ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: May 3, 2022

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

On April 18, 2022, Centers for Medicare & Medicaid Services (CMS) released a proposed rule with comment period entitled, *"Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) and Proposed Policy Changes and Fiscal Year 2023 Rates"* (proposed rule).[1] This memorandum summarizes the policy changes related to new technology add-on payments (NTAPs) and other drug- and device-related policies. **Comments on the proposed rule are due by 5 p.m. EDT on June 17, 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 proposed status for FY 2023, and **Appendix B** for a complete list of new applications for FY 2023 NTAPs.

[1] The proposed rule is available here: https://public-inspection.federalregister.gov/2022-08268.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 is not proposing any further extensions of NTAPs for FY 2023. Specifically, CMS proposes 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 proposed status for FY 2023.

CMS seeks 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 seeks 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.

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.

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

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

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 argue 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 proposes to use NDCs rather than Section X codes to identify therapeutic agents eligible for NTAPs beginning in FY 2024. For FY 2023, CMS proposes 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 will 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.

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 proposes 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 notes that applicants should not submit any proprietary or trade secret information they do not want published online, but notes that CMS generally does not consider such information when determining NTAP status.

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 notes 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:

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
	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 proposes 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 proposes 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 estimates 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 proposes to adjust the transfer-adjusted case count for MS-DRG 018 by applying the proposed adjustor of .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 will update the value of the adjustor based on more recent data for the final rule.

Finally, we note that 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).

* * *

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

Proposed 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

Proposed 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**	**Proposed 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*
Proposed FY 2023 NTAP Applications (Traditional Pathway)	
CARVYKTI (ciltacabtagene autoleucel)	Janssen Biotech
DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)	Janssen Biotech
Hemolung Respiratory Assist System (Hemolung RAS)	ALung Technologies, Inc.
Lifileucel	Iovance Biotherapeutics
LIVTENCITY™ (maribavir)	Takeda Pharmaceuticals
Mosunetuzumab	Genentech
Narsoplimab	The Omeros Corporation
Spesolimab	Boehringer Ingelheim
Teclistamab	Johnson & Johnson
TERLIVAZ® for injection (terlipressin)	Mallinckrodt Pharmaceuticals
Treosulfan	Medexus Pharma
UPLIZNA® (inebilizumab-cdon)	HTI-DAC
XENOVIEW (hyperpolarized Xenon-129 [$HP^{129}Xe$] gas for inhalation)	Polarean, Inc.
Proposed FY 2023 NTAP Applications (Alternative Pathways)	
Alternative Pathway for Breakthrough Devices	
CERAMENT® G	BONESUPPORT AB
GORE® TAG® Thoracic BranchEndoprosthesis (TBE device)	W.L. Gore and Associates, Inc.
iFuse Bedrock Granite Implant System	SI-BONE, Inc.
LigaPASS 2.0 PJK Prevention System	Medtronic
Magnus Neuromodulation System with SAINT Technology	Magnus Medical, Inc.
Nelli® Seizure Monitoring System	Neuro Event Labs, Inc.
Phagenyx® System	Phagenesis Ltd.
Precision TAVI™ Coronary Obstruction Module	DASI Simulations
Thoraflex™ Hybrid Device	Terumo Aortic
TOPS™ System	Premia Spine, Inc.
VITARIA® System	LivaNova, PLC
ViviStim® Paired VNS System	MicroTransponder, Inc.
Alternative Pathways for Qualified Infectious Disease Products (QIDPs)	
DefenCath™ (solution of taurolidine (13.5 mg/mL) and heparin (1000 USP Units/mL))	CorMedix Inc.

ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: April 20, 2022

RE: A&B Summary – FY 2023 IPPS Proposed Rule: Provisions Relating to Ambulances

On April 18, 2022, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule with comment period entitled, "*Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) and Proposed Policy Changes and Fiscal Year 2023 Rates*" (proposed rule).[1]

This memorandum summarizes the proposed policy changes relating to ambulance services. **Comments to the proposed rule are due no later than June 17, 2022.**

I. Critical Access Hospitals Frontier Community Health Integration Project Demonstration

The Frontier Community Health Integration Project (FCHIP) Demonstration allows eligible critical access hospitals (CAHs) to develop and test new models for delivering health care services to Medicare beneficiaries, with the purpose of improving access to and integration of delivery of care. CMS selected CAHs to participate in four interventions with waivers that allowed for enhanced payment for telehealth, skilled nursing facility and unskilled nursing facility beds, ambulance services, and home health services. Several CAHs elected to participate in the ambulance services intervention in the initial period, which ended on July 31, 2019, and three CAHs elected to participate in the ambulance services intervention during the extension period, which is currently ongoing.

