ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: August 8, 2022

RE: A&B Summary – Drug and Device Policies in the FY 2023 IPPS/LTCH PPS Final Rule

On August 1, 2022, Centers for Medicare & Medicaid Services (CMS) released a final rule entitled, *"Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) and Policy Changes and Fiscal Year 2023 Rates"* (final rule).[1] This memorandum summarizes the proposed and finalized changes related to new technology add-on payments (NTAPs) and other drug- and device-related policies. **The final rule is effective October 1, 2022.**

I. New Technology Add-on Payments (NTAPs)

CMS provides temporary additional payments for new, high-cost technologies in the inpatient setting above the standard MS-DRG payment amount for technologies that meet three criteria: (1) the medical service or technology must be new (the "newness criterion"); (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate (the "cost criterion"); and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies (the "substantial clinical improvement criterion"). In addition, as finalized in FY 2021, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient NTAP pathway—specifically, devices that are part of FDA's Breakthrough Devices Program, drugs designated by the FDA as a Qualified Infectious Disease Product (QIDP), and, beginning in FY 2022, a drug approved by the FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD). Under the alternative NTAP pathway, technologies are considered not substantially similar to an existing technology and are presumed to meet the substantial clinical improvement criterion.

For new technologies other than a QIDP or LPAD for which the cost of discharge exceeds the full DRG payment, Medicare provides an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For QIDPs and LPADs, the add-on payment is equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. The temporary add-on payment is typically granted for a period of no less than 2 years and no more than 3 years.

See **Appendix A** for a complete list of FY 2022 NTAPs and finalized status for FY 2023, and **Appendix B** for a complete list of new applications and final rule disposition for FY 2023 NTAPs.

[1] The final rule is available here: https://public-inspection.federalregister.gov/2022-16472.pdf

Comparison of NTAP Pathways under the IPPS				
	Traditional Pathway	Breakthrough Devices	Qualified Infectious Disease Product (QIDP)	Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD)
Deadline	Must have obtained FDA marketing authorization by July 1, 2021 for inclusion in FY 2023 payments		Can be provisionally approved if FDA marketing authorization not obtained by July 1, 2021 (for FY 2023)	
(1) Newness	Must prove newness by date **and** that it is not substantially similar to existing technology	Newness based only on date		
(2) Cost	Met if the charges of the cases involving the new technology will exceed a threshold amount that is the lesser of: • 75 percent of the standardized amount (increased to reflect the difference between cost and charges); or • 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS-DRG to which the new technology is assigned			
(3) Substantial Clinical Improvement	Must demonstrate	Presumed		
Resulting Add-on Payment	Lesser of: (1) 65% of device cost; or (2) 65% of case costs that exceed the standard DRG payment		Lesser of: (1) 75% of device cost; or (2) 75% of case costs that exceed the standard DRG payment	

a. Proposed FY 2023 Status of Technologies Approved for FY 2022 NTAPs

In general, CMS extends NTAPs for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming FY (i.e., on or after April 1). In FY 2022, CMS provided a one-year extension of NTAPs for 13 technologies for which the NTAP would otherwise be discontinued beginning in FY 2022 using its authority under section 1886(d)(5)(I) of the Social Security Act. CMS's rationale for this extension was that because the agency used FY 2019 MedPAR data instead of FY 2020 MedPAR data to develop FY 2022 MS-DRG relative weights, the costs for new technologies that would otherwise no longer receive NTAPs would not be fully reflected in the data used to recalibrate FY 2022 MS-DRG relative weights. CMS used 2019 MedPAR data for FY 2022 ratesetting because the agency determined that FY 2020 MedPAR data was not the best available data for ratesetting.

CMS believes the best available data for FY 2023 ratesetting is the FY 2021 MedPAR data. As such, CMS did not propose any further extensions of NTAPs for FY 2023. Specifically, CMS proposed to discontinue NTAPs for the 13 technologies that were provided a one-year extension of NTAP eligibility in FY 2022. The 11 technologies for which NTAPs expire at the end of FY 2022 (e.g., those that did not need a one-year extension in FY 2022 because their 3-year anniversary date falls in the latter half of FY 2022) would also no longer receive the add-on payment in FY 2023. Finally, 15 technologies currently eligible for NTAPs would continue to receive NTAPs in FY 2023 because their 3-year anniversary date falls on or after April 1, 2023. See **Appendix A** for a complete list of FY 2022 NTAPs and finalized status for FY 2023.

CMS sought comment on its proposals to discontinue NTAPs for the 13 technologies given a one-year NTAP extension in FY 2022 and the 11 technologies eligible for NTAPs in FY 2022 for which the 3-year anniversary date falls before April 1, 2023. CMS also sought comments on its proposal to continue NTAPs for the 15 technologies eligible for NTAPs in FY 2022 for which the 3-year anniversary date falls on or after April 1, 2023.

Final Rule: CMS finalized this proposal as proposed. In response to commenters that urged CMS to continue the one-year extension of NTAPs due to data distortions from the COVID-19 pandemic, including hospital staff shortages and financial instability, CMS said that technology is no longer considered "new" after 3 years, irrespective of how frequently the technology has been used in the Medicare population. CMS said it finalized a one-year extension in FY 2022 in light of the unique circumstances associated with ratesetting for FY 2022, referring to its decision to use FY 2019 data instead of FY 2020 data.

b. New Technology Liaisons

CMS has established a team of new technology liaisons to serve as an initial resource on coverage, coding, and payment processes for stakeholders, including device, biologic, and drug developers and manufacturers, industry consultants, and others. The intent of this team is to streamline stakeholder engagement by centralizing the different innovation pathways within CMS, including NTAPs. The new technology liaison team is available to assist with all of the following:

- Help to point stakeholders to or provide information and resources where possible regarding process, requirements, and timelines;
- Coordinate and facilitate opportunities for stakeholders to engage with various CMS components; and
- Serve as a primary point of contact for stakeholders and provide updates on developments where possible or appropriate.

The new technology liaison team can be contacted at MedicareInnovation@cms.hhs.gov.

c. Continued Status of New COVID-19 Treatments Add-on Payment (NCTAP)

In an interim final rule with comment period issued November 6, 2020,[2] CMS established the NCTAP under the IPPS for COVID-19 cases that meet certain criteria. The purpose of NCTAPs is to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID-19 treatments during the PHE. As such, effective for discharges occurring on or after November 2, 2020 and until the end of the COVID-19 PHE, CMS established the NCTAP to pay hospitals the lesser of: (1) 65 percent of the operating outlier threshold for the claim; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID-19. In the FY 2022 rulemaking cycle, CMS adjusted its policy to provide NCTAPs through the end of the FY in which the PHE ends.

[2] See 85 Fed. Reg. 71142 (Nov. 6, 2020) at 71157-58.

CMS proposed no changes to this policy, and thus continues its policy to continue NCTAP through the end of the FY in which the PHE ends.

d. Proposed Use of National Drug Codes (NDCs) to Identify Cases Using NTAPs Beginning FY 2024

Currently, CMS assigns Section "X" New Technology codes within the ICD-10-PCS classification to administer payments for drugs, biologics, and devices that are approved for NTAPs. CMS has received comments from stakeholders opposing the continued creation of new ICD-10-PCS procedure codes for NTAPs for drugs and biologics. Commenters explained that, since the implementation of ICD-19, Section X codes have been established for procedures describing the administration of a drug/therapeutic agent, which historically were not typically coded in the inpatient hospital setting. Commenters argued that it was not logical to expect hospital coding professionals to seek codes for the administration of drugs within the ICD-19-PCS classification system. Further, commenters argued that many Section X codes are created unnecessarily, because applicants must apply for Section X codes before they know whether the NTAP application is approved.

As such, CMS proposed to use NDCs rather than Section X codes to identify therapeutic agents eligible for NTAPs beginning in FY 2024. For FY 2023, CMS proposed a transition period where therapeutic agent NTAPs would be identified by using either NDCs or ICD-10-PCS procedure codes, in combination with ICD-10-CM codes when appropriate. Specifically, NTAPs approved before FY 2023 would continue to use ICD-10-PCS procedure codes to identify the administration of those therapeutic agents. NTAPs approved beginning in FY 2023 would be able to be identified by either code. NTAPs approved FY 2024 and later would only be identified by NDCs, with certain exceptions.

Certain products are not assigned NDCs, including blood products, and would continue to be identified based on the assigned ICD-10-PCS procedure code. Further, a unique ICD-10-PCS procedure code would also still be needed to identify cases involving the use of CAR T-cell and other immunotherapies that may be assigned to Pre-MDC MS-DRG 018, because the ICD-10 MS-DRG GROUPER logic for assignment to Pre-MDC MS-DRG 018 is comprised of the procedure codes describing these CAR T-cell and other immunotherapy products.

Final Rule: CMS did not finalize this proposal. CMS was persuaded by comments that this proposal would impose new administrative burdens on hospitals. CMS will reassess this policy proposal in future rulemaking to allow adequate time to evaluate and consider the issues raised by commenters.

e. Proposal to Publicly Post NTAP Applications Beginning FY 2024

Applicants hoping to obtain NTAPs for their new technology must submit a formal request, including a full description of the clinical applications of the technology and significant amounts of data to demonstrate substantial clinical improvement and satisfaction of the high-cost threshold. CMS posts brief descriptions of submitted applications so that interested parties can identify new technologies under review before the annual proposed rule. CMS also hosts an annual Town Hall meeting to obtain public input. In proposed rules, CMS summarizes the information contained in the application, including applicant assertions and supporting data, and tries to ensure that sufficient information is provided in the proposed rule to facilitate public comments on whether the

technology meets the NTAP criteria. Currently, however, CMS does not make the applications themselves publicly available.

CMS proposed to publicly post online future applications for NTAPs beginning with the FY 2024 application cycle. CMS would upload completed application forms and certain supporting materials, but would not post cost and volume information, nor any material included in the application that the applicant indicates is not releasable to the public because the applicant does not own the copyright or appropriate license to publish. CMS noted that applicants should not submit any proprietary or trade secret information they do not want published online, but noted that CMS generally does not consider such information when determining NTAP status.

Final Rule: CMS finalized this proposal with modification. Specifically, in response to commenter concerns, CMS will create a separate section or separate submission process for confidential information. CMS also clarified that it will publish the application information at the time the proposed rule is released, and no sooner.

II. Proposals Relating to CAR T-cell Therapy and Other Immunotherapies

CMS received comments from stakeholders recommending that the agency continue to assess the appropriateness of therapies assigned to Pre-MDC MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies). CMS noted that several diagnosis and procedure code proposals relating to CAR T-cell therapy and other immunotherapies were presented at the March ICD-10 Coordination and Maintenance Committee meeting, but that these proposals are not finalized in time to include in the proposed rule. CMS did not propose any changes to Pre-MDC MS-DRG 018 in the proposed rule, but noted that it will continue to evaluate if further modifications to Pre-MDC MS-DRG 018 are warranted as additional claims data become available. CMS included data from the September 2021 update of the FY 2021 MedPAR file for cases reporting the administration of CAR T-cell or other immunotherapy, as shown below:[3]

MS-DRG	ICD-10-PCS Code	Number of Cases	Average LOS	Average Costs	2ndy Dx
018	All cases	558	16.5	$194,717	185
	XW033C7 - Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7	50	13.2	$212,265	16
	XW033M7 - Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	11	14.1	$157,950	4
	XW033N7 - Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	4	11.3	$310,561	1
	XW043C7 - Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	435	16.7	$186,038	152
	XW043M7 - Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7	43	20.3	$264,932	7

[3] CMS did not include an updated table of data in the final rule.

	XW043N7 -Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7	15	14.2	$182,700	5
Note: ICD-10-PCS codes not included in this table did not have any claims data as of the September 2021 update of the FY 2021 MedPAR file.					

For FY 2023, CMS proposed to continue to apply a modification to its existing relative weight methodology to ensure that the relative weight for MS-DRG 018 appropriately reflects the relative resources required for providing CAR T-cell and non-CAR T-cell therapies and other immunotherapies outside of a clinical trial, while still accounting for the clinical trial cases in the overall average cost for all MS-DRGs. Specifically, CMS proposed to continue to use the proxy of standardized drug charges of less than $373,000, which was the average sales price of KYMRIAH and YESCARTA (the two CAR T-cell products in the FY 2021 MedPAR data), to identify clinical trial claims.

Based on the December 2021 update of the FY 2021 MedPAR file, CMS estimated that the average costs of cases assigned to MS-DRG 018 that are identified as clinical trial cases ($61,356) were 20 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as non-clinical trial cases ($299,460). Accordingly, CMS proposed to adjust the transfer-adjusted case count for MS-DRG 018 by applying the proposed adjustor of 0.20 to the applicable clinical trial and expanded access use immunotherapy cases, and to use this adjusted case count for MS-DRG 018 in calculating the national average cost per case, which is then used in the calculation of relative weights. CMS updated the value of the adjustor based on more recent data for the final rule.

Final Rule: Based on the March 2022 update of the FY 2021 MedPAR file, CMS estimated that the average cost of cases assigned to MS-DRG 018 that are identified as clinical trial cases ($61,540) were 21 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as non-clinical trial cases ($293,546). As such, CMS finalized its proposal to adjust the transfer-adjusted case count for MS-DRG 018 by applying the adjustor of 0.21 to the applicable clinical trial and expanded access use immunotherapy cases, and to use this adjusted case count for MS-DRG 018 in calculating the national average cost per case, which is then used in the calculation of relative weights.

Finally, several NTAP applications were submitted for CAR T-cell or other immunotherapies, including CARVYKTI (ciltacabtagene autoleucel), lifileucel, mosunetuzumab, and teclistamab. Of note, CMS seeks comments on CARVYKTI, and believes that it is substantially similar to ABECMA (a CAR T-cell therapy already on NTAP status).

Final Rule: CMS approved the CARVYKTI NTAP application, with a maximum NTAP of $289,532.75 for FY 2023. NTAP applications for lifileucel, mosunetuzumab, and teclistamab were withdrawn before publication of the final rule. See **Appendix B** for more information.

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We hope this summary was helpful to you. Please do not hesitate to reach out with any questions.

Appendix A: Status of FY 2022 NTAPs in FY 2023

Final FY 2023 NTAP Discontinuation of Technologies Approved for FY 2022 New Technology Add-On Payments (NTAP) *(** = received 1-year extension in FY 2022)*					
Technology	**Applicant**	**Newness Start Date**	**NTAP Start Date**	**3-year Anniversary Date of Entry onto US Market**	**Coding Used to Identify Cases Eligible for NTAP**
**Cablivi®	Sanofi	2/6/2019	10/1/2019	2/6/2022	XW013W5, XW033W5 and XW043W5
**Elzonris™	Stemline Therapeutics	12/21/2018	10/1/2019	12/31/2021	XW033Q5 and XW043Q5
**AndexXa™	Portola Pharmaceuticals, Inc.	5/3/2018	10/1/2018	5/3/2021	XW03372 or XW04372
**Spravato®	Johnson & Johnson o/b/o Janssen Oncology, Inc.	3/5/2019	10/1/2019	3/5/2022	XW097M5
**Zemdri®	Achaogen, Inc.	6/25/2018	10/1/2018	6/25/2021	XW033G4 and XW04G4
**T2 Bacteria® Panel	T2 Biosystems, Inc.	5/24/2018	10/1/2019	5/24/2021	XXE5XM5
**ContaCT	Viz.ai Inc.	10/1/2018	10/1/2020	10/1/2021	4A03X5D
**Eluvia™ Drug-Eluting Vascular Stent System	Boston Scientific	10/4/2018	10/1/2020	10/4/2021	X27H385, X27H395, X27H3B5, X27H3C5, X27J385, X27J395, X27J3B5, X27J3C5, X27K385, X27K395, X27K3B5, X27K3C5, X27L385, X27L395, X27L3B5, X27L3C5
**Hemospray®	Cook Medical	7/1/2018	10/1/2020	7/1/2021	XW0G886 and XW0H886
**IMFINZI®/ TECENTRIQ®	AstraZeneca PLC / Genentech, Inc.	3/18/2019	10/1/2020	3/18/2022	Imfinzi XW03336 or XW04336 Tecentriq XW033D6 or XW043D6
**NUZYRA®	Paratek Pharmaceuticals	2/1/2019	10/1/2020	2/1/2022	XW033B6 or XW043B6
**SpineJack® System	Stryker, Inc.	10/11/2018	10/1/2020	10/11/2021	XNU0356 and XNU4356
**Xospata®	Astellas Pharma U.S., Inc.	11/28/2018	10/1/2019	11/28/2021	XW0DXV5
Balversa™	Johnson & Johnson o/b/o Janssen Oncology, Inc.	4/12/2019	10/19/2019	4/12/2022	XW0DXL5
JAKAFI™	Incyte Corporation	5/24/2019	10/1/2019	5/24/2022	XW0DXT5
BAROSTIM NEO® System	CVRx	8/16/2019	10/1/2020	8/16/2022	0JH60MZ in combination with 03HK0MZ or 03HL0MZ
FETROJA® (Cefiderocol)	Shionogi & Co., Ltd	2/24/2020	10/1/2020	2/24/2023	XW03366 or XW04366
Optimizer® System	Impulse Dynamics	10/23/2019	10/23/2019	10/23/2022	0JH60AZ, 0JH63AZ, 0JH80AZ or 0JH83AZ
RECARBRIO™	Merck	1/6/2020	10/1/2020	1/6/2023	XW033U5 or XW043U5
Soliris®	Alexion	6/27/2019	10/1/2020	6/27/2022	XW033C6 and XW043C6
XENLETA™	Nabriva Therapeutics	9/10/2019	10/1/2020	9/10/2022	XW03366, XW04366 or XW0DX66
ZERBAXA®	Merck	6/3/2019	10/1/2020	6/3/2022	XW03396 or XW04396
Azedra	Progenics	5/21/2019	10/1/2019	5/21/2022	XW033S5 and XW043S5
EXALT Model D	Boston Scientific	12/13/2019	10/1/2021	12/13/2022	XFJB8A7 or XFJD8A7

