth a written participation agreement that includes the terms of any sharing arrangements, such as sharing of program savings or internal cost savings, or of repayments to Medicare. The written agreement detailing the sharing arrangements would be subject to extensive requirements, including descriptions of the methodologies used to calculate any payments to and from hospitals and TEAM collaborators (known as gainsharing and alignment payments); plans regarding care redesign, changes in care coordination or delivery, and a description of how success would be measured; and information on management and staffing personnel. Further, any gainsharing and alignment payments would be subject to specific requirements.

As CMS itself states in the proposed rule, "[w]e propose several requirements for sharing arrangements to help ensure that *their sole purpose is to create financial alignment between TEAM participants and TEAM collaborators toward the goals of the model while maintaining adequate program integrity safeguards*" (emphasis added). **We**

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agree and believe that satisfaction of these requirements and responsibilities should provide participant hospitals protection under fraud and abuse laws.

Collaborators

CMS proposes that several types of providers and suppliers that are Medicare-enrolled, eligible to participate in Medicare, or are participating in a Medicare ACO initiative may be TEAM collaborators. We urge CMS to also include the newly established Medicare provider type, the rural emergency hospital, as a collaborator. This would enable rural providers to better align their care delivery for model participants.

Beneficiary Incentives

In addition, the AHA urges the secretary to either waive the beneficiary inducement civil monetary penalty (CMP) for beneficiary incentives that comply with the requirements in the proposed rule or state explicitly that any incentive program established under TEAM that complies with the proposed requirements meets a statutory exception to the CMP law. In the proposed rule, CMS states that TEAM participant hospitals may want to provide in-kind patient engagement incentives to beneficiaries in TEAM episodes. The agency proposes to allow participant hospitals to provide these for free or below fair market value, subject to certain conditions that are laid out in the proposed rule. However, CMS has not proposed to waive the CMP that prohibits beneficiary inducement, nor to declare that compliance with the terms and conditions satisfies a statutory carve-out to the prohibition. Therefore, CMS's proposal, as drafted, risks giving hospitals a false sense of security that the beneficiary enhancements offered by CMS as a programmatic element of the TEAM do not run afoul of the law.

BENEFICIARY CONSIDERATIONS

Monitoring Access and Quality

CMS proposes to require participating hospitals to, as part of discharge planning, provide beneficiaries with a complete list of all available post-acute care options in the service area consistent with medical need. This list would include beneficiary cost-sharing and quality information. These requirements would supplement the existing discharge planning requirements. However, as noted above, the AHA strongly urges CMS to waive hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the information provided on post-hospital services. In addition, we note that hospitals do not have access to beneficiaries' post-acute care cost-sharing details. **As such, we urge CMS not to finalize this requirement.**

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Records Retention

CMS proposes to replicate audit and record retention requirements policies set forth in previous models for TEAM. It also proposes that the federal government would have a right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of TEAM, as with any other CMMI model. Additionally, to align with the policy of current models being tested by CMMI, CMS is proposing that the TEAM participant and its TEAM Collaborators must maintain and give the federal government access to all documents and other evidence sufficient to enable the audit, evaluation, inspection, or investigation. We urge CMS to use HIPPA standards of document retention rather than setting CMMI-specific standards.

DATA SHARING

Model participants should have timely access to data about their patient populations. Historically, the lack of transparent, real-time data has created confusion on trigger events, eligibility for episodes and program participation. CMS proposes to provide beneficiary claims data, aggregate regional data and historical baseline data. **We support provision of these data points.** However, providing them only one month prior to the start of performance is not sufficient. We urge the agency to convey this information at least 60 days prior to the start of the relevant performance period.

Moreover, a number of hospitals participating in historical models have indicated that the target prices for these programs have often changed during the performance period, sometimes significantly and inexplicably. To further stabilize the target prices for model participants, we urge CMS only to update its underlying assumptions related to the target price annually, and to do so through notice-and-comment rulemaking.

ADJUSTMENTS FOR OVERLAPS WITH OTHER CMMI MODELS AND CMS PROGRAMS

Aside from the Maryland Total Cost of Care Model, CMS proposes to allow overlap with other total cost of care or shared savings models (to include ACOs). **However, as mentioned in the Participant Exclusions section above, we recommend excluding organizations participating in A-APMs from participation in TEAM**.

ADVANCED APM CONSIDERATIONS

CMS proposes to have two APM options in TEAM. One option qualifies as an advanced-APM and one does not. The non-advanced APM option would be for participants in Track 1 and/or participants unable to meet Certified Electronic Health Record Technology or financial risk standards; these participants would still be considered Merit Based Incentive Payment System (MIPS) APM entities, however.

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We support CMS' proposal to create a track that would allow physicians to receive credit toward the Medicare Access and Children's Health Insurance Program incentives for partnering with hospitals to provide high-quality, cost-effective care and advance the goals of this model. We also appreciate that CMS proposed a non-advanced APM track aligned with MIPS.

REFERRAL TO PRIMARY CARE

TEAM participants would be required to provide a primary care referral as part of discharge planning. This would be required prior to discharge and in accordance with beneficiary choice requirements. Organizations that do not comply would be subject to remedial action. While many hospitals already provide such referrals, we urge CMS not to require this action and to remove penalties for non-compliance. This requirement fails to account for many hospital circumstances, such as those that may be in provider shortage areas, for example, and should not be mandated.

VOLUNTARY DECARBONIZATION AND RESILIENCE INITIATIVE

CMS proposes the creation of a voluntary Decarbonization and Resilience Initiative within TEAM comprised of technical assistance and voluntary reporting of scope 1 (direct emissions) and scope 2 (indirect emissions from purchased energy). CMS would potentially add scope 3 (other indirect greenhouse gas emissions) later in the model. Technical assistance would include developing approaches to enhance organizational sustainability, transitioning to care delivery methods that result in lower emissions and are clinically equivalent or better than previous methods, and identifying tools to measure emissions.

We appreciate CMS' focus on the important issue of climate change and its intersection with the U.S. health care sector. The AHA, in collaboration with the American Society for Health Care Engineering, a professional membership group of the AHA, has developed and made available several tools and resources aimed at improving sustainability. As an organization that represents nearly 5,000 hospitals and health systems, our members include a broad and diverse group of providers. While several of our members are far along in their sustainability efforts, some are in the infancy of their work in this space, while still others have yet to begin and are only starting to determine how to approach this issue.

Recognizing these differences from hospital to hospital, the AHA and its professional membership groups do not believe a "one-size-fits-all" approach is in the best interest of achieving this goal. For this reason, we urge CMS not to mandate participation in this initiative in future years of TEAM. Each hospital's needs and circumstances may dictate a different approach to this work, including resource availability, workforce expertise, state-level laws and regulations and other competing challenges. The top priority for our members is to provide high quality The Honorable Chiquita Brooks-LaSure June 10, 2024 Page 46 of 46

effective and efficient care to patients, which requires a thoughtful balancing of priorities and taking steps to ensure continuity of health services to their respective communities.