Specifically for the ambulance services intervention, CMS waives requirements that ambulance services furnished by a CAH or a CAH-operated entity are paid 101 percent of the reasonable costs of furnishing the ambulance services only if the CAH or CAH-operated entity is the only authorized provider or supplier of ambulance services within 35 miles. Under the waiver, the participating CAH is paid 101 percent of reasonable costs of furnishing ambulance services regardless of whether there are other providers or suppliers of ambulance services within 35 miles. However, CMS would not make payments to participating CAHs for new capital, such as vehicles, associated with ambulance services. Notably, this waiver does not modify any other Medicare rules relating to the provision of ambulance services.

CMS proposes to continue implementing the five-year extension period of this demonstration project with the same budget neutrality methodology and analytical approach as it used in the demonstration's initial period. CMS may update or modify the FCHIP budget neutrality methodology and analytical approach after receiving data from the extension period.

* * *

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

[1] Full text of the proposed rule can be found here: https://public-inspection.federalregister.gov/2022-08268.pdf

ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: April 26, 2022

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

On April 18, 2022, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule with comment period entitled, "*Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) and Proposed Policy Changes and Fiscal Year 2023 Rates*" (proposed rule).[1] This memorandum summarizes the proposed policy changes relating to indirect medical education (IME) and direct graduate medical education (DGME). **Comments on the proposed rule are due by 5 p.m. EDT on June 17, 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. Proposed 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 is proposing to establish a modified policy applicable to all teaching hospitals, retroactively effective as of October 1, 2001. CMS notes this would replace the existing policy at 42 CFR 413.79(c)(2)(iii). CMS notes that this retroactive proposal would cover cost reporting periods for which many Notice of Program Reimbursements (NPRs) have been settled. CMS is not aware

[1] Full text of the proposed rule can be found here: https://public-inspection.federalregister.gov/2022-08268.pdf

of any 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 welcomes comments notifying it of such NPRs.

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 proposes 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 proposes 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)).

Furthermore, CMS proposes 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.

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

CMS proposes 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.

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

CMS proposes 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 believes 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 proposes 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 proposes 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)

c. Proposal to Allow Medicare GME Affiliation Agreements Within Certain Rural Track FTE Limitations

CMS proposes 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 proposes 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 notes the Rural Track Medicare GME Affiliation Agreements will be structured similarly to Medicare GME Affiliation Agreements, but CMS highlights two proposed distinct requirements. First, CMS proposes 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 FTE caps associated with programs other than the RTP. Second, CMS proposes 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.

CMS proposes 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

[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 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.

CMS proposes 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 proposes that eligible urban and rural hospitals may enter into Rural Track Medicare GME Affiliation Agreements effective with the July 1, 2023, academic year.

III. Proposed 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.

* * *

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: April 20, 2022

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

On April 18, 2022, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule with comment period entitled, "*Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) and Proposed Policy Changes and Fiscal Year 2023 Rates*" (proposed rule).[1]

This memorandum summarizes the proposed policy changes relating to maternal health and health equity. **Comments to the proposed rule are due no later than June 17, 2022.**

I. Key Proposed 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. CMS intends to promote policies that ensure Americans living in rural areas have access to high quality health care, particularly maternal health care. Americans in rural areas have a nine percent greater probability of experiencing SMM and maternal mortality compared to Americans in urban areas.