Final FY 2023 Continuation of Technologies Approved for FY 2022 New Technology Add-On Payments (NTAP)						
Technology	**Applicant**	**Newness Start Date**	**NTAP Start Date**	**3-Year Anniversary Date of Entry onto US Market**	**Maximum NTAP Amount for FY 2023**	**Coding Used to Identify Cases Eligible for NTAP**
Rybrevant™	Johnson & Johnson	5/21/2021	10/1/2021	5/21/2024	$6,405.89	XW033B7 or XW043B7
Cosela™	G1 Therapeutics	2/12/2021	10/1/2021	2/12/2024	$5,526.30	XW03377 or XW04377
ABECMA®	Celgene Corporation	3/26/2021	10/1/2021	3/26/2024	$272,675	XW033K7 or XW043K7
StrataGraft®	Stratatech Corporation	6/15/2021	10/1/2021	6/15/2024	$44,200	XHRPXF7
TECARTUS®	Kite Pharma	7/4/2020	10/1/2021	7/4/2023	$259,350	XW033M7 or XW043M7
VEKLURY®	Gilead Sciences, Inc.	7/1/2020	10/1/2021	7/1/2023	$2,028	XW033E5 or XW043E5
Zepzelca™	Jazz Pharmaceuticals	6/15/2020	10/1/2021	6/15/2023	$8,622.90	XW03387 or XW04387
aprevo® Intervertebral Body Fusion Device	Carlsmed, Inc.	12/3/2020	10/1/2021	12/3/2023	$40,950	XRGA0R7 or XRGA3R7 or XRGA4R7 or XRGB0R7 or XRGB3R7 or XRGB4R7 or XRGC0R7 or XRGC3R7 or XRGC4R7 or XRGD0R7 or XRGD3R7 or XRGD4R7
aScope® Duodeno	Ambu, Inc.	7/17/2020	10/1/2021	7/17/2023	$1,715.59	XFJB8A7 or XFJD8A7
Caption Guidance™	Caption Health, Inc.	9/15/2020	10/1/2021	9/15/2023	$1,868.10	X2JAX47
Harmony™ Transcatheter Pulmonary Valve (TPV) System	Medtronic	3/26/2021	10/1/2021	3/26/2024	$26,975	02RH38M
Intercept® (PRCFC)	Cerus Corporation	5/5/2021	10/1/2021	5/5/2024	$2,535	30233D1 or 30243D1 in combination with one of the following D62, D65, D68.2, D68.4 or D68.9
ShockWave C2 Intravascular Lithotripsy (IVL) System	Shockwave Medical Inc.	2/12/2021	10/1/2021	2/12/2024	$3,666	02F03ZZ or 02F13ZZ or 02F23ZZ or 02F33ZZ
Fetroja® (HABP/VABP)	Shionogi & Co., Ltd	9/25/2020	10/1/2021	9/25/2023	$8,579.84	XW033A6 or XW043A6 in combination with ICD-10-CM code Y95 and one of the following: J14, J15.0, J15.1, J15.5, J15.6, J15.8, or J95.851 and one of the following: B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89
Recarbrio™ (HABP/VABP)	Merck & Co.	6/4/2020	10/1/2021	6/4/2023	$9,576.51	XW033U5 or XW043U5 in combination with ICD-10-CM code Y95 and one of the following: J14, J15.0, J15.1, J15.5, J15.6, J15.8, or J95.851 and one of the following: B96.1, B96.20, B96.21, B96.22, B96.23, B96.29, B96.3, B96.5, or B96.89

Appendix B: FY 2023 NTAP Applications

New Technology	*Applicant*	*Final Rule*	*Maximum NTAP*	*Coding Used to Identify Cases Eligible for NTAP*
Final FY 2023 NTAP Applications (Traditional Pathway)				
CARVYKTI (ciltacabtagene autoleucel)	Janssen Biotech	Approved	$289,532.75	XW033A7 or XW043A7
DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)	Janssen Biotech	Approved	$5,159.41	XW01318 in combination with E85.81
Hemolung Respiratory Assist System (Hemolung RAS)	ALung Technologies, Inc.	Approved	$6,500	5A0920Z
Lifileucel	Iovance Biotherapeutics	*Application withdrawn*		
LIVTENCITY™ (maribavir)	Takeda Pharmaceuticals	Approved	$32,500	XW0DX38, XW0G738, or XW0H738
Mosunetuzumab	Genentech	*Application withdrawn*		
Narsoplimab	The Omeros Corporation	*Application withdrawn*		
Spesolimab	Boehringer Ingelheim	*FDA approval or clearance not received by July 1, 2022*		
Teclistamab	Johnson & Johnson	*Application withdrawn*		
TERLIVAZ® for injection (terlipressin)	Mallinckrodt Pharmaceuticals	*Application withdrawn*		
Treosulfan	Medexus Pharma	*Application withdrawn*		
UPLIZNA® (inebilizumab-cdon)	HTI-DAC	Not approved	N/A	N/A
XENOVIEW (hyperpolarized Xenon-129 [$HP^{129}Xe$] gas for inhalation)	Polarean, Inc.	*Application withdrawn*		
Final FY 2023 NTAP Applications (Alternative Pathways)				
Alternative Pathway for Breakthrough Devices				
CERAMENT® G	BONESUPPORT AB	Approved	$4,918.55	XW0V0P7
GORE® TAG® Thoracic BranchEndoprosthesis (TBE device)	W.L. Gore and Associates, Inc.	Approved	$27,807	02VW3DZ with 02VX3EZ
iFuse Bedrock Granite Implant System	SI-BONE, Inc.	Approved	$15,120	XNH6058, XNH6358, XNH7058, XNH7358, XRGE058, XRGE358, XRGF058, or XRGF358
LigaPASS 2.0 PJK Prevention System	Medtronic	*Application withdrawn*		
Magnus Neuromodulation System with SAINT Technology	Magnus Medical, Inc.	*Application withdrawn*		
Nelli® Seizure Monitoring System	Neuro Event Labs, Inc.	*FDA approval or clearance not received by July 1, 2022*		
Phagenyx® System	Phagenesis Ltd.	*FDA approval or clearance not received by July 1, 2022*		
Precision TAVI™ Coronary Obstruction Module	DASI Simulations	*Application withdrawn*		
Thoraflex™ Hybrid Device	Terumo Aortic	Approved	$22,750	X2RX0N7 with X2VW0N7
TOPS™ System	Premia Spine, Inc.	*Application withdrawn*		
VITARIA® System	LivaNova, PLC	*Application withdrawn*		
ViviStim® Paired VNS System	MicroTransponder, Inc.	Approved	$23,400	X0HQ3R8
Alternative Pathway for Qualified Infectious Disease Products (QIDPs)				
DefenCath™ (solution of taurolidine (13.5 mg/mL) and heparin (1000 USP Units/mL))	CorMedix Inc.	Approved	$4,387.50	XY0YX28

ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: August 8, 2022

RE: A&B Summary – FY 2023 IPPS Final Rule: CMS Changes to the Hospital Wage Index

On August 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released a final rule entitled, *Medicare 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 2023 Rates; etc.*[1]

This memorandum summarizes the final policy changes relating to the Hospital Wage Index. **This final rule is effective October 1, 2022.**

I. Overview

The inpatient hospital wage index specifies how inpatient payment rates are adjusted to account for local differences in wages between hospital labor markets. The wage index measures differences in hospital wage rates across geographic regions and is updated annually based on wage data reported by hospitals. A labor market area's wage index value is the ratio of the area's average hourly wage to the national average hourly wage. The wage index adjustment factor is applied only to the labor portion of the inpatient payment rate.

CMS proposed a number of changes regarding the area wage index with the most significant being the continuation of the low wage index hospital policy and permanent cap on wage index increases. CMS also proposed changes regarding Federal Information Processing Standard (FIPS) code updates, application of the rural floor, and reclassification from urban to rural, among others.

II. Changes to the Hospital Wage Index for Acute Care Hospitals

a. Codes for Constituent Counties in Core-Based Statistical Areas (CBSAs)

The U.S. Census Bureau made updates to the FIPS codes for counties or county equivalent entities. As a result, CMS proposed to implement these FIPS code updates, effective October 1, 2022, beginning with the FY 2023 wage indexes. CMS proposed to use these update changes to calculate area wage indexes in a manner that is consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule (69 FR 49026 through 49034) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963). Tables 2 and 3 of the final rule reflect the latest FIPS code updates for FY 2023.

Final Rule: finalized as proposed.

b. Verification of Worksheet S–3 Wage Data

[1] Full text of the final rule can be found here: https://public-inspection.federalregister.gov/2022-16472.pdf

Consistent with the IPPS and LTCH PPS ratesetting, in general, CMS's wage index policy principles include using the most current data and information available which is typically data on a four-year lag (e.g., the FY 2022 wage indexes were based on data from cost reporting periods beginning during FY 2018). In the proposed rule, CMS noted that the overall impact of the COVID-19 public health emergency (PHE) on the FY 2019 wage data has been minimal and that changes in the wage data from FY 2018 to FY 2019 show similar trends in the change of the data from FY 2017 to FY 2018. As a result, CMS proposed to use the FY 2019 wage data for the FY 2023 wage index.

Final Rule: finalized as proposed.

c. Method for Computing the FY 2023 Unadjusted Wage Index

CMS did not propose changes to the methodology it used to compute the proposed FY 2023 wage index without an occupational mix adjustment. CMS also did not propose to make any changes to the usage of the employment cost index (ECI) for FY 2023. Based on the previous methodology in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58758 through 58761), CMS proposed the FY 2023 unadjusted national average hourly wage to be $47.77.

Final Rule: finalized as proposed; based on the described methodology, the final FY 2023 unadjusted national average hourly wage is $47.79.

d. Occupational Mix Adjustment to the FY 2023 Wage Index

For FY 2023, CMS proposed to calculate the occupational mix adjustment factor using the same methodology it has used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the proposed FY 2023 wage index. As a result of applying this methodology, CMS proposed the FY 2023 occupational mix adjusted national average hourly wage to be $47.71.

Final Rule: finalized as proposed; based on the described methodology, the final FY 2023 occupational mix adjusted national average hourly wage is $47.73.

e. Application of the Rural Floor

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), CMS removed urban to rural reclassifications from the calculation of the rural floor to prevent payment increases under the rural floor due to rural reclassifications. Beginning in FY 2020, the rural floor is calculated without including the wage data of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Social Security Act (the Act) (as implemented at 42 CFR 412.103). For FY 2023, CMS proposed to continue to calculate the rural floor without the wage data of hospitals that have reclassified as rural.

CMS noted that the FY 2020 rural floor policy and the related budget neutrality adjustment are the subject of pending litigation in *Citrus HMA, LLC, d/b/a Seven Rivers Regional Medical Center v. Becerra*, No. 1:20-cv-00707 (D.D.C.) (hereafter referred to as *Citrus*). On April 8, 2022, the district court in *Citrus* found that the Secretary of the Department of Health and Human Services (HHS) did not have authority under section 4410(a) of the Balanced Budget Act of 1997 to establish a rural floor lower than the rural wage index for a state. Although *Citrus* involves only FY 2020, the court's decision may impact the FY 2023 payment rates. CMS stated it will continue to evaluate the court's decision. Although CMS proposed for the rural floor wage index policy (and the related budget neutrality adjustment) to continue for FY 2023, CMS noted it may change its approach in the final rule, depending on public comments or developments in the court proceedings.

Pursuant to the proposed rule, CMS estimated that 192 hospitals would receive an increase in their FY 2023 proposed wage index.

CMS proposed to apply the imputed floor in accordance with the policies adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45164 through 45165). CMS did not propose any changes to the frontier floor policy. 44 hospitals in Montana, North Dakota, South Dakota, and Wyoming would receive the frontier floor value of 1.0000 for their FY 2023 proposed wage index.

Final Rule: CMS finalized a policy that calculates the rural floor as it was calculated before FY 2020. Specifically for FY 2023 and subsequent years, CMS finalized a policy to include the wage data of hospitals that have reclassified from urban to rural under the Act and have no additional form of reclassification (Medicare Geographic Classification Review Board or Lugar) in the calculation of the rural floor, and to include the wage data of such hospitals in the calculation of "the wage index for rural areas in the State in which the county is located". CMS estimates that 275 hospitals would receive an increase in their FY 2023 wage index due to the application of the rural floor.

f. Continuation of the Low Wage Index Hospital Policy; Budget Neutrality Adjustment

To offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, for FY 2023 and for subsequent FYs when the low wage index hospital policy is in effect, CMS proposed to apply a budget neutrality adjustment in the same manner as applied in FYs 2020, 2021, and 2022, as a uniform budget neutrality factor applied to the standardized amount. For FY 2023, the proposed 25th percentile wage index value is 0.8401.

In addition, CMS noted that the FY 2020 low wage index hospital policy and the related budget neutrality adjustment are the subject of pending litigation, including in *Bridgeport Hospital, et al., v. Becerra*, No. 1:20-cv-01574 (D.D.C.) (hereafter referred to as *Bridgeport*). On March 2, 2022, the district court found that the Secretary did not have authority under section 1886(d)(3)(E) or 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy and ordered additional briefing on the appropriate remedy. Although *Bridgeport* involves only the FY 2020 policy, the court's decision – which is not final at this time and is also subject to potential appeal – may impact the FY 2023 payment rates. CMS stated it will continue to evaluate the court's decision. Although CMS proposed for the low wage index hospital policy (and the related budget neutrality adjustment) to continue for FY 2023, CMS noted it may change its approach in the final rule, depending on public comments or developments in the court proceedings.

Final Rule: finalized as proposed; based on the data for the final rule, the 25th percentile wage index value is 0.8427.

g. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

To eliminate potential confusion about how to submit withdrawal, termination, or cancelation (reinstatement) requests to the Medicare Geographic Classification Review Board (MGCRB), CMS proposed to align the regulations at 42 CFR 412.273 for withdrawal, termination, or cancelation (reinstatement) requests with the regulations at 42 CFR 412.256 for new applications by specifying that withdrawal, termination, or cancelation (reinstatement) requests are required to be submitted to the MGCRB according to the method prescribed by the MGCRB.

CMS proposed to revise 42 CFR 412.273(d)(2) to establish that cancellation requests must be submitted in writing to the MGCRB in the method prescribed by the MGCRB no later than the deadline. CMS also proposed to revise 42 CFR 412.273(e) by adding that requests to withdraw an application or terminate an

approved reclassification are required to be submitted in writing to the MGCRB in the method prescribed by the MGCRB.

Final Rule: finalized as proposed.

h. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

For FY 2023, CMS proposed to continue to use its existing policies, procedures, and computations to determine the out-migration adjustments and applicable counties. These have been used since FY 2012. For FY 2016, CMS analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), utilizing 2008 through 2012 (5-year) Microdata. For FY 2023, CMS proposed that the out-migration adjustment will continue to be based on the data derived from the custom tabulation of the ACS utilizing the 2008 through 2012 Microdata. CMS stated that for future FYs, it may consider out-migration adjustments based on data from the next Census or other available data sources.

Final Rule: finalized as proposed. Table 2 includes the out-migration adjustments for the FY 2023 wage index.

i. Reclassification From Urban to Rural Under Section 1886(d)(8)(E) of the Act Implemented at 42 CFR 412.103

Under section 1886(d)(8)(E) of the Act, rural reclassification is only available to a hospital located in an urban area and meets the criteria specified in statute. As a result, a remote location in a rural area would not qualify for rural reclassification under section 1886(d)(8)(E) of the Act, as implemented under 42 CFR 412.103. CMS proposed to add 42 CFR 412.103(a)(8) to clarify that for a multicampus hospital, approved rural reclassification status is applicable to the main campus and any remote location in an urban area, including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act. CMS noted that the wage index implications of this policy are that a main campus or remote location with approved rural reclassification status would be assigned the rural wage index of its state (barring another form of wage index reclassification). For FY 2023, only one remote location would be assigned its state's rural wage index.

Final Rule: finalized as proposed.

j. Labor-Related Share for the FY 2023 Wage Index

The labor-related share is utilized to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. For FY 2023, CMS proposed to:

- Continue to utilize a labor-related share of 67.6 percent for discharges which occur on or after October 1, 2022;
- Apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000; and
- Apply the wage index to a proposed labor-related share of 67.6 percent of the national standardized amount for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are more than 1.000.

Final Rule: finalized as proposed.

k. Permanent Cap on Wage Index Decreases

i. Permanent Cap Policy for the Wage Index

CMS proposed a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. CMS proposed a policy that it believes increases the predictability of IPPS payments for hospitals and mitigates instability and substantial negative impacts to hospitals because of changes to the wage index. CMS believes the proposed permanent policy would eliminate the need for transition adjustments to the wage index in the future due to specific policy changes or circumstances outside hospitals' control. Under this proposal, a relatively large year-to-year decrease in the wage index value for an individual hospital would be phased in, which is intended to provide the hospital more time to plan and explore potential reclassification options, if applicable.

In addition, CMS believed a 5-percent cap on wage index decreases would be suitable for the IPPS in particular because year-to-year variation has historically been within 5 percent. For FY 2023 and subsequent years, CMS proposed to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the previous FY, regardless of the circumstances creating the decline. Specifically, CMS proposed that a hospital's wage index for FY 2023 would not be less than 95 percent of its final wage index for FY 2022, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the previous FY. If a hospital's prior FY wage index is calculated with the application of the 5-percent cap, the subsequent year's wage index would not be less than 95 percent of the hospital's capped wage index in the previous FY. CMS proposed to establish this proposal by via new paragraph at 42 CFR 412.64(h)(7).

CMS also proposed to apply the proposed wage index cap policy for a FY using the final wage index applicable to the hospital on the last day of the prior FY, except for newly opened hospitals. For newly opened hospitals, CMS proposed to apply the proposed wage index cap policy for a FY using the wage index value the hospital was assigned for the previous FY.

Final Rule: finalized as proposed.

ii. Permanent Cap Budget Neutrality

CMS proposed to implement the proposed wage index cap policy in a budget neutral manner through a national adjustment to the standardized amount each FY as CMS has implemented similar past transition policies involving a cap on wage index decreases (i.e., the FY 2021 IPPS/LTCH PPS final rule (85 FR 58755) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45164 through 45165)). Specifically, CMS proposed to apply a budget neutrality adjustment to ensure that approximated aggregate payments under the proposed wage index cap policy for hospitals that would have a decrease in their wage indexes for the upcoming FY of more than 5 percent would equal the approximated aggregate payments without the proposed wage index cap policy.

Final Rule: finalized as proposed.

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We hope this summary was helpful to you. Please do not hesitate to reach out with any questions.

ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: August 8, 2022

RE: A&B Summary – FY 2023 IPPS Final Rule: Provisions Relating to Data Reporting

On August 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released a final rule entitled, *Medicare 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 2023 Rates; etc.*[1]

This memorandum summarizes the final policy changes relating to data reporting. **This final rule is effective October 1, 2022.**

I. Key Medicare Data Reporting Policies

a. Changes Relating to Quality Data Reporting Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

i. Hospital-Harm—Opioid-Related Adverse Events eCQM (NQF #3501e) Beginning with the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

CMS proposed to adopt the Hospital Harm—Opioid-Related Adverse Events electronic clinical quality measure (eCQM) as part of the Hospital IQR Program for which hospitals can self-select beginning with the CY 2024 reporting period and the FY 2026 payment determination. This proposed eCQM is an outcome measure focusing specifically on opioid-related adverse events during an admission to an acute care hospital by assessing the administration of naloxone.

Final Rule: finalized as proposed.

ii. Global Malnutrition Composite Score eCQM (NQF #3592e) Beginning with the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

Currently, CMS quality reporting programs do not include quality measures that specifically address malnutrition. In response, CMS proposed to adopt the Global Malnutrition Composite Score eCQM beginning with the CY 2024 reporting period and the FY 2026 payment determination. The Global Malnutrition Composite Score eCQM assesses adults 65 years of age and older admitted to inpatient hospital service who received care appropriate to their level of malnutrition risk and malnutrition diagnosis, if properly identified. The proposed measure includes four component measures: (1) screening for malnutrition risk at admission; (2) completing a nutrition assessment for patients who screened for risk of

[1] Full text of the final rule can be found here: https://public-inspection.federalregister.gov/2022-16472.pdf

malnutrition; (3) appropriate documentation of malnutrition diagnosis in the patient's medical record if indicated by the assessment findings; and (4) development of a nutrition care plan for malnourished patients including the recommended treatment plan.

Final Rule: finalized as proposed.

iii. Hospital-Level, Risk Standardized Patient-Reported Outcomes Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #3559), Beginning with Two Voluntary Reporting Periods in CYs 2025 and 2026, Followed by Mandatory Reporting for Eligible Elective Procedures Occurring July 1, 2025 through June 30, 2026, Impacting the FY 2028 Payment Determination and for Subsequent Years

CMS proposed to adopt the Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA). This proposed measure would report the hospital-level risk-standardized improvement rate (RSIR) in patient reported outcomes following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older. CMS proposed to implement the Hospital-Level, Risk Standardized Patient-Reported Outcomes Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) with a phased approach, beginning with two voluntary reporting periods in CY 2025 and 2026 reporting periods prior to mandatory reporting beginning with the CY 2027 reporting period and the FY 2028 payment determination.

Final Rule: finalized as proposed.

iv. Medicare Spending Per Beneficiary (MSPB) Hospital Measure (NQF #2158) Beginning with the FY 2024 Payment Determination

CMS developed a prior version of the Medicare Spending Per Beneficiary (MSPB) Hospital Measure in 2012, which was removed from the Hospital IQR Program beginning with the FY 2020 payment determination. CMS proposed to keep the measure the same as the prior iteration except for an update to allow readmissions to trigger a new episode, a new indicator variable in the risk adjustment model, and an updated MSPB amount calculation methodology. CMS proposed to adopt the re-evaluated version of the MSPB Hospital measure in the Hospital IQR Program, beginning with the FY 2024 payment determination. This measure would allow CMS to assess hospitals' efficiency and resource use and meet statutory requirements for future adoption in the Hospital Value Based Payment (VBP) Program.

Final Rule: finalized as proposed.

v. Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure (NQF # 1550) Beginning with the FY 2024 Payment Determination

CMS proposed to adopt the re-evaluated form of the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure (the THA/TKA Complication measure) with an expanded measure outcome beginning in 2024. Since the measure was removed from the Hospital IQR Program in 2018, it has been revised to include 26 additional mechanical complication ICD-10 codes, which were identified during measure maintenance.

Final Rule: finalized as proposed.

vi. Refinement of the Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure (NQF #3474) Beginning with the FY 2024 Payment Determination and for Subsequent Years

CMS proposed to refine the Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective THA and/or TKA Measure (the THA/TKA Payment measure). In particular, CMS proposed to expand the measure outcome to include 26 clinically vetted mechanism complication ICD-10 codes. These 26 codes would increase the national observed complication rate, addressing the risk of missed complications. CMS proposed to adopt this refined measure beginning with the FY 2024 payment determination. Notably, the THA/TKA Payment measure was first adopted into the Hospital IQR Program beginning in the FY 2018 payment determination.

Final Rule: finalized as proposed.

vii. Refinement of the Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) Measure (NQF #2881) Beginning with the FY 2024 Payment Determination and for Subsequent Years

CMS proposed to refine the Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) measure, which was initially adopted in the Hospital IQR Program beginning with the FY 2018 payment determination. The EDAC AMI measure is intended to capture the quality-of-care transitions provided to discharged patients with AMI. The measure assesses the following adverse acute care outcomes that may occur post-discharge: (1) Emergency Department visits; (2) observation stays; and (3) unplanned readmissions at any time during the 30 days after discharge.

CMS proposed to increase the minimum case count for reporting in this measure. Specifically, CMS proposes to increase reporting requirements from 25 cases to 50 cases to include as many hospitals as possible while maintaining measure reliability. The increase is intended to improve the measure's reliability. CMS proposed to implement this increase beginning with the FY 2024 payment determination. CMS further proposes that hospitals with fewer than 50 cases would continue to receive confidential feedback reports containing measure results.

Final Rule: finalized as proposed.

b. Updates to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program: Changes to the Requirements

i. Adoption of a Patient Safety Exception to the Measure Removal Policy

CMS proposed that if continued use of a measure in the PCHQR Program raises specific patient safety concerns, CMS would be permitted to promptly remove the measure from the program without rulemaking and notify hospitals and the public of the removal of the measure, including reasons for the removal, through routine communication channels and with notice in the *Federal Register*.

Final Rule: finalized as proposed.

ii. Public Display of the End-of-Life (EOL) Measures

Under current regulation, CMS is required to establish procedures for making public the data submitted under the PCHQR Program. Specifically, CMS must report quality measures of process, structure, outcome,

patients' perspective on care, efficiency, and costs of care relating to services furnished by PPS-Exempt Cancer Hospitals (PCHs).

CMS proposed to begin public display of several End-of-Life (EOL) measures, specifically, the EOL-Chemo, EOL-Hospice, EOL-ICU, and EOL-3DH measures beginning with FY 2024 program year data. CMS adopted these measures for the PCHQR measure set beginning with FY 2020 program year data.

Final Rule: finalized as proposed with modification to begin public reporting beginning with FY 2025 program year data; public display will occur during the July 2024 refresh cycle or as soon as feasible thereafter. CMS will announce the exact timeframe on a CMS website and PCHQR Program listservs.

iii. Public Display of the 30-Day Unplanned Readmissions for Cancer Patients Measure Beginning with the FY 2024 Program Year Data

CMS proposed to begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measure beginning with FY 2024 program year data. CMS adopted this measure for the PCHQR measure set beginning with FY 2021 program year data.

Final Rule: finalized as proposed.

c. Changes to the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs

i. Changes to the Query of Prescription Drug Monitoring Program (PDMP) Measure and Related Policies

CMS adopted the Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing Objective. The measure is intended to support initiatives related to the treatment of opioid and substance use disorders by helping health care providers avoid inappropriate prescriptions, improving coordination of prescriptions among providers, and advancing the use of certified electronic health record technology (CEHRT).

Currently, the measure provides that for at least one Schedule II opioid electronically prescribed using CEHRT during the electronic health record (EHR) reporting period, the eligible hospital or CAH must use data from CEHRT to conduct a query of a PDMP for prescription drug history. Previous rulemaking finalized that the Query of PDMP measure is optional for hospitals and CAHs. In response to stakeholder concerns that it is premature for the Medicare Promoting Interoperability Program to require the Query of PDMP measure and score its performance, CMS notes that all 50 states and several localities host PDMPs.

CMS proposed to require the Query of PDMP measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program, beginning with the EHR reporting period in CY 2023. The measure is intended to expand the use of PDMPs and integrate them with health information technology systems. The measure further offers a way to reward health care providers participating in current PDMP initiatives supported by federal agencies. However, CMS proposed exclusions to this requirement for any eligible provider that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any such pharmacy, or any eligible provider that cannot report on this measure in accordance with applicable law.

CMS further proposed to change the Query of PDMP measure to include Schedules II, III, and IV drugs, as classified by the Drug Enforcement Administration (DEA). Expanding the requirements for this measure to include additional schedules of drugs is intended to further support initiatives; facilitate more informed

prescribing practices; and improve patient outcomes. CMS further proposed that the query of the PDMP for prescription drug history must occur prior to the electronic transmission of an electronic prescription for all Schedule II, III, or IV drugs. CMS invited public comment on these proposed changes and exclusions, as well as whether to include Schedule V or other drugs in this measure.

Final Rule: finalized as proposed with modification to include a third exclusion for the Query of PDMP measure for any eligible hospital or CAH for which querying a PDMP would impose an excessive workflow or cost burden prior to the start of the EHR reporting period they select in CY 2023; this exclusion will no longer be available for EHR reporting periods after CY 2023.

ii. Technical Update to the E-Prescribing Measure

The Office of the National Coordinator for Health Information Technology (ONC) *21st Century Cures Act* final rule retired the "drug-formulary and preferred drug list checks" certification criterion after January 1, 2022. CMS subsequently finalized that this criterion would no longer be associated with measures under the Electronic Prescribing Objective and would no longer be required for CEHRT. However, CMS inadvertently omitted technical revisions to the Medicare Promoting Interoperability Program that would have reflected this change. Thus, CMS proposed to revise descriptions to reflect this change.

Final Rule: finalized as proposed.

iii. Health Information Exchange (HIE): Addition of an Alternative Measure for Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

The Health Information Exchange (HIE) Objective currently includes three measures. CMS intended for these measures to reward providers for connecting with HIEs that enabled robust information sharing. TEFCA is intended to advance interoperability for the purpose of ensuring full network-to-network exchange of health information. In 2022, prospective Qualified Health Information Networks (QHINs) are anticipated to begin participating in exchange of health information under the Trusted Exchange Framework and Common Agreement (TEFCA).

CMS proposed to add a third reporting option through which an eligible hospital or CAH could earn credit for the HIE Objective by connecting to a QHIN or an entity connected to a QHIN. Specifically, CMS proposed to add the Enabling Exchange Under TEFCA measure, beginning with the EHR reporting period in CY 2023. This measure would also incentivize eligible hospitals and CAHs to exchange health information. CMS further proposed that the Enabling Exchange Under TEFCA measure would be worth the total amount of points available for the HIE Objective within its current scoring methodology. CMS also proposed that eligible hospitals and CAHs would report on this measure by attesting to certain criteria and use the capabilities of CEHRT.

Final Rule: finalized as proposed with modification to not finalize the proposal that this measure be calculated by reviewing only the actions for patients whose records are maintained using CEHRT as calculations are not necessary for this measure, which instead requires attestation to the specified statements.

iv. Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective: Antimicrobial Use and Resistance (AUR) Surveillance Measure

The Public Health and Clinical Data Exchange Objective includes six measures. Under current regulations, eligible hospitals and CAHs must report on four of the six measures: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. However, CMS aims to strengthen infection prevention and control and antibiotic stewardship by systematically collecting data on antimicrobial use and resistance (AUR) in robust systems, and currently, incomplete participation in NHSN's AUR surveillance limits the generalizability of AUR data.

CMS proposed to require an AUR measure under the Medicare Promoting Interoperability Program to develop an accurate national picture of the threat posed by antimicrobial overuse and resistance. Specifically, CMS proposed a new AUR Surveillance measure, in which the eligible hospital or CAH is actively engaging with the NHSN to submit AUR data. CMS proposed to require eligible hospitals and CAHs to report this measure beginning with the EHR reporting period in CY 2023. However, CMS also proposed three exclusions to this measure for eligible hospitals or CAHs that do not have any patients in any care location for which data are collected by NHSN; do not have certain electronic health records; or do not have an electronic laboratory information system or admission discharge transfer (ADT) system. Notably, CMS anticipates reevaluating the last two exclusions in future rulemaking. CMS further proposed that this measure must be calculated by reviewing all patient records.

Final Rule: finalized as proposed with modification that the AUR surveillance measure will be required beginning with the EHR reporting period in CY 2024.

v. Revisions to Active Engagement under the Public Health and Clinical Data Exchange Objective

CMS previously defined active engagement under the Public Health and Clinical Data Exchange Objective as when an eligible hospital or CAH is in the process of sending "production data" to a public health agency or clinical data registry. CMS also established three options for eligible hospitals and CAHs to demonstrate active engagement. CMS proposed to consolidate these options into two options to incentivize eligible hospitals and CAHs to move towards submitting production data. Specifically, CMS proposed to offer one option for Pre-Production and Validation of Production Data and one option for Validated Data Production.

Notably, eligible hospitals and CAHs currently are not required to report their level of engagement. CMS further proposed to require that eligible hospitals and CAHs report their level of active engagement for each measure they report, beginning with the EHR reporting period in CY 2023. To do so, eligible hospitals and CAHs must submit their level of active engagement, choosing from the proposed Pre-Production and Validation option or the Validated Data Production option, when they report each measure. CMS also proposed that eligible hospitals and CAHs may spend only one EHR reporting period of active engagement in the proposed Pre-Production and Validation of Production Data option; they must progress to the Validated Data Production option by the next EHR reporting period.

Final Rule: finalized as proposed.

vi. Changes to Scoring Methodology for the EHR Reporting Period in CY 2023

Currently, CMS has a performance-based scoring methodology for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. Under this methodology, eligible hospitals and CAHs must meet a minimum scoring threshold of 60 points to satisfy reporting requirements. Hospitals and CAHs may score up to 100 points by reporting required measures and additional bonus points by reporting optional measures.

In the proposed rule, various proposals impacted the scoring of the objectives and measures for the EHR reporting period for CY 2023. In particular, CMS proposed to require the Query of PDMP measure. In response, CMS proposed to adjust its scoring methodology to compensate for the impact of the proposal by reducing the points associated with the HIE Objective measures, beginning with the CY 2023 EHR reporting period. CMS also proposed to increase the points value for the Public Health and Clinical Data Exchange Objective to incentivize eligible hospitals and CAHs to engage in electronic reporting of public health information. CMS proposed implement this increase beginning with the CY 2023 EHR reporting period. Notably, this proposal is independent of CMS's proposal to add the AUR Surveillance measure. Additionally, to account for this proposed increase in points, CMS proposed to reduce the points associated with the Provide Patients Electronic Access to Their Health Information measure.

Final Rule: finalized as proposed.

vii. Public Reporting of Medicare Promoting Interoperability Program Data

Currently, CMS does not publicly report eligible hospitals and CAHs' data reporting scores for the Medicare Promoting Interoperability Program. CMS proposed to publicly post program scores for each eligible hospital or CAH, beginning with the EHR reporting period in CY 2023. As a first step, CMS proposed to publish this information on a publicly available CMS website. This proposal is intended to provide consumers with more information about their health care team and electronic access to health information. Notably, while CMS proposed only to report a total score at this time, CMS will evaluate the option of posting a hospital or CAH's individual measure scores in future rulemaking. CMS further proposed to provide eligible hospitals and CAHs an opportunity to review their data during a 30-day preview period before publication, in alignment with existing processes.

CMS requested public comment on these proposals. Specifically, CMS invited public comments that provide information on how these proposals might affect existing incentives and burdens under the Medicare Promoting Interoperability Program. CMS also invited public comment on which Medicare Promoting Interoperability Program data points to publish in future years, including specific objectives or measures.

Final Rule: finalized as proposed; CMS also finalized its proposal to post the Medicare Promoting Interoperability Program data using the Compare tool.

viii. Changes to Clinical Quality Measures in Alignment with the Hospital IQR Program

Eligible hospitals and CAHs must report on clinical quality measures using CEHRT, also referred to as eCQMs, under the Medicare Promoting Interoperability Program. CMS proposed to align the eCQM reporting requirements for the Medicare Promoting Interoperability Program with similar requirements under the Hospital IQR Program. Specifically, CMS proposed to adopt four new eCQMs for the Medicare Promoting Interoperability Program in alignment with the Hospital IQR Program: the Severe Obstetric Complications of eCQM; the Cesarean Birth eCQM; the Hospital-Harm—Opioid-Related Adverse Event eCQM; and the Global Malnutrition Composite Score eCQM. CMS further proposed to modify the eCQM reporting and submission requirements under the Medicare Promoting Interoperability Program beginning in the CY 2024 reporting period to align with its proposals for modifying the eCQM reporting and submission requirements under the Hospital IQR Program.

Final Rule: finalized as proposed.

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We hope this summary was helpful to you. Please do not hesitate to reach out with any questions.

ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: August 3, 2022

RE: A&B Summary – FY 2023 IPPS Final Rule: Provisions Relating to Indirect Medical Education (IME) and Direct Graduate Medical Education (DGME)

On August 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released a final rule entitled, Medicare 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 2023 Rates; etc.[1]

This memorandum summarizes proposed and finalized policy changes relating to indirect medical education (IME) and direct graduate medical education (DGME). **This rule is effective October 1, 2022.**

I. Overview

CMS made a number of proposals regarding indirect medical education (IME) and direct graduate medical education (DGME). The most significant proposed graduate medical education (GME) changes include the following: a modified policy that would cap a hospital's weighted full-time equivalent (FTE) count to its FTE cap in response to *Milton S. Hershey Medical Center, et al. v. Becerra* (Slip. Op., 2021 WL 1966572, May 17, 2021) (hereinafter *Hershey*); and allowing urban and rural hospitals participating in the same Rural Track Program (RTP) to enter into an RTP Medicare GME Affiliation Agreement effective for the academic year beginning July 1, 2023, in order to allow flexibility to share RTP cap slots.

II. Payment for Indirect and Direct Graduate Medical Education Costs

a. Litigation: *Milton S. Hershey Medical Center, et al. v. Becerra*

On May 17, 2021, the U.S. District Court for the District of Columbia (the "Court") ruled against CMS's method of calculating DGME payments to teaching hospitals when those hospitals' weighted FTE counts exceed their DGME FTE cap. In *Hershey*, the plaintiffs claimed the proportional reduction that CMS applied to the weighted FTE count when the weighted FTE count surpassed the FTE cap conflicted with the Medicare statute, and the agency's action was arbitrary and capricious under the Administrative Procedure Act. The Court held that the proportional reduction methodology inappropriately modified the weighting factors statutorily assigned to residents and fellows. Subsequently, the Court ordered CMS to recalculate the reimbursement owed pursuant to the statutory weighting factors. As described in the proposed rule, this recalculation would be more favorable to those hospitals with an FTE count that exceeds the cap.