Currently, CMS's Hospital Inpatient Quality Reporting (IQR) Program includes the Elective Delivery measure and the Maternal Morbidity Structural measure, which are intended to address maternal health. Pursuant to current Electronic Clinical Quality Measures (eCQM) reporting and submission requirements, hospitals must report on three self-selected eCQMs as well as the Safe Use of Opioids—Concurrent Prescribing eCQM. However, CMS states that neither measure directly addresses factors contributing to maternal mortality rates, such as the high rates of Cesarean sections (C-sections) in the U.S. or maternal

[1] Full text of the proposed rule can be found here: https://public-inspection.federalregister.gov/2022-08268.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

morbidity and obstetric complications outcomes. As such, CMS proposes to establish additional measures that address these factors and mandate reporting on these measures.

b. Proposed Adoption of Cesarean Birth and Severe Obstetric Complications eCQMs

i. Proposed Cesarean Birth eCQM

CMS proposes 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 proposes 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.

ii. Proposed Severe Obstetric Complications eCQM

CMS proposes 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 proposes 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. 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.

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

CMS proposes 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.

d. Proposed 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 proposes to establish a maternity care quality hospital designation, which would be publicly reported on CMS's website beginning in Fall 2023. CMS proposes 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 requests public comment on the designation name and additional data sources to consider for awarding this designation.

e. Request for Information to Advance Maternal Health Equity

CMS seeks to understand how to address the U.S. maternal health crisis through policies and programs to advance equity for all. Specifically, CMS seeks 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 seeks to explore how to improve measures in CMS quality reporting programs to address maternal health inequities. Specifically, CMS requests stakeholders respond to several questions as part of the Request for Information (see Appendix, Section I for more information).

II. Additional Proposed 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. Proposed Health Equity-Focused Measures in the Hospital IQR Program

i. Proposed Hospital Commitment to Health Equity Measure

CMS identifies hospital leadership as an important factor in promoting better quality care, improved patient outcomes, increased safety, and positive patient experience. CMS proposes 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.

ii. Proposed Measures to Improve Screening for Social Drivers of Health

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 proposes 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 proposes 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.

c. Proposed Supplemental Payment for Indian Health Service, Tribal Hospitals, and Puerto Rico Hospitals

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 this proposed rule, CMS proposes to modify its methodology in calculating DSH and uncompensated care payments. Notably, CMS proposes 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. However, 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 and may be disproportionately impacted by these changes.

In response, CMS proposes 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 proposes 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.

d. Proposed Approaches to Addressing Drivers of Health Care Quality Disparities and Developing Measures of Healthcare Equity in the LTCH QRP

i. Proposed Approach to Identify Potential Drivers of Quality Disparities

Currently, long-term care hospitals (LTCHs) must attempt to identify factors they believe are causing performance gaps and health care disparities, and LTCHs are responsible for developing strategies to address them with little guidance. CMS proposes to use already available enrollment, claims, and assessment data to help LTCHs better estimate the impact of various SDOH on health disparities. To do so,

CMS proposes to use a regression decomposition method to estimate the extent to which disparities in measure performance between patient populations can be attributed to specific clinical or non-clinical factors. The regression decomposition could also identify and calculate the specific impact of SDOHs and other factors on disparities. CMS proposes to use the results to inform CMS's understanding of how to narrow gaps in health care outcomes. CMS also proposes to share the results with providers to help LTCHs better address the disparities within their facilities with targeted prioritization of certain performance areas.

ii. Proposed Measures of Equity for Inclusion in LTCH QRP

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 proposes that some measures could be adapted for use in the LTCH QRP. In particular, CMS proposes 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.

iii. Request for Information on LTCH QRP Quality Measure Concepts under Consideration for Future Years

CMS issued a Request for Information regarding these principles and proposed approaches for the LTCH QRP, as well as additional conceptual and measurement priorities for the LTCH QRP to assess organizational commitment to health equity. Specifically, CMS seeks input on the importance, relevance, and applicability of the future quality measures under consideration for the LTCH QRP. In particular, CMS seeks input on measures of health equity, such as measures that assess leadership's investment in advancing equity goals or progress towards achieving equity priorities. (See Appendix, Section III for more information.)

e. Request for Information on Reporting Social Determinants of Health

CMS seeks 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 seeks 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 requests stakeholders respond to a series of specific questions (see Appendix, Section II for more information). CMS intends to use the feedback in designing future payment policies. Specifically, CMS asks whether it should consider requiring more robust documentation and claims data reporting of SDOH. CMS also requests 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 seeks comment on which SDOH codes are most likely to increase hospital inpatient care resource utilization. In particular, CMS proposes understanding the impact of homelessness on health.

f. Additional Requests for Information Relating to Health Equity

In addition to the Requests for Information detailed in this memorandum, CMS issued several additional Requests for Information relating to health equity. See Appendix, Section IV-VII for more information.