In response to the court's decision, CMS proposed to establish a modified policy applicable to all teaching hospitals, retroactively effective as of October 1, 2001. CMS noted this would replace the existing policy at 42 CFR 413.79(c)(2)(iii). CMS noted that this retroactive proposal would cover cost reporting periods for which many Notice of Program Reimbursements (NPRs) have been settled. CMS is not aware of any

[1] Full text of the final rule can be found here: https://public-inspection.federalregister.gov/2022-16472.pdf

open or reopenable NPRs for the 1997-2001 period where the proportional reduction method created a provider's payments to be lower than they would be under its proposed new policy, but CMS welcomed comments notifying it of such NPRs.

Final Rule: Finalized as proposed.

i. Change to DGME Calculation in Response to Decision in Milton S. Hershey Medical Center et al. v. Becerra

CMS's proposed modified policy would address situations for applying the FTE cap when a hospital's weighted FTE count is more than its FTE cap but would not decrease the weighting factor of residents that are beyond their initial residency period (IRP) to an amount less than 0.5.

In addition, when a hospital's unweighted allopathic and osteopathic FTE count is more than its FTE cap, CMS proposed to add a step to compare the total weighted allopathic and osteopathic FTE count to the FTE cap. If the total weighted allopathic and osteopathic FTE count is equal to or less than the FTE cap, then no adjustments would be made to the respective primary care & obstetrics/gynecology (OB/GYN) weighted FTE counts or the other weighted FTE counts. If the total weighted allopathic and osteopathic FTE count is more than the FTE cap, then CMS would adjust the respective primary care & OB/GYN weighted FTE counts or the other weighted FTE counts to make the total weighted FTE count equal the FTE cap, as follows:

> ((primary care & OB/GYN weighted FTEs/total weighted FTEs) x FTE cap)) + ((other weighted FTEs/ total weighted FTEs) x FTE cap)). The sum would be the current year total allowable weighted FTE count, which would be recorded on Worksheet E-4, line 9, column 3.

CMS also proposed to edit the instructions to Worksheet E-4, line 9 to state:

> If line 6 is less than or equal to line 5, enter the amounts from line 8, columns 1 and 2, in columns 1 and 2, of this line. Otherwise, if the total weighted FTE count from line 8, column 3 is greater than the amount on line 5, then enter in column 1 the result of ((primary care & OBGYN weighted FTEs/total weighted FTEs) x FTE cap)). Enter in column 2 the result of ((other weighted FTEs/ total weighted FTEs) x FTE cap)). Enter in column 3 the sum of ((primary care & OBGYN weighted FTEs/total weighted FTEs) x FTE cap)) + ((other weighted FTEs/ total weighted FTEs) x FTE cap)).

Final Rule: CMS is finalizing the proposal but revising the instructions to Worksheet E-4, line 9 to address requests for more clarity from commenters. The instructions will now read:

> If the total weighted FTE count from line 8, column 3 is less than or equal to the amount on line 5, then enter the amounts from line 8, columns 1 and 2, in columns 1 and 2 of this line. Otherwise, if the total weighted FTE count from line 8, column 3 is greater than the amount on line 5, then enter in column 1 the result of ((primary care & OBGYN weighted FTEs/total weighted FTEs) x FTE cap)). Enter in column 2 the result of ((other weighted FTEs/ total weighted FTEs) x FTE cap)). Enter in column 3 the sum of columns 1 and 2.

Furthermore, CMS proposed to modify the cost report instructions on Worksheet E-4, lines 12 and 13. Under this proposal effective for cost reporting periods beginning on or after October 1, 2001, if the hospital

is subject to the cap in the prior year (line 12) or penultimate year (line 13), the instructions would include the following:

> If the prior/penultimate year total weighted FTE count from line 8, column 3 is greater than the amount on line 5 from the prior/penultimate year, then enter in column 1 the result of ((primary care & OBGYN weighted FTEs/total weighted FTEs) x FTE cap)). Enter in column 2 the result of ((other weighted FTEs/ total weighted FTEs) x FTE cap)) plus the amount on line 10, column 2.

Final Rule: CMS is finalizing the proposal but revising the instructions to Worksheet E-4, lines 12 and 13 in response to requests for more clarity from commenters. The instructions will now read:

> Effective for cost reporting periods beginning on or after October 1, 2001, if the prior/penultimate year total weighted FTE count from line 8, column 3 is less than or equal to line 5 from the prior/penultimate year, then enter the amounts from line 8, columns 1 and 2, in columns 1 and 2 of this line. If subject to the cap in the prior year or penultimate year respectively, if the prior/penultimate year total weighted FTE count from line 8, column 3 is greater than the amount on line 5 from the prior/penultimate year, then enter in column 1 the result of ((primary care & OBGYN weighted FTEs/total weighted FTEs) x FTE cap)). Enter in column 2 the result of ((other weighted FTEs/ total weighted FTEs) x FTE cap)) plus the amount on line 10, column 2.

CMS noted these instructions do not modify or reopen final-settled prior and penultimate year NPRs.

CMS proposed to amend 42 CFR 413.79(c)(2)(iii) to state the following:

> Effective for cost reporting periods beginning on or after October 1, 2001, if the hospital's unweighted number of FTE residents exceeds the limit, and the number of weighted FTE residents in accordance with § 413.79(b) also exceeds that limit, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the limit. If the number of FTE residents weighted in accordance with § 413.79(b) does not exceed that limit, then the allowable weighted FTE count is the actual weighted FTE count.

Final Rule: CMS is finalizing its proposal to amend 42 CFR 413.79(c)(2)(iii), while also applying the proposed payment methodology to the Medicare Modernization Act (MMA) section 422 FTE cap because the mathematical cap concept is the same for the 422 FTE cap as it is for the regular FTE cap.

b. Reasonable Cost Payment for Nursing and Allied Health Education Programs

CMS proposed the nursing and allied health (NAH) Medicare Advantage (MA) add-on rates and the DGME MA percent reductions for calendar years (CYs) 2020 and 2021. CMS believed it has sufficient Hospital Cost Report Information System (HCRIS) data to develop the rates for these years, and these rate years are most needed to ensure accurate and timely cost report settlements for those cost reports with parts overlapping with CYs 2020 and 2021. CMS expects to propose to issue the rates for CY 2022 in the fiscal year (FY) 2024 IPPS proposed rule, and the rates for CY 2023 in the FY 2025 IPPS proposed rule.

CMS proposed to use data from cost reports ending in FY 2018 HCRIS (the FY that is 2 years prior to the calendar year of 2020) to compile the following national amounts: NAH pass-through payment, Part A

Inpatient Days, and MA Inpatient Days. CMS proposed to utilize data from cost reports ending in FY 2019 HCRIS (the FY that is 2 years prior to the calendar year of 2021) to collect the same national amounts for CY 2021. However, to calculate the "pool" and the DGME MA percent reduction, CMS "project[s]" Part A DGME payments and MA DGME payments for the current calendar years, which in this proposed rule, are CYs 2020 and 2021, based on the "best available cost report data from the HCRIS" (65 FR 47038). In addition, CMS increases the payment amounts from midpoint to midpoint of the appropriate CY using the increases allowed by section 1886(h) of the Social Security Act (the Act) for these services (using the percentage applicable for the current calendar year for MA DGME, and the Consumer Price Index - Urban (CPI-U) increases for Part A DGME. For both CY 2020 and CY 2021, the DGME projections are based on FY 2019 HCRIS. The proposed national rates and percentages for CYs 2020 and 2021, and their data sources listed in the table below. CMS intends to update these numbers in the FY 2023 final rule based on the most recent cost report data.

	CY 2020	**SOURCE**	**CY 2021**	**SOURCE**
NAH Pass-Through	$272,775,476	Cost reports ending in FY 2018 HCRIS	$277,240,471	Cost reports ending in FY 2019 HCRIS
Part A Inpatient Days	64,510,859	Cost reports ending in FY 2018 HCRIS	66,521,096	Cost reports ending in FY 2019 HCRIS
MA Inpatient Days	9,481,755	Cost reports ending in FY 2018 HCRIS	10,705,665	Cost reports ending in FY 2019 HCRIS
Part A Direct GME	$2,770,987,049	CY 2019 HCRIS + CPI-U	$2,749,561,756	CY 2019 HCRIS + CPI-U
MA Direct GME	$1,617,557,770	CY 2019 HCRIS + CPI-U	$1,862,798,849	CY 2019 HCRIS + CPI-U
Pool (not to exceed $60 million)	$60,000,000	((Part A DGME/MA DGME) * (NAH Pass-through))	$60,000,000	((Part A DGME/MA DGME) * (NAH Pass-through))
Percent Reduction to MA DGME Payments	3.71%	(Pool/MA direct GME)	3.22%	(Pool/MA direct GME)

Final Rule: All provisions finalized as proposed.

c. Allowance of Medicare GME Affiliation Agreements Within Certain Rural Track FTE Limitations

CMS proposed to permit urban and rural hospitals that participate in the same separately accredited 1-2 family medicine RTP and have Rural Track FTE limitations to enter into "Rural Track Medicare GME Affiliation Agreements."[2] CMS proposed that programs that are not separately accredited in the 1-2 format and are not in family medicine would not be permitted to enter into "Rural Track Medicare GME Affiliation Agreements."

CMS noted the Rural Track Medicare GME Affiliation Agreements will be structured similarly to Medicare GME Affiliation Agreements, but CMS highlighted two proposed distinct requirements. First, CMS proposed that the responsible representatives of each urban and rural hospital entering into the Rural Track Medicare GME Affiliation Agreement must affirm in the written agreement that each participating hospital's FTE counts and Rural Track FTE limitations in the agreement do not reflect FTE residents nor

[2] Historically, the Accreditation Council for Graduate Medical Education (ACGME) has separately accredited family medicine programs in the "1-2 format" (i.e., residents receive their first year experience at a core family medicine program, and their second and third year experiences at another site, which may or may not be rural).

FTE caps associated with programs other than the RTP. Second, CMS proposed to only permit urban and rural hospitals to participate in the Rural Track Medicare GME Affiliation Group if they are separately accredited 1-2 family medicine programs that have Rural Track FTE limitations in place before October 1, 2022.

Final Rule: Finalized as proposed.

CMS proposed the following new definitions at 42 CFR 413.75(b) and requirements:

- Rural Track Medicare GME affiliated group is an urban hospital and a rural hospital that participate in a RTP defined in 42 CFR 413.75(b), and that have Rural Track FTE limitations in effect prior to October 1, 2022, and that comply with 42 CFR 413.79(f)(1) through (6) for Medicare GME affiliated groups.
- Rural Track Medicare GME Affiliation Agreement is a written, signed, and dated agreement by responsible representatives of each respective hospital in a Rural Track Medicare GME affiliated group, as defined in 42 CFR 413.75(b), that specifies:
    - A statement attesting that each participating hospital's FTE counts and Rural Track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the RTP;
    - The term of the Rural Track Medicare GME Affiliation Agreement (which, at a minimum is 1 year), beginning on July 1 of a year;
    - Each participating hospital's DGME and IME Rural Track FTE limitations in effect prior to the Rural Track Medicare GME Affiliation Agreement;
    - The total adjustment to each hospital's Rural Track FTE limitations in each year that the Rural Track Medicare GME Affiliation Agreement is in effect, for both DGME and IME, that reflects a positive adjustment to one hospital's direct and indirect Rural Track FTE limitations that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect Rural Track FTE limitations of at least the same amount;
    - The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the Rural Track Medicare GME affiliated group for each year the Medicare GME Affiliation Agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's Rural Track FTE limitations (in accordance with the third bullet in this list); and
    - The names of the participating hospitals and their Medicare provider numbers.

Final Rule: Finalized as proposed.

CMS proposed to require that no later than July 1 of the residency year during which the Rural Track Medicare GME Affiliation Agreement will be in effect, the urban and rural hospital must submit the signed agreement to the CMS contractor or Medicare Administrative Contractor (MAC) servicing the hospital and send a copy to the CMS Central Office. The hospitals may submit amendments to the adjustments to their respective Rural Track FTE limitations to the MAC with a copy to CMS by June 30 of the residency year that the agreement is in effect. CMS also proposed that eligible urban and rural hospitals may enter into Rural Track Medicare GME Affiliation Agreements effective with the July 1, 2023, academic year.

Final Rule: Finalized as proposed.

III. IME Payment Adjustment Factor

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved GME program to reflect the higher indirect patient care costs of teaching hospitals compared to nonteaching hospitals. The payment amount is determined by a statutorily specified adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Thus, for discharges occurring during FY 2023, the formula multiplier is 1.35. CMS estimates that application of this formula multiplier for the FY 2023 IME adjustment will produce an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

Final Rule: CMS made no changes to the IME formula multiplier.

* * *

We hope this summary was helpful to you. Please do not hesitate to reach out with any questions.

ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: August 8, 2022

RE: A&B Summary – FY 2023 IPPS Final Rule: Provisions Relating to Maternal Health and Health Equity

On August 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released a final rule entitled, *Medicare 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 2023 Rates; etc.*[1]

This memorandum summarizes the final policy changes relating to maternal health and health equity. **This final rule is effective October 1, 2022.**

I. Key Medicare Maternal Health Policies

a. Background on Medicare Maternal Health Policies

Maternal mortality and morbidity in the U.S. are disproportionately high compared to other developed countries and continues to rise; further, data indicate significant racial and ethnic disparities in maternal health care and outcomes. In December 2020, the Department of Health and Human Services (HHS) released its Maternal Action Plan entitled, *Healthy Women, Healthy Pregnancies, Healthy Futures: Action Plan to Improve Maternal Health in America.*[2] As set forth in the Maternal Action Plan and summarized in the IPPS proposed rule, HHS aims to reduce maternal mortality and related disparities over the next five years; reduce severe maternal morbidity (SMM), or unexpected outcomes due to complications at labor and delivery that result in significant consequences to a woman's health, including hemorrhage, embolism, severe hypertension, stroke, and other serious complications; and increase hospital participation in HHS-sponsored maternal health quality improvement initiatives. Additionally, the Maternal Action Plan set a specific target of reducing low-risk C-sections by 25 percent over the next five years. CMS emphasized that a critical focus of its maternal health efforts is reducing existing disparities in maternal health outcomes across race, ethnicity, and geography.

Currently, CMS's Hospital Inpatient Quality Reporting (IQR) Program includes the Elective Delivery measure and the Maternal Morbidity Structural measure, which neither directly address factors contributing to maternal mortality, such as the high rates of Cesarean sections (C-sections) in the U.S. CMS believes adopting measures such as the Cesarean Birth Electronic Clinical Quality Measures (eCQM) can address such factors for large-scale quality measurement and activities that can improve short- and long-term health outcomes for mothers and children.

b. Adoption of Cesarean Birth and Severe Obstetric Complications eCQMs

[1] Full text of the final rule can be found here: https://public-inspection.federalregister.gov/2022-16472.pdf
[2] Full Maternal Action Plan can be found here: https://aspe.hhs.gov/sites/default/files/private/aspe-files/264076/healthy-women-healthy-pregnancies-healthy-future-action-plan_0.pdf

i. Cesarean Birth eCQM Beginning with the CY 2023 Reporting Period/FY 2025 Payment Determination with Mandatory Reporting Beginning with the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

CMS proposed to adopt the Cesarean Birth eCQM as one of the eCQMs in the Hospital IQR Program measure set, to be available for hospitals to select for reporting beginning in the Calendar Year (CY) 2023 reporting period and the FY 2025 payment determination. CMS further proposed to mandate reporting of the Cesarean Birth eCQM beginning in the CY 2024 reporting period and the FY 2026 payment determination, except for hospitals without an obstetrics department that do not perform deliveries.

The Cesarean Birth eCQM is intended to facilitate safer patient care by ultimately reducing the number of non-medically indicated C-sections. It also aims to promote adherence to clinical guidelines and improve hospitals' practices for monitoring and care delivery for pregnant and postpartum patients. Overall, this eCQM is intended to further the goal of improving maternal health outcomes in the Hospital IQR program.

Final Rule: finalized as proposed.

ii. Severe Obstetric Complications eCQM Beginning with the CY 2023 Reporting Period/FY 2025 Payment Determination with Mandatory Reporting Beginning with the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

CMS proposed to adopt the Severe Obstetric Complications eCQM as one of the eCQMs in the Hospital IQR Program measure set, to be available for hospitals to select for reporting beginning in the Calendar Year (CY) 2023 reporting period and the FY 2025 payment determination. CMS further proposed to mandate reporting of the Severe Obstetric Complications eCQM beginning in the CY 2024 reporting period and the FY 2026 payment determination, except for hospitals that do not perform deliveries or do not have an obstetrics department.

The Severe Obstetric Complications eCQM is intended to address high maternal morbidity and mortality rates in the U.S. This measure is intended to report two outcomes: (1) Severe obstetric complications; and (2) severe obstetric complications. In particular, this eCQM is intended to facilitate safer patient care by increasing awareness of the risks of obstetric complications; improving adherence to clinical guidelines; and encouraging hospitals' practices for appropriate monitoring and care delivery for pregnant and postpartum patients.

Final Rule: finalized as proposed.

c. Final Modifications to eCQM Reporting and Submission Requirements to Include the Cesarean Birth and Severe Obstetric Complications eCQMs

CMS proposed to modify the Hospital IQR Program reporting and submission requirements for eCQMs, beginning in the CY 2024 reporting period and FY 2026 payment determination, to include mandatory reporting of the Cesarean Birth eCQM and the Severe Obstetric Complications eCQM, if finalized. This modification would establish that hospitals must report four calendar quarters of data for each required eCQM: (1) three self-selected eCQMs; (2) the Safe Use of Opioids—Concurrent Prescribing eCQM; (3) the proposed Cesarean Birth eCQM; and (4) the proposed Severe Obstetric Complications eCQM. Overall, this modification would increase eCQM reporting requirements from four to six required eCQMs. This modification is intended to address maternal health and reduce health disparities related to maternal health.

Final Rule: finalized as proposed.

d. Establishment of a Publicly Reported Hospital Designation to Capture the Quality and Safety of Maternity Care

In the FY 2022 IPPS/LTCH PPS final rule, the Hospital IQR Program adopted the Maternal Morbidity Structural measure, designed to assess whether hospitals are: (1) participating in a state or national Perinatal Quality Improvement (QI) Collaborative; and (2) implementing patient safety practices or bundles as part of these QI initiatives.

CMS proposed to establish a maternity care quality hospital designation, which would be publicly reported on CMS's website beginning in Fall 2023. CMS proposed to initially give this designation to hospitals that meet both criteria under the Maternal Morbidity Structural Measure and are currently reporting on the Maternal Morbidity Structural measure in the Hospital IQR Program. Through future rulemaking, CMS intends to expand the designation eligibility components into a more robust scoring methodology that may include other maternal health-related measures as appropriate for the Hospital IQR Program Measure data set, such the Cesarean Birth and Severe Obstetric Complications eCQMs or future maternal health measures adopted in the Hospital IQR Program. CMS also requested public comment on the designation name and additional data sources to consider for awarding this designation.

Final Rule: finalized as proposed; CMS will take comments into consideration for a future name for the designation.

e. Request for Information to Advance Maternal Health Equity

CMS sought to understand how to address the U.S. maternal health crisis through policies and programs to advance equity for all. Specifically, CMS sought to explore how to leverage its Conditions of Participation (CoPs), or the health and safety standards that certified providers and suppliers must meet to receive payment from Medicare and Medicaid. CMS also sought to explore how to improve measures in CMS quality reporting programs to address maternal health inequities. Specifically, CMS requested stakeholders respond to several questions as part of the Request for Information.

Final Rule: CMS thanked stakeholders for their many comments on programs and practices to improve maternity care, recommendations, and measure suggestions. CMS will consider the input as the agency develops the Hospital IQR Program, through potential new conditions of participation (CoPs), and other CMs activities.

II. Additional Medicare Policies to Broadly Advance Health Equity

a. Background of Medicare Policies on Advancing Health Equity

CMS states that it is re-envisioning health care quality and patient safety through a health equity lens. CMS intends to advance health equity by designing, implementing, and operationalizing policies and programs that improve health for all patients served by CMS. Specifically, CMS recognizes the significant impact of social determinants of health (SDOH) on health, functioning, and quality-of-life outcomes and risks. CMS states that SDOH can contribute to health disparities and inequities and are important potential predictors of risk for developing certain medical conditions.

b. Health Equity-Focused Measures in the Hospital IQR Program

i. Hospital Commitment to Health Equity Measure Beginning with the CY 2023 Reporting Period/FY 2025 Payment Determination and for Subsequent Years

CMS identifies hospital leadership as an important factor in promoting better quality care, improved patient outcomes, increased safety, and positive patient experience. CMS proposed to mandate reporting of the Hospital Commitment to Health Equity measure beginning in the CY 2023 reporting period and the FY 2025 payment determination. The measure would assess hospitals' commitment to establishing a culture of equity and delivering more equitable health care. To do so, the measure evaluates hospitals' activities across five key domains: strategic planning that prioritizes equity; improved data collection; effective data analysis; quality improvement efforts; and leadership engagement on fostering a culture of equity. Hospitals would need to attest to their activities in each of these domains.

Final Rule: finalized as proposed.

ii. Adoption of Two Social Drivers of Health Measures Beginning with Voluntary Reporting in the CY 2023 Reporting Period and Mandatory Reporting Beginning with the CY 2024 Reporting Period/FY 2026 Payment Determination and for Subsequent Years

CMS identifies health-related social needs (HRSNs), or individual-level, adverse social conditions that negatively impact an individual's health or health care, as significant risk factors associated with worse health. To screen for HSRNs, CMS proposed reporting on two measures: the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure. Both measures aim to identify specific risk factors for inadequate health care access and adverse health outcomes and encourage systematic collection of HRSN data. In particular, these measures would screen and identify HSRNs of food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

The proposed Screening for Social Drivers of Health measure aims to identify patients with HRSNs. To do so, this measure would evaluate the percent of patients, age 18 or older, who are admitted to the hospital and screened for HSRNs. This measure would assess the quality of care furnished by hospitals in inpatient settings, as well as allow health care providers to identify and potentially help address HRSNs during discharge planning to improve patient outcomes in the long term.

The proposed Screen Positive Rate for Social Drivers of Health structural measure would estimate the impact of individual-level HRSNs on an individual's health care utilization, including hospitalizations, to evaluate quality of care. To do so, this measure would capture the percent of patients, age 18 or older, who screen positive for one or more HRSN. This measure is intended to track the prevalence of each HRSN among patients help hospitals close health equity gaps and develop personalized patient action plans for care, as well as improve data transparency.

CMS states that reporting data from both measures will quantify the levels of HRSNs in communities and provide greater insight into the relationship between HRSNs and health status, health care utilization, and quality of care. CMS proposed voluntary reporting of these measures in the CY 2023 reporting period and mandatory reporting beginning in the CY 2024 reporting period and FY 2026 payment determination.

Final Rule: finalized as proposed.

c. Supplemental Payment for Indian Health Service, Tribal Hospitals, and Puerto Rico Hospitals for FY 2023 and Subsequent Fiscal Years

Currently, Medicare disproportionate share hospitals (DSHs) receive Medicare DSH payments for providing uncompensated care for uninsured individuals. These payments are calculated using data across several measures. In the proposed rule, CMS proposed to modify its methodology in calculating DSH and uncompensated care payments. Notably, CMS proposed to discontinue the use of low-income insured days as a proxy for uncompensated care costs in determining DSH payments for IHS, Tribal, and Puerto Rico

hospitals. CMS recognizes that the Indian Health Services (IHS), Tribal, and Puerto Rico hospitals face unique challenges related to uncompensated care due to structural differences in health care delivery and financing.

In response, CMS proposed to establish a new permanent supplemental payment for these hospitals beginning in FY 2023. This payment would be determined based on the difference between the new uncompensated care payment amount using CMS's new DSH calculation methodology and an estimate of the previous uncompensated care payment amount using proxy data. CMS also proposed to align the new supplemental payment's eligibility and payment processes with existing uncompensated care payment processes.

This supplemental payment would not affect CMS's existing DSH payment or uncompensated care payment methodologies. Additionally, if a hospital is not DSH eligible for a fiscal year, then that hospital is also not eligible for a supplemental payment. Hospitals that do not have FY 2022 proxy data or are new to the Medicare program would also not be eligible for the supplemental payment.

Final Rule: CMS finalized its proposals to discontinue the use of the low-income insured days proxy, to establish a new supplemental payment, and to establish § 412.106(h) governing the new supplemental payment, without modification.

Final Rule: The percent change between the final FY 2023 uncompensated care amount and final FY2022 uncompensated care amount is negative 4.4 percent (calculated as the difference between the final FY 2023 uncompensated care amount of approximately $6.874 billion and the final FY 2022 uncompensated care amount of approximately $7.192 billion, divided by the final FY 2022 uncompensated care amount). Consistent with this methodology, CMS will calculate each hospital's base year amount for FY 2023 by multiplying its FY 2022 uncompensated care amount by 0.956 (1-0.044).

i. LTCH QRP Quality Measure Concepts under Consideration for Future Years: Request for Information (RFI) Included in the FY 2023 IPPS/LTCH PPS Proposed Rule

CMS is interested in developing measures of health equity that reflect an organization's performance in the LTCH Quality Reporting Program (QRP). CMS has developed measures to assess or promote health equity in other programs, and CMS proposed that some measures could be adapted for use in the LTCH QRP. In particular, CMS proposed to adapt the Health Equity Summary Score (HESS) measure and the proposed Hospital Commitment to Health Equity measure for the LTCH QRP. The HESS measure aims to identify and reward health care providers that demonstrate good performance in providing care to beneficiaries with social risk factors. The measure also aims to discourage providers from not treating potentially high-risk patients. The measure summarizes equity of care delivery by assessing performance and improvement across multiple measures and multiple at-risk patient populations. The proposed Hospital Commitment to Health Equity measure assesses hospitals' commitment to health equity across various measures.

Final Rule: CMS intends to use the input in future measure development efforts.

d. Request for Information on Reporting Social Determinants of Diagnosis Codes

CMS sought to better understand how hospitals' reporting of SDOH-related diagnosis codes in Medicare claims may improve CMS's ability to evaluate the severity or complexity of illness or the utilization of resources under the Medicare Severity Diagnosis Related Groups (MS-DRGs). CMS specifically sought feedback on how to improve the documentation and reporting of diagnosis codes detailing a patient's social and economic circumstances, as well as on how to increase the reliability and validity of the code data. CMS states that reporting SDOH codes in inpatient claims data could enhance quality improvement

activities; monitor factors that impact health; and increase insight into existing health inequities. This data could also help CMS develop policies to address health equity.

In particular, CMS requested stakeholders respond to a series of specific questions. CMS intends to use the feedback in designing future payment policies. Specifically, CMS asked whether it should consider requiring more robust documentation and claims data reporting of SDOH. CMS also requested comment on developing protocols to standardize SDOH screening for all patients and consistently documenting and reporting SDOH, as well as whether these protocols should vary by hospital size and type. CMS further sought comment on which SDOH codes are most likely to increase hospital inpatient care resource utilization. In particular, CMS proposed understanding the impact of homelessness on health.

Final Rule: Overall, commenters agreed that better reporting of SDOH Z codes through inpatient claims could enhance coordination within hospitals across clinical care teams and discharge planning, and with post-acute care providers. Commenters worried about the burden on facilities and providers as well as the operational and technology impacts. Commenters also noted there is a lack of standard, nationally accepted definitions of the SDOH Z codes and potential gaps that may come with their use and reporting. Commenters recommended CMS provide incentives for documenting and reporting SDOH Z codes and assess other Z codes (e.g., food insecurity, extreme poverty, and lack of transportation). Commentors also expressed concern that patients may be hesitant to provide such data and that SDOH diagnoses should generally have limited impact on severity of illness. Many commenters stated that the most immediate and important action CMS could take to increase the use of SDOH Z codes is to finalize the evidence-based "Screening for Social Drivers of Health" and "Screen Positive Rate for Social Drivers of Health" measures for the Hospital Inpatient Quality Reporting (IQR) Program

CMS said it will take the commenters' feedback into consideration in future policy development

* * *

We hope this summary was helpful to you. Please do not hesitate to reach out with any questions.

ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: August 4, 2022

RE: A&B Summary – FY 2023 IPPS Proposed Rule: Selected Provisions

On August 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released a final rule entitled, Medicare 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 2023 Rates; etc.[1]

This memorandum summarizes the proposed and finalized policy changes relating to the following:

1. Hospital Value-Based Purchasing (VBP) Program;
2. Hospital-Acquired Condition (HAC) Reduction Program;
3. Hospital Readmissions Reduction Program;
4. Medicare data reporting policies; and
5. Medicare conditions of participation policies.

This rule is effective October 1, 2022.

[1] Full text of the final rule can be found here: https://public-inspection.federalregister.gov/2022-16472.pdf

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I. Key Hospital Value-Based Purchasing (VBP) Program Policies

a. Overview of Policy Changes to the Hospital Value-Based Purchasing (VBP) Program

CMS made a number of proposals to the Hospital Value-Based Purchasing (VBP) Program for fiscal year (FY) 2023. The most significant changes included the following: (1) suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) and five Hospital Acquired Infection (HAI) measures for the FY 2023 program year; (2) update the baseline periods for certain measures for the FY 2025 program year; and (3) revise the scoring and payment methodology for the FY 2023 program year such that hospitals will not receive a Total Performance Score (TPS), rather, CMS would award each hospital a payment incentive multiplier that results in a payment equal to the amount withheld for the FY (two percent).

b. Flexibilities for the Hospital VBP Program in Response to the Public Health Emergency (PHE) Due to COVID-19

i. Measure Suppression Policy for the Duration of the COVID-19 PHE

Since publishing the FY 2022 IPPS/LTCH PPS final rule, CMS has conducted analyses on all Hospital VBP Program measures to determine whether and how COVID-19 has impacted the validity of the data used to calculate the measures for the FY 2023 program year. Based on the analyses, CMS proposed to suppress the following measures for the FY 2023 program year:

- Hospital Consumer Assessment of HCAHPS (NQF #0166)
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
- NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
- American College of Surgeons- Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753)
- NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716)
- NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)

ii. Proposal to Suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure (NQF #0166) for the FY 2023 Hospital VBP Program Year

CMS proposed to suppress the HCAHPS measure for the FY 2023 program year under Measure Suppression Factor 1, "significant deviation in national performance on the measure during the COVID-19 Public Health Emergency (PHE), which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years." In addition, CMS proposed to suppress the HCAHPS measure for the FY 2023 program year under Measure Suppression Factor 4, "significant national shortage or rapid or unprecedented changes in healthcare personnel."

CMS welcomed public comment on this proposal.

Final Rule: Finalized as proposed.

iii. Suppression of the Five Healthcare-Associated Infection (HAI) Safety Measures for the FY 2023 Hospital VBP Program Year

CMS proposed to suppress the five HAI Safety measures (CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) for the FY 2023 program year under Measure Suppression Factor 1, "significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years"; Measure Suppression Factor 3, "rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials"; and Measure Suppression Factor 4, "significant national shortages or rapid or unprecedented changes in healthcare personnel and patient case volumes."

In addition, CMS proposed to suppress three of the five Centers for Disease Control and Prevention (CDC) NHSN HAI measures (CLABSI, CAUTI, and MSRA bacteremia) under Measure Suppression Factor 1, "significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years." Although the changes in the national standardized infection ratios (SIRs) for SSI and CDI were not as large compared to the other safety domain measures, CMS proposed to suppress these measures under Measure Suppression Factor 4, "significant national shortages or rapid or unprecedented changes in patient case volumes" and Measure Suppression Factor 3, "rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials." Specifically, for the SSI measure, CMS proposed to suppress the measure for FY 2023 under Measure Suppression Factor 4, "rapid or unprecedented changes in patient case volumes." For the CDI measure, CMS proposed to suppress the measure under Measure Suppression Factor 3, "rapid or unprecedented changes in clinical guidelines, care delivery or practice, related protocols, or equipment or diagnostic tools or materials."

CMS also proposed to suppress the five CDC NHSN HAI measures for the FY 2023 program year under Measure Suppression Factor 4, "significant national shortage or rapid or unprecedented changes in healthcare personnel." In addition, CMS proposed to suppress the CY 2021 HAI measure data to address the impact of the ongoing COVID-19 PHE on HAI incidence

CMS welcomed public comment on its proposal to suppress the five HAI Safety domain measures for the FY 2023 program year.

Final Rule: Finalized as proposed.

iv. Proposed Scoring and Payment Methodology for the FY 2023 Program Year Due to the COVID-19 PHE

CMS proposed to use a special rule for FY 2023 scoring. Specifically, CMS proposed it would calculate measure rates for all measures in the FY 2023 program year, and it would only calculate achievement and improvement points, and a domain score, for remaining measures in the Clinical Outcomes domain and the Efficiency and Cost Reduction domain that have not been proposed for suppression. Also, because no other domains receive scores for the FY 2023 program year, the agency would not award TPSs to any hospital for FY 2023.

CMS also proposed that it would reduce each hospital's base-operating diagnosis-related group (DRG) payment amount by two percent and then assign to each hospital a value-based incentive payment amount

that matches the two percent reduction to the base operating DRG payment amount. The net result of the payment adjustments for hospitals would be neutral.

In addition, CMS proposed to provide FY 2023 confidential feedback reports that contain the measure rates it has calculated for the FY 2023 program year, along with achievement and improvement scores for all the measures in the Cost and Efficiency Reduction domain and the Clinical Outcomes domain that have not been finalized for suppression and domain scores for Cost and Efficiency Reduction and Clinical Outcomes.

CMS invited public comment on the proposals.

Final Rule: Finalized as proposed.

c. Retention and Removal of Quality Measures

i. Summary of Previously Adopted Measures for FY 2023 Through FY 2026 Program Years

CMS proposed to suppress the HCAHPS and HAI measures for the FY 2023 program year and did not propose to add new measures. CMS notes that if these measure suppression proposals were to be finalized as proposed, the Hospital VBP Program measure set for the FY 2023, FY 2024, FY 2025, and FY 2026 program years would contain the measures listed in the table below:

d. Previously Adopted Baseline and Performance Periods

i. Update to Baseline Periods for Certain Measures Due to the COVID-19 PHE

1. Background

CMS previously finalized baseline periods for the FY 2024, 2025, 2026, 2027, and 2028 program years for all the measures included in the Hospital VBP Program. However, since CMS proposed to suppress the HCAHPS and five HAI measures for the purposes of scoring and payment for FY 2023, the agency proposed several updates to the baseline periods in the proposed rule for the FY 2025 program year. CMS noted it was not proposing to update the baseline periods for certain measures under the Hospital VBP Program that have a 1-year baseline period.

TABLE V.I.-03: SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2023, FY 2024, FY 2025, FY 2026 PROGRAM YEARS

Measure Short Name	Domain/Measure Name	NQF #
Person and Community Engagement Domain		
HCAHPS*	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition measure)	0166 (0228)
Safety Domain		
CAUTI*	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI*	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI*	American College of Surgeons - Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	1716
CDI*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	1717
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)**	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) - Hospital	2158

* Per section V.I.1.b. of the preamble of this proposed rule, we are proposing to suppress the HCAHPS and five HAI measures for the FY 2023 program year.
** In the FY 2022 IPPS/LTCH PPS final rule, we finalized our proposal to suppress the MORT-30-PN measure for the FY 2023 program year (86 FR 45274 through 45276).

2. Updated FY 2025 Baseline Period for the Person and Community Engagement Domain Measure (HCAHPS Survey)

CMS proposed to use a baseline period of January 1, 2019 through December 31, 2019 for the FY 2025 program year in order to best mitigate the impact of using measure data affected by the COVID-19 PHE when determining achievement thresholds or awarding improvement points.

Final Rule: Finalized as proposed.

3. Updated the FY 2025 Baseline Period for the Safety Domain Measures

To mitigate the impact of using measure data affected by the COVID-19 PHE when determining achievement thresholds or awarding improvement points, CMS proposed to use a baseline period of January 1, 2019 through December 31, 2019 for the FY 2025 program year.

Final Rule: Finalized as proposed.

e. Performance Standards for the Hospital VBP Program

i. Newly Established Performance Standards for Certain Measures for the FY 2028 Program Year

CMS established performance standards for the FY 2028 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain in the table below:

TABLE V.I.-13 NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2027 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain**		
MORT-30-AMI	0.877260	0.893229
MORT-30-HF	0.885427	0.910649
MORT-30-PN (updated cohort)	0.831776	0.866166
MORT-30-COPD	0.913752	0.929652
MORT-30-CABG	0.971052	0.980570
COMP-HIP-KNEE*	0.029758	0.022002
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.
** We note that these performance standards are calculated using some data from CY 2020 and CY 2021, which are included the COVID-19 PHE. However, these performance standards have been calculated using the updated technical specifications described in sections V.I.3.c. and V.I.3.d. of this proposed rule, which excludes patients diagnosed with COVID-19 and risk-adjusts for history of COVID-19 for these measures.

f. Data Requirements

i. NHSN Digital Quality Measures

CMS requested information on the potential future adoption of the NHSN Healthcare-Associated Clostridioides difficile Infection Outcome Measure and the NHSN Hospital-Onset Bacteremia & Fungemia Outcome Measure into the Hospital Inpatient Quality Reporting (IQR) Program. CMS also requested information on the potential future inclusion of these digital CDC NHSN measures in the Hospital VBP Program.