* * *

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

Appendix – Requests for Information (RFIs)

I. Request for Information to Advance Maternal Health Equity

CMS requests public comment on the following questions:

- CMS outlines best practices in the memorandum to state survey agencies entitled "Evidence-Based Best Practices for Hospitals in Managing Obstetric emergencies and Other Key Contributors to Maternal Health Disparities." What other additional effective best practices or quality improvement initiatives are currently being utilized by hospitals? How else can hospitals improve maternal health outcomes, enhance their quality of maternity care, and reduce maternal health disparities?
- For hospitals that offer inpatient maternity services, how could the CoPs be modified to improve maternity care and address disparities in maternal health outcomes? How would hospitals focus their governance, provider and staff training, and care-delivery activities to effectively demonstrate compliance with CoPs related to improving maternal health outcomes? What types of measurable activities targeting maternal health outcomes might demonstrate a reduction in maternal health care disparities or improvement in maternal health care delivery?
- Are there new requirements that could be established in the CoPs that would require hospitals to address and improve the quality of postpartum care and support provided to patients? How can the CoPs specifically address the need to improve behavioral health services and monitoring offered during prenatal and postpartum care?
- Might the potential additional maternal health-focused CoPs have unintended consequences on providers with certain characteristics (such as being located in a rural area or having low-volume)? Are there barriers or facilitators that would influence rural hospital achievement of a publicly-reported maternal health designation that may not relate directly to the quality of services provided? How might maternal health CoPs impact providers considering whether it is feasible or viable to offer labor and delivery services in their area?
- What services and staff training should hospitals without inpatient maternity services have in place in preparation for patients in labor?
- What are the best practices that hospitals are utilizing to educate and conduct outreach to patients in underserved communities to increase access to timely maternity care?
- What are best practices for hospitals to actively engage with patients and their families, community-based organizations, and others within their local community to obtain information on ways to improve maternity care? Are there barriers to such engagement (if so, what are the barriers)?
- Do hospitals provide prevention-related education and community outreach on the specific maternal health conditions that have the greatest impact on disadvantaged and underserved communities?
- How can hospitals review and monitor aggregate data on the maternal health risks of the patient population that they serve? What data should hospitals review related to the maternal health risks of the patient population they serve? What data sharing best practices are required for hospitals to share data with external entities, including local and state health departments, community-based organizations, or other health care providers? How can hospitals connect data collected for mothers and their babies after delivery to support research and evaluation of maternal health care after delivery?
- What challenges are there to collecting data on patients with specific maternal health risks? Can these data be stratified by demographics (for example, race and ethnicity)? In addition, how can these data be used in a hospital's quality improvement efforts, and specifically, in their quality assurance and performance improvement (QAPI) program, to improve maternal health outcomes and advance health equity and reduce disparities within their facility? How can maternity care be incorporated into an ongoing QAPI program?
- How do hospitals conduct reviews of maternal deaths that have occurred within the facility?

- Are hospitals currently utilizing community health needs assessments to determine the specific maternity care needs and social determinants of health of the patient population that they serve? For those hospitals that are utilizing community health needs assessments, are there certain best practices or examples of ways that this assessment can be used to reduce disparities in maternal outcomes?
- Do hospitals have reporting relationships or mechanisms among primary care physicians, obstetrician-gynecologists, and other healthcare providers such as nurses and certified nurse midwives, and community-based perinatal workers, such as doulas, for optimal coordination of care?
- Do hospitals have readily available referral relationships and points of contact with community resources or community-based organizations to address additional services that a postpartum patient may need upon discharge? This could include the consideration of behavioral and mental health services or resources to address health-related social needs, such as food insecurity, housing instability, and transportation challenges. If hospitals do not have readily available referral relationships and points of contact within the community, what barriers and facilitators impact hospital relationships with community resources or community-based organizations?
- How do hospitals evaluate their perinatal customer experience? What are best practices that are currently being utilized for getting robust input from patients on their perinatal experience?
- What best practices exist for ensuring systemic racism and biases, including implicit bias, are not perpetuated in maternity care?