Final Rule: CMS acknowledged and thanked the public for their comments.

ii. Reference to the Request for Information (RFI): Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

CMS is committed to achieving equity in healthcare outcomes for beneficiaries by supporting healthcare providers' quality improvement activities to decrease health disparities, allowing beneficiaries to make more informed decisions, and promoting healthcare provider accountability for healthcare disparities. CMS

sought input on overarching principles in measuring healthcare quality disparities in hospital quality and VBP Programs.

Specifically, CMS sought comments on CMS's principles and approaches as well as additional thoughts regarding disparity measurement or stratification guidelines suitable for overarching consideration across its quality programs. CMS invited comments on:

- Overarching goals for measuring disparity that should be considered across CMS quality programs, including the importance of pairing stratified results with overall measure results to evaluate gaps in care among groups of patients attributed to a given healthcare provider and comparison of care for a subgroup of patients across healthcare providers;
- Principles to consider for prioritization of measures for disparity reporting, including prioritizing stratification for: valid clinical quality measures; measures with established disparities in care; measures that have adequate sample size and representation among healthcare providers; and measures that consider access and appropriateness of care;
- Principles to be considered for the selection of social risk factors and demographic data for use measuring disparities, include the importance of identifying new social risk factor and demographic variables to use to stratify measures. CMS also sought comment on the use of imputed and area-based social risk and demographic indicators for measure stratification when patient reported data are unavailable;
- Preferred ways that meaningful differences in disparity results can be identified or should be considered; and
- Guiding principles for the use and application of the results of disparity measurement such as providing confidential reporting initially.

Final Rule: CMS acknowledged and thanked the public for their comments.

II. Hospital-Acquired Condition (HAC) Reduction Program

a. Overview

Section 1886(p) of the Social Security Act (the Act) creates an adjustment to hospital payments for Hospital-Acquired Conditions (HACs), or a HAC Reduction Program, under which payments to applicable hospitals are adjusted to give an incentive to reduce the incidence of HACs, effective for discharges beginning on October 1, 2014 and for subsequent program years. CMS made a number of proposals to the HAC Reduction Program for FY 2023. Specifically, CMS proposed to: (1) suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures from the calculation of measure scores and the Total HAC Score, thus not penalizing any hospital under the HAC Reduction Program FY 2023 program year; (2) publicly and confidentially report CDC NHSN HAI measure results but not calculate or report measure results for the CMS PSI 90 measure for the HAC Reduction Program FY 2023 program year; (3) suppress calendar year (CY) 2021 CDC NHSN HAI measures data from the FY 2024 HAC Reduction Program Year; (4) update the measure specification to the minimum volume threshold for the CMS PSI 90 measure starting with the FY 2023 program year; (5) update the measure specifications to risk-adjust for COVID-19 diagnosis in the CMS PSI 90 measure starting with the FY 2024 HAC Reduction Program Year; (6) request information from stakeholders on the possible adoption of two digital NHSN measures: the NHSN Healthcare-associated *Clostridioides difficile* Infection Outcome measure and NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure; (7) request information on overall principles for measuring healthcare quality disparities across CMS Quality Programs; (8) update the NHSN CDC HAI data

submission requirements for newly-opened hospitals starting in the FY 2024 HAC Reduction Program Year; and (9) clarify the removal of the no mapped location policy starting with the FY 2023 program year.

b. Proposed Changes to the HAC Reduction Program

i. Flexibility for Changes that Affect Quality Measures During a Performance or Measurement Period in the HAC Reduction Program

1. Measure Suppression Policy to FY 2023 and FY 2024 HAC Reduction Program Years

CMS proposed two updates for the FY 2023 HAC Reduction Program's measure suppression policy: (1) suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures (six measures total) from the calculation of measure scores and the Total HAC Score, thus not penalizing any hospital under the HAC Reduction Program FY 2023 program year;

Final Rule: Finalized as proposed.

and (2) for the CMS PSI 90 measure, not calculate or report measure results for the HAC Reduction Program FY 2023 program year.

Final Rule: CMS is finalizing its proposal to suppress all six measures in the HAC Reduction Program. However, CMS is not finalizing its proposal to suppress the calculating and reporting of CMS PSI 90 measure results for the FY 2023 HAC Reduction Program. Although CMS will not calculate or report CMS PSI 90 measure (and the other five measures) results for use in the HAC Reduction Program scoring calculations for the program year, CMS will still calculate and report the measure displayed on the main pages of the Care Compare tool hosted by HHS after confidentially reporting these results to hospitals via CMS PSI 90-specific HSRs and a 30-day preview period.

CMS also proposed to suppress all HAC Reduction Program measures (CMS PSI 90, CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) from the calculation of the Total HAC Score for the FY 2023 HAC Reduction Program under Measure Suppression Factor 1, "significant deviation in national performance on the measure, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years"; Measure Suppression Factor 3, "rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials"; and the Measure Suppression Factor 4, "significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix."

In addition, CMS proposed to suppress three of the five CDC NSHN HAI measures (CLABSI, CAUTI, and MRSA) under Measure Suppression Factor 1, "significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years."

CMS also proposed to suppress the SSI and CDI measures under Measure Suppression Factor 4, "significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix" and Measure Suppression Factor 3, "rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials." For the SSI measure, CMS proposed to suppress the measure for FY 2023 under Measure Suppression

Factor 4, "significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix." For the CDI measure, CMS proposed to suppress the measure under Measure Suppression Factor 3, "rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials." CMS also proposed to suppress all five CDC NHSN HAI measures from the HAC Reduction Program for the FY 2023 program year, to make certain an accurate and reliable national comparison of performance on hospital safety.

For FY 2023, CMS proposed it will not calculate measure results for CMS PSI 90, not provide the measure results for the CMS PSI 90 measure to hospitals via their hospital-specific reports (HSRs), and not publicly report those measure results on the Care Compare tool hosted by Health and Human Services (HHS) and the Provider Data Catalog.

Final Rule: Finalized as proposed.

CMS will continue to assess the impact of the PHE on measure data used for the HAC Reduction Program.

CMS invited public comment on its proposals including the temporary suppression of all measures from the FY 2023 HAC Reduction Program.

2. Proposal to Suppress CY 2021 CDC NHSN HAI Measure Data from the FY 2024 HAC Reduction Program Year

CMS proposed to suppress CY 2021 CDC NHSN HAI data from the FY 2024 HAC Reduction Program under Measure Suppression Factor 1, "significant deviation in national performance on the measure, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years"; and the Measure Suppression Factor 4 subfactor, "significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix."

CMS invited public comments on the proposal to suppress CY 2021 CDC NHSN HAI Measure data from the FY 2024 HAC Reduction Program year.

Final Rule: Finalized as proposed.

c. Measures for FY 2023 and Subsequent Years

i. Technical Measure Specification Update to the Minimum Volume Threshold for the CMS PSI 90 Measure beginning with the FY 2023 Program Year

Currently, the minimum volume threshold for the CMS PSI 90 measure requires hospitals to have three or more eligible discharges for at least one component indicator to receive a CMS PSI 90 measure score for the HAC Reduction Program. CMS noted an increased minimum volume threshold for the CMS PSI 90 measure, under which hospitals must meet the following criteria to receive a CMS PSI 90 composite score: (1) one or more component PSI measure with at least 25 eligible discharges; and (2) seven or more component PSI measures with at least three eligible discharges.

ii. Technical Measure Specification Update to Risk-Adjust for COVID-19 Diagnoses in the CMS PSI 90 Measure beginning with the FY 2024 HAC Reduction Program Year

CMS noted a technical update to the CMS PSI 90 software to include COVID-19 diagnosis as a risk-adjustment parameter for the FY 2024 program year and subsequent years to address the effect of the COVID-19 PHE on the CMS PSI 90 measure.

d. HAC Reduction Program Requests for Information

i. Digital CDC NHSN Measures

CMS strives to move to digital quality measurement in CMS quality reporting and VBP Programs, including the HAC Reduction Program. CMS requested information on the potential future adoption of two digital NHSN measures, the NHSN Healthcare-associated Clostridioides difficile Infection Outcome Measure and the NHSN Hospital-Onset Bacteremia & Fungemia Outcome Measure, into the Hospital IQR Program, PCHQR Program, and the Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP). CMS also requested information on the potential inclusion of these digital CDC NHSN measures in the HAC Reduction Program.

Final Rule: CMS acknowledged and thanked the public for their comments.

ii. Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

CMS is committed to achieving equity in healthcare outcomes for beneficiaries by supporting healthcare providers' quality improvement activities to decrease health disparities, allowing beneficiaries to make more informed decisions, and promoting healthcare provider accountability for healthcare disparities. CMS sought input on overarching principles in measuring healthcare quality disparities in hospital quality and VBP Programs.

Specifically, CMS sought comments on CMS's principles and approaches as well as additional thoughts regarding disparity measurement or stratification guidelines suitable for overarching consideration across its quality programs.

Final Rule: CMS acknowledged and thanked the public for their comments.

e. Proposal to Update the CDC NHSN HAI Data Submission Requirements for Newly Opened Hospitals beginning in the FY 2023 HAC Reduction Program Year

CMS proposed to update the definition of "newly-opened hospitals" for the CDC NHSN HAI measures to include hospitals with a Medicare Accept Date within the last 12 months of the performance period. Hospitals defined as newly-opened hospitals for the CDC NHSN HAI measures do not receive a measure score for any of the CDC NHSN HAI measures under the HAC Reduction Program scoring methodology.

CMS invited public comments on the proposal to update the newly-opened hospital definition for CDC NHSN HAI measures beginning in the FY 2023 program year.

Final Rule: Finalized as proposed.

f. Clarification of the Removal of the No Mapped Locations Policy beginning with the FY 2023 Program Year

CMS noted that in FY 2023 and subsequent years, the "no mapped locations (NML)" designation will no longer apply, and hospitals must properly submit data to the NHSN or, if hospitals do not have the applicable locations for the CLABSI and CAUTI measures, the hospital is required to submit an IPPS Measure Exception Form to be excused from CLABSI and CAUTI reporting for CMS programs. If a hospital fails to submit an IPPS Measure Exception Form and does not submit data to the NHSN, the hospitals will get the maximum measure under the HAC Reduction Program for not reporting data.

Final Rule: CMS clarified that beginning in FY 2023 and subsequent years, the NML designation will no longer apply, and hospitals will be required to appropriately submit data to the NHSN or, if hospitals do not have the applicable locations for the CLABSI and CAUTI measures, the hospital must submit an IPPS Measure Exception Form to be exempt from CLABSI and CAUTI reporting for CMS programs. If the hospitals do not submit an IPPS Measure Exception Form and continue to not submit data to the NHSN, these hospitals would receive the maximum measure score (that is., Winsorized z-score) under the HAC Reduction Program for not reporting data.

III. Hospital Readmissions Reduction Program: Proposed Updates and Changes

a. Background on the Hospital Readmissions Reduction Program

The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2017 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery.

b. Resumption of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) for the FY 2024 program year.

CMS' measure suppression policy focuses on a short-term, equitable approach during the PHE and was not intended for indefinite application. In the FY 2022 IPPS/LTCH PPS final rule, CMS finalized the suppression of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2023 Program Year and stated that it would continue to monitor the claims that form the basis for this measure's calculations to evaluate the effect of the circumstances on quality measurement and to determine the appropriate policies in the future. CMS proposed that beginning in FY 2024, the Pneumonia Readmission Measure (NQF #0506) will no longer be suppressed under the Hospital Readmissions Reduction Program. CMS believes that the clinical proximity of the measure's focus is no longer close enough to the health impacts of the COVID-19 PHE for the suppression factor to continue to apply.

Final Rule: Finalized as proposed.

c. Modification of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) to exclude COVID-19 diagnosed patients from the measure denominator

Along with the resumption of the 30-Day Pneumonia Readmission Measure (NQF #0506), CMS proposed to modify the measure to exclude patients with a primary or secondary diagnosis of COVID-19 beginning with the FY 2024 program year. This update is meant to minimize the effect of COVID-19 on the pneumonia measure, which was not developed to account for COVID-19 diagnosed patients. CMS believes

that excluding COVID-19 patients from the measure denominator (cohort) and numerator (outcome) and adding a covariate to adjust for a history of a COVID-19 diagnosis in the 12 months prior to an admission will ensure that this condition-specific readmission measure continues to account for readmissions as intended and meets the goals of the Hospital Readmissions Reduction Program.

Final Rule: Finalized as proposed.

d. Modification of all six condition/procedure specific measures to include a covariate adjustment for patient history of COVID-19 within one year prior to the index admission beginning with the FY 2023 program year

CMS has observed that for some patients, COVID-19 continues to have lasting effects, including fatigue, cough, palpitations, and others potentially related to organ damage, post-viral syndrome, post-critical care syndrome or other reasons. These clinical conditions could affect a patient's risk factors for being readmitted following an index admission for any of the six conditions/procedures included in the Hospital Readmissions Reduction Program. CMS modified the technical measure specifications of each of its six condition/procedure specific risk-standardized readmission measures to include a covariate adjustment for patient history of COVID-19 in the 12 months prior to the admission beginning with the FY 2023 program year. This inclusion of the covariate adjustment for patient history of COVID-19 in the 12 months prior to the admission will be effective beginning with the FY 2023 program year and for subsequent years for the five non-pneumonia condition- and procedure-specific readmission measures. The pneumonia readmission measure remains suppressed from scoring and payment adjustments for the FY 2023 program year and will be resumed for the FY 2024 program year. However, this update will be reflected in the confidential and public reporting of the pneumonia readmission measure for FY 2023. This provision is a technical change made by CMS, but it was not proposed in the FY 2023 IPPS Proposed Rule.

e. Request for Public Comment on Possible Future Inclusion of Health Equity Performance in the Hospital Readmissions Reduction Program

CMS requested comment on overarching principles for measuring health care quality disparities to provide more actionable and comprehensive information on health care disparities across multiple social risk factors and demographic variables.

CMS asked for public comment on the following:

- The benefit and potential risks, unintended consequences, and costs of incorporating hospital performance for beneficiaries with social risk factors in the Hospital Readmissions Reduction Program.
- The approach of linking performance in caring for socially at-risk populations and payment reductions by calculating the reductions based on readmission outcomes for socially at-risk beneficiaries compared to other hospitals or compared to performance for other beneficiaries within the hospital.
- Measures or indices of social risk, in addition to dual eligibility, that should be used to measure hospitals' performance in achieving equity in the Hospital Readmissions Reduction Program.

Final Rule: CMS acknowledged and thanked the public for their comments.

IV. <u>Key Medicare Quality Data Reporting Policies</u>

a. Changes Relating to Quality Data Reporting Requirements for the Hospital IQR Program

i. Hospital-Harm—Opioid-Related Adverse Events eCQM

CMS proposed to adopt the Hospital Harm—Opioid-Related Adverse Events electronic clinical quality measure (eCQM) as part of the Hospital IQR Program for which hospitals can self-select beginning with the CY 2024 reporting period and the FY 2026 payment determination. This proposed eCQM is an outcome measure focusing specifically on opioid-related adverse events during an admission to an acute care hospital by assessing the administration of naloxone.

Final Rule: Finalized as proposed.

ii. Global Malnutrition Composite Score eCQM

Currently, CMS quality reporting programs do not include quality measures that specifically address malnutrition. In response, CMS proposed to adopt the Global Malnutrition Composite Score eCQM beginning with the CY 2024 reporting period and the FY 2026 payment determination. The Global Malnutrition Composite Score eCQM assesses adults 65 years of age and older admitted to inpatient hospital service who received care appropriate to their level of malnutrition risk and malnutrition diagnosis, if properly identified. The proposed measure includes four component measures: (1) screening for malnutrition risk at admission; (2) completing a nutrition assessment for patients who screened for risk of malnutrition; (3) appropriate documentation of malnutrition diagnosis in the patient's medical record if indicated by the assessment findings; and (4) development of a nutrition care plan for malnourished patients including the recommended treatment plan.

Final Rule: Finalized as proposed.

iii. Hospital-Level, Risk Standardized Patient-Reported Outcomes Following Elective Primary THA and/or TKA

CMS proposed to adopt the measure, Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary THA and/or TKA. This proposed measure would report the hospital-level risk-standardized improvement rate (RSIR) in patient reported outcomes following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older. CMS proposed to implement the Hospital-Level, Risk Standardized Patient-Reported Outcomes Following Elective Primary THA and/or TKA with a phased approach, beginning with two voluntary reporting periods in CY 2025 and 2026 reporting periods prior to mandatory reporting beginning with the CY 2027 reporting period and the FY 2028 payment determination.

Final Rule: Finalized as proposed.

iv. Medicare Spending Per Beneficiary (MSPB) Hospital Measure

CMS developed a prior version of the Medicare Spending Per Beneficiary (MSPB) Hospital Measure in 2012, which was removed from the Hospital IQR Program beginning with the FY 2020 payment determination. CMS proposed to keep the measure the same as the prior iteration except for an update to allow readmissions to trigger a new episode, a new indicator variable in the risk adjustment model, and an updated MSPB amount calculation methodology. CMS proposed to adopt the re-evaluated version of the MSPB Hospital measure in the Hospital IQR Program, beginning with the FY 2024 payment determination. This measure would allow CMS to assess hospitals' efficiency and resource use and meet statutory requirements for future adoption in the VBP Program.

Final Rule: Finalized as proposed.

v. Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA Measure

CMS proposed to adopt the re-evaluated form of the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA Measure (the THA/TKA complication measure) with an expanded measure outcome beginning in 2024. Since the measure was removed from the Hospital IQR Program in 2018, it has been revised to include 26 additional mechanical complication ICD-10 codes, which were identified during measure maintenance.

Final Rule: Finalized as proposed.

vi. Refinement of the Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective THA and/or TKA Measure

CMS proposed to refine the Hospital-Level, Risk-Standardized Payment Associated with an Episode of Care for Primary Elective THA and/or TKA Measure (the THA/TKA Payment measure). In particular, CMS proposed to expand the measure outcome to include 26 clinically vetted mechanism complication ICD-10 codes. These 26 codes would increase the national observed complication rate, addressing the risk of missed complications. CMS proposed to adopt this refined measure beginning with the FY 2024 payment determination. Notably, the THA/TKA Payment measure was first adopted into the Hospital IQR Program beginning in the FY 2018 payment determination.

Final Rule: Finalized as proposed.

vii. Refinement of the Excess Days in Acute Care (EDAC) After Hospitalization for AMI Measure

CMS proposed to refine the Excess Days in Acute Care (EDAC) After Hospitalization for AMI measure, which was initially adopted in the Hospital IQR Program beginning with the FY 2018 payment determination. The EDAC AMI measure is intended to capture the quality-of-care transitions provided to discharged patients with AMI. The measure assesses the following adverse acute care outcomes that may occur post-discharge: (1) Emergency Department visits; (2) observation stays; and (3) unplanned readmissions at any time during the 30 days after discharge.

CMS proposed to increase the minimum case count for reporting in this measure. Specifically, CMS proposed to increase reporting requirements from 25 cases to 50 cases to include as many hospitals as possible while maintaining measure reliability. The increase is intended to improve the measure's reliability. CMS proposed to implement this increase beginning with the FY 2024 payment determination. CMS further proposed that hospitals with fewer than 50 cases would continue to receive confidential feedback reports containing measure results.

Final Rule: Finalized as proposed.

b. Updates to the Quality Reporting Program for PPS-Exempt Cancer Hospitals (PCHQR Program)

i. Adoption of a Patient Safety Exception to the Measure Removal Policy

CMS proposed that if continued use of a measure in the PCHQR Program raises specific patient safety concerns, CMS would be permitted to promptly remove the measure from the program without rulemaking and notify hospitals and the public of the removal of the measure, including reasons for the removal, through routine communication channels and with notice in the *Federal Register*.

Final Rule: Finalized as proposed.

1. Public Display of End-of-Life (EOL) Measures

Under current regulation, CMS is required to establish procedures for making public the data submitted under the PCHQR Program. Specifically, CMS must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care relating to services furnished by PPS-Exempt Cancer Hospitals (PCHs).

CMS proposed to begin public display of several End-of-Life (EOL) measures, specifically, the EOL-Chemo, EOL-Hospice, EOL-ICU, and EOL-3DH measures beginning with FY 2024 program year data. CMS adopted these measures for the PCHQR measure set beginning with FY 2020 program year data.

Final Rule: Finalized with modification. CMS will begin public reporting beginning with FY 2025 program year data, which corresponds to data collected from July 1, 2022, through June 30, 2023, to provide hospitals with enough time to review their confidential reports. Public display will occur during the July 2024 refresh cycle or as soon as feasible thereafter. CMS will announce an exact timeframe at a later date.

2. Public Display of the 30-Day Unplanned Readmissions for Cancer Patients Measure Beginning with the FY 2024 Program Year Data

CMS proposed to begin public display of the 30-Day Unplanned Readmissions for Cancer Patients measure beginning with FY 2024 program year data. CMS adopted this measure for the PCHQR measure set beginning with FY 2021 program year data.

Final Rule: Finalized as proposed.

c. Requirements Pertaining to Eligible Hospitals and critical access hospitals (CAHs) in the Medicare Promoting Interoperability Program

i. Changes to the Query of Prescription Drug Monitoring Program (PDMP) Measure and Related Policies

CMS adopted the Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing Objective. The measure is intended to support initiatives related to the treatment of opioid and substance use disorders by helping health care providers avoid inappropriate prescriptions, improving coordination of prescriptions among providers, and advancing the use of certified electronic health record technology (CEHRT).

Currently, the measure provides that for at least one Schedule II opioid electronically prescribed using CEHRT during the electronic health record (EHR) reporting period, the eligible hospital or CAH must use data from CEHRT to conduct a query of a PDMP for prescription drug history. Previous rulemaking finalized that the Query of PDMP measure is optional for hospitals and critical access hospitals (CAHs). In response to stakeholder concerns that it is premature for the Medicare Promoting Interoperability Program

to require the Query of PDMP measure and score its performance, CMS noted that all 50 states and several localities host PDMPs.

CMS proposed to require the Query of PDMP measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program, beginning with the EHR reporting period in CY 2023. The measure is intended to expand the use of PDMPs and integrate them with health information technology systems. The measure further offers a way to reward health care providers participating in current PDMP initiatives supported by federal agencies. However, CMS proposed exclusions to this requirement for any eligible provider that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any such pharmacy, or any eligible provider that cannot report on this measure in accordance with applicable law.

Final Rule: Finalized as proposed.

CMS further proposed to change the Query of PDMP measure to include Schedules II, III, and IV drugs, as classified by the Drug Enforcement Administration (DEA). Expanding the requirements for this measure to include additional schedules of drugs is intended to further support initiatives; facilitate more informed prescribing practices; and improve patient outcomes. CMS further proposed that the query of the PDMP for prescription drug history must occur prior to the electronic transmission of an electronic prescription for all Schedule II, III, or IV drugs. CMS invited public comment on these proposed changes and exclusions, as well as whether to include Schedule V or other drugs in this measure.

Final Rule: Finalized as proposed.

ii. Technical Update to the E-Prescribing Measure

The Office of the National Coordinator for Health Information Technology (ONC) *21st Century Cures Act* final rule retired the "drug-formulary and preferred drug list checks" certification criterion after January 1, 2022. CMS subsequently finalized that this criterion would no longer be associated with measures under the Electronic Prescribing Objective and would no longer be required for CEHRT. However, CMS inadvertently omitted technical revisions to the Medicare Promoting Interoperability Program that would have reflected this change. Thus, CMS proposed to revise descriptions to reflect this change.

Final Rule: Finalized as proposed.

iii. Health Information Exchange (HIE): Proposed Addition of an Alternative Measure for Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

The Health Information Exchange (HIE) Objective currently includes three measures. CMS intended for these measures to reward providers for connecting with HIEs that enabled robust information sharing. The Trusted Exchange Framework and Common Agreement (TEFCA) is intended to advance interoperability for the purpose of ensuring full network-to-network exchange of health information. In 2022, prospective Qualified Health Information Networks (QHINs) are anticipated to begin participating in exchange of health information under TEFCA.

CMS proposed to add a third reporting option through which an eligible hospital or CAH could earn credit for the HIE Objective by connecting to a QHIN or an entity connected to a QHIN. Specifically, CMS proposed to add the Enabling Exchange Under TEFCA measure, beginning with the EHR reporting period in CY 2023. This measure would also incentivize eligible hospitals and CAHs to exchange health

information. CMS further proposed that the Enabling Exchange Under TEFCA measure would be worth the total amount of points available for the HIE Objective within its current scoring methodology. CMS also proposed that eligible hospitals and CAHs would report on this measure by attesting to certain criteria and use the capabilities of CEHRT.

Final Rule: Finalized as proposed.

iv. Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective: Antimicrobial Use and Resistance (AUR) Surveillance Measure

The Public Health and Clinical Data Exchange Objective includes six measures. Under current regulations, eligible hospitals and CAHs must report on four of the six measures: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. However, CMS aims to strengthen infection prevention and control and antibiotic stewardship by systematically collecting data on antimicrobial use and resistance (AUR) in robust systems, and currently, incomplete participation in NHSN's AUR surveillance limits the generalizability of AUR data.

CMS proposed to require an AUR measure under the Medicare Promoting Interoperability Program to develop an accurate national picture of the threat posed by antimicrobial overuse and resistance. Specifically, CMS proposed a new AUR Surveillance measure, in which the eligible hospital or CAH is actively engaging with the NHSN to submit AUR data. CMS proposed to require eligible hospitals and CAHs to report this measure beginning with the EHR reporting period in CY 2023.

Final Rule: Finalized with modification. The proposal will be delayed for a year and implemented in CY 2024.

However, CMS also proposed three exclusions to this measure for eligible hospitals or CAHs that do not have any patients in any care location for which data are collected by NHSN; do not have certain electronic health records; or do not have an electronic laboratory information system or admission discharge transfer (ADT) system. Notably, CMS anticipates reevaluating the last two exclusions in future rulemaking. CMS further proposed that this measure must be calculated by reviewing all patient records.

Final Rule: Finalized as proposed.

v. Revisions to Active Engagement under the Public Health and Clinical Data Exchange Objective

CMS previously defined active engagement under the Public Health and Clinical Data Exchange Objective as when an eligible hospital or CAH is in the process of sending "production data" to a public health agency or clinical data registry. CMS also established three options for eligible hospitals and CAHs to demonstrate active engagement. CMS proposed to consolidate these options into two options to incentivize eligible hospitals and CAHs to move towards submitting production data. Specifically, CMS proposed to offer one option for Pre-Production and Validation of Production Data and one option for Validated Data Production.

Final Rule: Finalized as proposed beginning in CY 2023.

Notably, eligible hospitals and CAHs currently are not required to report their level of engagement. CMS further proposed to require that eligible hospitals and CAHs report their level of active engagement for each measure they report, beginning with the EHR reporting period in CY 2023. To do so, eligible hospitals and

CAHs must submit their level of active engagement, choosing from the proposed Pre-Production and Validation option or the Validated Data Production option, when they report each measure. CMS also proposed that eligible hospitals and CAHs may spend only one EHR reporting period of active engagement in the proposed Pre-Production and Validation of Production Data option; they must progress to the Validated Data Production option by the next EHR reporting period.

Final Rule: Finalized as proposed beginning in CY 2023.

vi. Changes to Scoring Methodology for the EHR Reporting Period in CY 2023

Currently, CMS has a performance-based scoring methodology for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. Under this methodology, eligible hospitals and CAHs must meet a minimum scoring threshold of 60 points to satisfy reporting requirements. Hospitals and CAHs may score up to 100 points by reporting required measures and additional bonus points by reporting optional measures.

In the proposed rule, various proposals would impact the scoring of the objectives and measures for the EHR reporting period for CY 2023. In particular, CMS proposed to require the Query of PDMP measure. In response, CMS proposed to adjust its scoring methodology to compensate for the impact of the proposal by reducing the points associated with the HIE Objective measures, beginning with the CY 2023 EHR reporting period. CMS also proposed to increase the points value for the Public Health and Clinical Data Exchange Objective to incentivize eligible hospitals and CAHs to engage in electronic reporting of public health information. CMS proposed to implement this increase beginning with the CY 2023 EHR reporting period. Notably, this proposal is independent of CMS's proposal to add the AUR Surveillance measure. Additionally, to account for this proposed increase in points, CMS proposed to reduce the points associated with the Provide Patients Electronic Access to Their Health Information measure.

Final Rule: Finalized as proposed.

vii. Proposed Public Reporting of Medicare Promoting Interoperability Program Data

Currently, CMS does not publicly report eligible hospitals and CAHs' data reporting scores for the Medicare Promoting Interoperability Program. CMS proposed to publicly post program scores for each eligible hospital or CAH, beginning with the EHR reporting period in CY 2023. As a first step, CMS proposed to publish this information on a publicly-available CMS website. This proposal is intended to provide consumers with more information about their health care team and electronic access to health information. Notably, while CMS proposed only to report a total score at this time, CMS will evaluate the option of posting a hospital or CAH's individual measure scores in future rulemaking. CMS further proposed to provide eligible hospitals and CAHs an opportunity to review their data during a 30-day preview period before publication, in alignment with existing processes.

CMS requested public comment on these proposals. Specifically, CMS invited public comments that provide information on how these proposals might affect existing incentives and burdens under the Medicare Promoting Interoperability Program. CMS also invited public comment on which Medicare Promoting Interoperability Program data points to publish in future years, including specific objectives or measures.

Final Rule: Finalized as proposed.

viii. Changes to Clinical Quality Measures in Alignment with the Hospital IQR Program

Eligible hospitals and CAHs must report on clinical quality measures using CEHRT, also referred to as eCQMs, under the Medicare Promoting Interoperability Program. CMS proposed to align the eCQM reporting requirements for the Medicare Promoting Interoperability Program with similar requirements under the Hospital IQR Program. Specifically, CMS proposed to adopt four new eCQMs for the Medicare Promoting Interoperability Program in alignment with the Hospital IQR Program: the Severe Obstetric Complications of eCQM; the Cesarean Birth eCQM; the Hospital-Harm—Opioid-Related Adverse Event eCQM; and the Global Malnutrition Composite Score eCQM. CMS further proposed to modify the eCQM reporting and submission requirements under the Medicare Promoting Interoperability Program beginning in the CY 2024 reporting period to align with its proposals for modifying the eCQM reporting and submission requirements under the Hospital IQR Program.

Final Rule: Finalized as proposed.

d. RFIs Relating to Quality Data Reporting Requirements

i. Advancement of Digital Quality Measurement and Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs

CMS invited public comments on the following issues:

- *Refined potential future Definition of dQMs*.
  - Do you have feedback on the potential refined definition of digital quality measures (dQMs)?
  - Do you have feedback on potential considerations or challenges related to non-EHR data sources?
- *Data Standardization Activities to Leverage and Advance Standards for Digital Data*.
  - Do you have feedback on the specific implementation guides we are considering, additional FHIR implementation guides we should consider, or other data and reporting components where standardization should be considered to advance data standardization for a learning health system?
- *Approaches to Achieve FHIR eCQM Reporting*.
  - Are there additional venues to engage with implementors during the transition to digital quality measurement?
  - What data flow options should we consider for FHIR-based eCQM reporting, including retrieving data from EHRs via FHIR APIs and other mechanisms?
  - Are there other critical considerations during the transition?

Final Rule: CMS acknowledged and thanked the public for their comments.

ii. RFI on the Proposed Enabling Exchange Under TEFCA Measure in the Medicare Promoting Interoperability Program

CMS proposed to add a new Enabling Exchange Under TEFCA measure in the Medicare Promoting Interoperability Program. This proposed measure would provide eligible hospitals and CAHs with the opportunity to earn credit for the Health Information Exchange objective if they are a signatory to a "Framework Agreement" as defined in the Common Agreement; enable secure, bi-directional exchange of information to occur for all patients discharged from the eligible hospital or CAH inpatient or emergency

department and all patient records stored or maintained in the EHR for these departments; and use the functions of CEHRT to support bi-directional exchange.

CMS sought feedback on the following questions:

- What are the most important use cases for different stakeholder groups that could be enabled through widespread information exchange under TEFCA? What key benefits would be associated with effectively implementing these use cases, such as improved care coordination, reduced burden, or greater efficiency in care delivery?
- What are key ways that the capabilities of TEFCA can help to advance the goals of CMS programs? Should CMS explore policy and program mechanisms to encourage exchange between different stakeholders, including those in rural areas, under TEFCA? In addition to the ideas discussed previously, are there other programs CMS should consider in order to advance exchange under TEFCA?
- How should CMS approach be incentivizing or encouraging information exchange under TEFCA through CMS programs? Under what conditions would it be appropriate to require information exchange under TEFCA by stakeholders for specific use cases?
- What concerns do commenters have about enabling exchange under TEFCA? Could enabling exchange under TEFCA increase burden for some stakeholders? Are there other financial or technical barriers to enabling exchange under TEFCA? If so, what could CMS do to reduce these barriers?

Final Rule: CMS acknowledged and thanked the public for their comments.

iii. RFI for Future LTCH QRP Quality Measure Concepts

The LTCH QRP currently has 18 measures for FY 2023. Under current law, LTCHs are required to submit certain quality measure data and other data to CMS. In the proposed rule, CMS sought input on the importance, relevance, and applicability of certain quality measure concepts: (1) cross-setting function; (2) health equity measures; and (3) post-acute care (PAC) COVID-19 vaccination coverage among patients. CMS did not respond to specific responses to this RFI in the FY 2023 IPPS/LTCH PPS final rule; however, CMS plans to use stakeholder input to inform future measure development efforts.

iv. RFI on the Potential Inclusion of the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome Measure

Clostridioides difficile is a bacterium that causes diarrhea, pseudomembranous colitis, and toxic megacolon which can lead to sepsis or death. *Clostridioides difficile* infections (CDI) are one of the most common HAIs in the U.S. and significantly contribute to inpatient morbidity and mortality. Currently, CMS requires reporting of CDI outcomes and other HAIs in VBP Programs. CMS has also developed NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure, which is intended to increase prevention practices to reduce the number of CDI cases as well as morbidity and mortality in patients.

1. Inclusion in the Hospital IQR Program Measure Set

CMS requested feedback on the potential future inclusion of the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure into the Hospital IQR Program measure set, to aid in disease monitoring, provide hospitals and patients with more information to inform care delivery, and improve patient outcomes.

Final Rule: CMS acknowledged and thanked the public for their comments.

2. Inclusion in the LTCH QRP Measure Set

CMS requested feedback on the potential future inclusion of the NHSN Healthcare-Associated *Clostridioides difficile* Infection Outcome measure into the LTCH QRP. CMS has identified this measure as a potential measure which utilizes EHR-derived data to address adverse hospital-based events, specifically hospital-onset infections.

Specifically, CMS requested public comment on the following questions:

- Would you support utilizing LTCH EHRs as the mechanism of data collection and submission for LTCH QRP measures?
- Would your EHR support exposing data via HL7 FHIR to a locally installed Measure Calculation Tool (MCT)? For LTCHs using certified health IT systems, how can existing certification criteria under ONC Health Information Technology (IT) Certification Program support reporting of these data? What updates, if any, to the Certification Program would be needed to better support capture and submission of these data?
- Is a transition period between the current method of data submission and an electronic submission method necessary? If so, how long of a transition would be necessary, and what specific factors are relevant in determining the length of any transition?
- Would vendors, including those that service LTCHs, be interested in or willing to participate in pilots or voluntary electronic submission of quality data?
- Do LTCHs anticipate challenges, other than the adoption of EHR, to adopting the NHSN HA-CDI measure, and if so, what are potential solutions for those challenges?

CMS did not respond to specific responses to this RFI in the FY 2023 IPPS/LTCH PPS final rule; however, CMS will consider all input when developing future regulatory proposals.

3. Inclusion in Other Program Measure Sets

CMS is also considering including this measure in the PCHQR Program and replacing current measures in the Hospital-Acquired Condition Reduction Program and the VBP Program.

v. RFI on the Potential Inclusion of the National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

The frequency of hospital fungemia and bacteremia infection rates in the U.S. present an opportunity for large-scale quality measurement and improvement activities. In particular, incidence rates of central line-associated bloodstream infections (CLABSI) increased significantly during the COVID-19 pandemic. CMS developed the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure to address patient safety outcomes in the hospital care setting. The measure is intended to increase awareness of the dangers of fungemia and bacteremia; promote adherence to recommended clinical guidelines; and encourage hospitals to improve monitoring and care delivery practices.

1. Inclusion in the Hospital IQR Program Measure Set

CMS requested feedback on the potential future inclusion of the NHSN Hospital-Onset Bacteremia & Fungemia Outcome measure into the Hospital IQR Program measure set. This measure is intended to aid in disease monitoring, provide hospitals and patients with more information to inform care delivery, and improve patient outcomes.

Final Rule: CMS acknowledged and thanked the public for their comments.

2. Inclusion in Other Program Measure Sets

CMS is also considering including this measure in the PCHQR Program and replacing current measures in the Hospital-Acquired Condition Reduction Program and the VBP Program. CMS also requested feedback on potential data reporting formats for this measure.

Final Rule: CMS acknowledged and thanked the public for their comments.

vi. RFI on the Patient Access to Health Information Measure

CMS sought public comment regarding how to further promote equitable patient access and use of patients' health information without adding unnecessary burden on the hospital or health care provider.

Specifically, CMS sought public comment on the following questions:

- Moving beyond providing the information and technical capabilities to access their data, are there additional approaches to promote patient access and use of their health information? Are there examples of successful approaches or initiatives that have enhanced patient access and use of their health information?
    - Would allowing patients to add information to their records be useful in promoting patient access and utilization? Are there other incentives that would promote patient access? Are there potential unintended consequences in allowing patients to add information to their records? What could be done to mitigate any potential unintended consequences?
    - Are there certain tools found to be useful in promoting patient access and use of their health information?
- Recent studies have raised concerns about the presence of racial bias and stigmatizing language within EHRs that could lead to unintended consequences if patients were to obtain disparaging notes regarding their medical care.
    - What policy, implementation strategies, or other considerations are necessary to address existing racial bias or other biases and prevent use of stigmatizing language?
- Additional analysis of the Health Information National Trends Survey (HINTS) data provides insights into common barriers to patient portal access and use as well as characteristics that can help predict which individuals are more likely to experience certain barriers (for example, preference for in-person communication with their provider is one of the most prevalent barriers experienced more often by older adults and women).
    - What are the most common barriers to patient access and use of their health information that have been observed? Are there differences by populations or individual characteristics?
- Patients' health information may be found in multiple patient portals. How could CMS or HHS facilitate individuals' ability to access all their health information in one place?

  - If patient portals connected to a network participating in the recently launched TEFCA, would this enable more seamless access to individual health information across various patient portals?
- With the advancement of HIT, EHRs and other health-related communication technologies, there are concerns of equity to health outcomes and access with populations who could receive greater benefits from these technologies but are less likely to adopt them.
  - What policy, governance and implementation strategies or other considerations are necessary to ensure equal access to patient portals, equitable portal implementation, appropriate design and encouragement of use?
- What challenges do eligible hospitals and CAHs face when addressing patient questions and requests resulting from patient access of patient portals or access of data through use of a mobile app? What can be done to mitigate potential burden?
- For patients who access their health information, how could CMS, HHS, and health care providers help patients manage their health through the use of their personal health information?
- Do you believe the API and app ecosystem is at the point where it would be beneficial to revisit adding a measure of patient access to their health information which assesses providers on the degree to which their patients actively access their health information? What should be considered when designing a measure of patient access of their health information through portals or apps?

Final Rule: CMS acknowledged and thanked the public for their comments.

V. Key Proposed Medicare Conditions of Participation Policies (CoPs)

a. Background on Medicare Conditions of Participation Policies

The CMS Conditions of Participation (CoPs) are the health and safety standards that certified providers and suppliers must meet to receive payment from Medicare and Medicaid. Currently, the CMS CoPs require that hospitals and CAHs have active facility-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases. Hospitals and CAHs must also have programs for optimizing antibiotic use through stewardship. These programs must adhere to nationally recognized infection prevention and control guidelines, as well as best practices for improving antibiotic use and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Any shortcomings must be addressed in coordination with facility-wide quality assessment and performance improvement (QAPI) programs. Infection prevention and control program policies are also required to address any infection control issues identified by public health authorities. Furthermore, current regulations only establish epidemic and pandemic-related data reporting requirements during the current COVID-19 PHE.

b. Conditions of Participation Requirements for Hospitals and CAHs to Report Data Elements to Address Future Pandemics and Epidemics

i. Continued COVID-19 and Seasonal Influenza-Related Reporting

The proposed rule revised the hospital and CAH CoPs for infection prevention and control and antibiotic stewardship programs. In particular, CMS proposed to extend the current COVID-19 reporting requirements, beginning on the later of the conclusion of the current COVID-19 PHE declaration or the effective date of the proposed rule until April 30, 2024. Specifically, CMS proposed to revise the COVID-19 and Seasonal Influenza reporting standards for hospitals and CAHs to require that hospitals and CAHs electronically report information about COVID-19 and Seasonal Influenza in a standardized format. The

proposed rule allowed for the scope and frequency of data reporting to adapt in response to evolving clinical and epidemiological circumstances.

For the COVID-19 reporting standard, CMS proposed that the required data elements include: (1) suspected and confirmed COVID-19 infections among patients and staff; (2) total deaths attributable to COVID-19 among patients and stuff; (3) personal protective equipment (PPE) and testing supplies; (4) ventilator use, capacity, and supplies; (5) total hospital bed and intensive care unit bed census and capacity; (6) staffing shortages; (7) COVID-19 vaccine administration data for patients and staff; and (8) relevant therapeutic inventories and usage data. For the Seasonal Influenza reporting standard, CMS proposed that the required data elements include: (1) confirmed influenza infections among patients and staff; (2) total deaths attributable to influenza among patients and staff; and (3) confirmed co-morbid influenza and COVID-19 infections among patients and staff.

ii. Future Reporting in the Event of a PHE Declaration

The proposed rule also established new reporting requirements to address future PHEs related to epidemics and pandemics. Specifically, CMS proposed to require hospitals and CAHs to report information on Acute Respiratory Illness, SARS-CoV-2 or COVID-19, and other viral and bacterial pathogens or infectious diseases with pandemic and epidemic potential. In particular, CMS proposed to require reporting of specific data elements to CDC NHSN or other CDC surveillance systems.

CMS proposed that the required data elements include: (1) suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff; (2) total deaths attributed to the relevant infectious disease pathogen among patients and staff; (3) PPE and other relevant supplies; capacity and supplies relevant to the immediate and long term treatment of the relevant infectious disease pathogen; (4) total hospital bed and intensive care unit bed census, capacity, and capability; (5) staffing shortages; (6) vaccine administration status of patients and staff where applicable; (7) relevant therapeutic inventories and/or usage; (8) isolation capacity; and (9) key co-morbidities and exposure risk factors of patients. CMS further proposed that data reporting would be required in a standardized format providing person-level information and on a daily basis, unless specified otherwise.

Final Rule: CMS is finalizing its proposal with changes. First, CMS is modifying its proposal for hospitals and CAHs to decrease the scope of data categories required for continued COVID-19 and seasonal influenza reporting. CMS does not expect continued daily reporting for COVID-19 or influenza outside of a declared PHE. Moreover, the final rule allows for the scope of data categories and frequency of data collection and reporting to be reduced and limited, as determined by the HHS Secretary, responsive to evolving clinical and epidemiology circumstances. CMS believes this approach to reducing the proposed set of required data categories will provide a path towards winding down the overall reporting of COVID-19-related data between the end of the current PHE and April 2024, when these requirements will sunset. CMS stated that the requirements will not be implemented and enforced until the current COVID-19 PHE declaration concludes, and CMS will issue guidance indicating such a transition.

CMS is also withdrawing its proposal for hospitals and CAHs to establish reporting requirements for an infectious disease in the event of a PHE declaration. CMS believes that additional consideration is necessary to establish a longer-term solution for data collection and reporting that ensures the ongoing preparedness of the entire health care system in the event of another PHE involving an infectious disease or a PHE resulting from natural or human-made factors.

* * *

We hope this summary was helpful to you. Please do not hesitate to reach out with any questions.

ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: August 2, 2022

RE: Rural Hospital Policies included in the FY 2023 IPPS Final Rule (CMS-1771-F)

On August 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released a final rule entitled, Medicare 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 2023 Rates; etc.[1]

This memorandum summarizes proposed and finalized policy changes relating to rural hospitals. **This rule is effective October 1, 2022.**

I. Critical Access Hospitals (CAHs)

a. Frontier Community Health Integration Project (FCHIP) Demonstration

FCHIP is a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. Eligible entities are CAHs that are located in a state in which at least 65 percent of the counties in the state are counties that have six or less residents per square mile. FCHIP was extended under the *Consolidated Appropriations Act, 2021*. For the FY 2023 proposed rule, CMS proposed to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period to be used for the demonstration extension period.

Final Rule: Finalized as proposed.

b. CAH infection prevention and control CoP requirements

CMS proposed to continue COVID-19 reporting requirements for CAHs with the conclusion of the current COVID-19 Public Health Emergency (PHE) declaration or the effective date of the IPPS proposed rule, whichever is later, and lasting until April 30, 2024. In addition, CMS proposed to establish reporting requirements for future PHEs related to epidemics and pandemics by requiring hospitals and CAHs to electronically report information on Acute Respiratory Illness (including Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), COVID-19, and other viral and bacterial pathogens or infectious diseases. This data collection would only occur when the Department of Health and Human Services (HHS) Secretary has declared a PHE.

[1] Full text of the final rule can be found here: https://public-inspection.federalregister.gov/2022-16472.pdf

Final Rule: Finalized as proposed.

CMS proposed that the categories of data elements that hospitals and CAHs report would include: suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff; total deaths attributed to the relevant infectious disease pathogen among patients and staff; personal protective equipment and other relevant supplies in the facility; and capacity and supplies in the facility relevant to the immediate and long term treatment of the relevant infectious disease pathogen; relevant therapeutic inventories and/or usage; isolation capacity, including airborne isolation capacity; and key co-morbidities and/or exposure risk factors of patients being treated for the pathogen or disease of interest. The reporting entity would be required to provide person-level information that includes a medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients. The reporting would also be required daily unless otherwise specified by HHS.

Final Rule: CMS has withdrawn its proposal to establish additional data reporting requirements to address future PHEs related to epidemics and infectious diseases. CMS agreed with commenters that additional consideration is necessary to fully establish a long-term solution for ensuring the preparedness of the healthcare system in the event of another PHE. CMS believes that continued collaboration among government and interested parties would be beneficial to standardize and streamline data reporting to lessen the burden on facilities, particularly during emergencies when resources are stretched and patient care-related work demands are increased.

c. Changes to the Medicare Promoting Interoperability Program for Eligible Hospitals and CAHs

CMS proposed several changes for CAHs that are part of the Medicare Promoting Interoperability Program. One is to require and modify the Electronic Prescribing Objective's Query of PDMP measure while maintaining the associated points at 10 points beginning with the electronic health record (EHR) reporting period in CY 2023. CMS proposed to expand the Query of PDMP measure to include Schedule II, III, and IV drugs beginning with the CY 2023 EHR reporting period. CMS also proposed to add a new Health Information Exchange (HIE) Objective option, the Enabling Exchange Under Trusted Exchange Framework and Common Agreement (TEFCA) measure (requiring a yes/no response) beginning with the CY 2023 EHR reporting period.

Final Rule: Finalized as proposed.

CMS proposed to modify the Public Health and Clinical Data Exchange Objective by adding an Antibiotic Use and Resistance (AUR) measure, in addition to the current four required measures, beginning in the CY 2023 EHR reporting period.

Final Rule: CMS is delaying implementation of this proposal until CY 2024. CMS agreed with commenters that more time may be beneficial for eligible hospitals and CAHs to implement the necessary infrastructure to implement the AUR measure.

CMS proposed to consolidate the current options from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective and to require the reporting of active engagement for the measures beginning with the CY 2023 EHR reporting period.

Final Rule: CMS is delaying implementation of this proposal until CY 2024. CMS believes delaying implementation will balance the need to move eligible hospitals and CAHs into data production with the need identified by the commenters for additional time for public health agencies and health care providers to prepare for this change.

CMS proposed to institute public reporting of certain Medicare Promoting Interoperability Program data beginning with the CY 2023 EHR reporting period. CMS proposed to modify the scoring methodology for the Promoting Interoperability Program beginning in the CY 2023 reporting period.

Final Rule: Finalized as proposed.

CMS also proposed to adopt four electronic clinical quality measures (eCQMs). Two would be adopted for the 2023 reporting period and two for the 2024 reporting period. In 2023, the Severe Obstetric Complications eCQM, which would begin with the CY 2023 reporting period, followed by mandatory reporting for the CY 2024 reporting period. The Cesarean Birth (ePC-02) eCQM would begin in the CY 2023 reporting period followed by mandatory reporting in the CY 2024 reporting period. In 2024, the Hospital-Harm—Opioid-Related Adverse Events eCQM and Global Malnutrition Composite Score eCQM would be adopted. Additionally, CMS proposed a modification to eCQM reporting and submission requirements whereby CMS is increasing the total number of eCQMs to be reported from four to six eCQMs beginning with the CY 2024 reporting period.

Final Rule: Finalized as proposed.

II. Rural Referral Centers (RRCs)

a. Annual Updates to Case-Mix Index (CMI) and Discharge Criteria

RRCs are not subject to the 12 percent cap on Disproportionate Share Hospital (DSH) payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area where the hospital is located. A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites, a minimum case-mix index (CMI) and a minimum number of discharges, as well as at least one of three optional criteria relating to specialty composition of medical staff, source of inpatients, or referral volume.

CMS proposed that if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2022, they must have a CMI value for FY 2021 that is at least 1.8262 (national--all urban) or the median CMI value (not transfer-adjusted) for urban hospitals.

Final Rule: Finalized as proposed.

For purposes of qualifying for RRC status, the national threshold is set at 5,000 discharges. To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2022, a hospital must have at least 5,000 (3,000 for an osteopathic hospital) discharges or the median number of discharges for urban hospitals in the census region in which the hospital is located. CMS will be using the data for FY 2020 as the best available data for the purposes of FY 2023 rulemaking.

III. Medicare Disproportionate Share Hospitals (DSHs)

CMS provides additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. A hospital can qualify for the Medicare disproportionate

share hospital (DSH) adjustment by being located in an urban area and have 100 or more beds if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from state and local government payments for care furnished to patients with low incomes. Hospitals can also qualify based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the "Medicare fraction" and the "Medicaid fraction."

a. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Starting in FY 2014, Medicare DSHs began receiving 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments previously. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH receives an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs.

CMS proposed to continue using uninsured estimates produced by CMS's Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) along with more recently available data in the calculation of Factor 2. For FY 2023, CMS proposed to use the two most recent years of audited data on uncompensated care costs from Worksheet S–10 of the FY 2018 cost reports and the FY 2019 cost reports to calculate Factor 3 in the uncompensated care payment methodology for all eligible hospitals. In addition, for FY 2024 and subsequent fiscal years, CMS proposed to use a three-year average of the data on uncompensated care costs from Worksheet S-10 for the three most recent fiscal years for which audited data are available.

Final Rule: Finalized as proposed.

CMS also proposed to revise the regulation for the calculation of the Medicaid fraction of the DSH calculation. Under the proposal, CMS would revise their interpretation of individuals regarded as eligible for medical assistance under a state plan approved under title XIX. The revision would change to interpretation of eligibility to mean patients who receive health insurance authorized by a section 1115 demonstration or patients who pay for all or substantially all of the cost of health insurance with premium assistance authorized by a section 1115 demonstration, where state expenditures to provide the health insurance or premium assistance may be matched with funds from Title XIX. Additionally, CMS proposed to include in the Medicaid fraction only the days of those patients who obtain health insurance directly or with premium assistance that provides essential health benefits (EHB) for an Alternative Benefit Plan (ABP), and for patients obtaining premium assistance, only the days of those patients for which the premium assistance is equal to or greater than 90 percent of the cost of the health insurance, provided the patient is not also entitled to Medicare Part A.

Final Rule: CMS decided not to go forward with its proposal following many comments from the public. CMS expects to revisit the treatment of section 1115 demonstration days for purposes of the DSH adjustment in future rulemaking.

IV. Medicare-Dependent, Small Rural Hospital (MDH) Program

a. Changes in the MDH Program

Under the IPPS, MDHs have been provided special payment protections that will expire at the end of FY 2022. Beginning with discharges occurring on or after October 1, 2022, all hospitals that previously qualified for MDH status will be paid based on the Federal rate.

CMS allows MDHs to apply for sole community hospital (SCH) status in advance of the expiration of the MDH program and be paid as such under certain conditions. For an MDH to receive SCH status effective October 1, 2022, the MDH must apply for SCH status at least 30 days before the expiration of the MDH program. CMS proposed that if the MDH program is extended by law as it has been before, CMS would make conforming changes to the regulations governing the MDH program and the general payment rules to reflect an extension of the MDH program.

Final Rule: Since there has been no change in law to extend the MDH program past October 1, 2022, CMS is not proposing to make any conforming changes to the rules governing the MDH program.

V. Rural Community Hospital Demonstration (RCHD) Program in FY 2023.

a. Methodology for Estimating Demonstration Costs for FY 2023

The RCHD program pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries.

CMS is using a methodology to estimate demonstration costs similar to previous years, in which an estimate of the costs of the demonstration for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for fiscal year 2023. CMS is conducting an FY 2023 estimate based on the 26 hospitals that are continuing participation in the demonstration for FY 2023.

b. Reconciling Actual and Estimated Costs of the Demonstration for Previous Years

For the FY 2023 proposed rule, CMS is including the actual costs of the RCHD demonstration as determined from finalized cost reports for FY 2017 within the budget neutrality offset amount for this upcoming fiscal year. CMS acknowledged that cost reports may change based on revised resettlements by Medicare Administrative Contractors (MACs). CMS proposed that if there is a resettlement of the FY 2017 finalized cost reports occurs ahead of the FY 2023 IPPS final rule, CMS would adjust the amount for the actual costs of the demonstration for FY 2017 when compiling the total budget neutrality offset amount for the FY 2023 final rule.

Final Rule: The FY 2023 budget neutrality offset is based on two amounts: the difference applicable to FY 2023 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration for covered inpatient services to the 26 hospitals participating in the fiscal year and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $72,449,896. Additionally, the budget neutrality offset is determined by the amount by which the actual costs of the demonstration in FY 2017 exceed the estimated amount identified in the FY 2017. The amount of the difference is $35,989,928. Therefore, CMS is subtracting the sum of these amounts ($108,439,824) from the national IPPS rates for FY 2023.