II. Request for Information on Reporting Codes for Social Determinants of Health

CMS requests comment on the 96 diagnosis codes that currently describe SDOH.[3] CMS also requests comment on the following questions:

- How the reporting of certain Z codes – and if so, which Z codes24 - may improve our ability to recognize severity of illness, complexity of illness, and utilization of resources under the MS-DRGs?
- Whether CMS should require the reporting of certain Z codes – and if so, which ones – to be reported on hospital inpatient claims to strengthen data analysis?
- The additional provider burden and potential benefits of documenting and reporting of certain Z codes, including potential benefits to beneficiaries.
- Whether codes in category Z59 (Homelessness) have been underreported and if so, why? In particular, we are interested in hearing the perspectives of large urban hospitals, rural hospitals, and other hospital types in regard to their experience. We also seek comments on how factors such as hospital size and type might impact a hospital's ability to develop standardized consistent protocols to better screen, document and report homelessness.

III. Request for Information on LTCH QRP Quality Measure Concepts under Consideration for Future Years

CMS requests comments on the following topics:

- *Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Reporting Programs –*
    - The use of the within- and between-hospital disparity methods in LTCHs to present stratified measure results;

[3] Full list of CMS IPPS diagnosis codes can be found here: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS

    - The use of decomposition approaches to explain possible causes of measure performance disparities; and
    - Alternative methods to identify disparities and the drivers of disparities.
- *Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting –*
    - Principles to consider for prioritization of health equity measures and measures for disparity reporting, including prioritizing stratification for validated clinical quality measures, those measures with established disparities in care, measures that have adequate sample size and representation among healthcare providers and outcomes, and measures of appropriate access and care.
- *Principles for Social Risk Factor and Demographic Data Selection and Use –*
    - Principles to be considered for the selection of SRFs and demographic data for use in collecting disparity data including the importance of expanding variables used in measure stratification to consider a wide range of SRFs, demographic variables, and other markers of historic disadvantage. In the absence of patient-reported data, CMS will consider use of administrative data, area-based indicators, and imputed variables as appropriate.
- *Identification of Meaningful Performance Differences –*
    - Ways that meaningful difference in disparity results should be considered.
- *Guiding Principles for Reporting Disparity Measures –*
    - Guiding principles for the use and application of the results of disparity measurement.
- *Measures Related to Health Equity –*
    - The usefulness of a HESS score for LTCHs, both in terms of provider actionability to improve health equity, and in terms of whether this information would support Care Compare website users in making informed healthcare decisions.
    - The potential for a structural measure assessing an LTCH's commitment to health equity, the specific domains that should be captured, and options for reporting these data in a manner that would minimize burden.
    - Options to collect facility-level information that could be used to support the calculation of a structural measure of health equity.
    - Other options for measures that address health equity.

Notably, CMS will not respond to specific comments submitted in response to this Request for Information in the FY 2023 IPPS/LTCH PPS final rule. However, CMS states that it will consider all stakeholder input when developing future regulatory proposals or policy guidance.

IV. Request for Information on Inclusion of Health Equity Performance in the Hospital Readmissions Reduction Program

The Hospital Readmissions Reduction Program currently groups hospitals into peer groups based on their proportion of dually eligible beneficiaries for Medicare and Medicaid, which is a widely used and accepted proxy for a beneficiary's financial risk.

CMS seeks comment on approaches to update the Hospital Readmissions Reduction Program by including measures of hospitals' performance for socially at-risk populations across readmissions, treatment, or other measures. CMS intends to encourage providers to improve health equity and reduce health care disparities without disincentivizing or disproportionately penalizing hospitals that treat socially at-risk beneficiaries.

In particular, CMS is seeking comment on data variables associated with, or measures of, social risk and beneficiary demographics. CMS is also seeking comment on potentially broadening the definition of dual eligibility to include beneficiaries enrolled in a Medicare Savings Program or the Medicare Part D Low Income Subsidy. CMS requests that comments include information about publicly available data sources and methodologies used to calculate social risk.

V. Request for Information: Current Assessment of Climate Change Impacts on Outcomes, Care, and Health Equity

CMS seeks comment on the following:

- How hospitals, nursing homes, hospices, home health agencies, and other providers can better prepare for the harmful impacts of climate change on their patients, and how CMS can support them in doing so.
- What the U.S. Department of Health and Human Services (HHS) and CMS can do to support hospitals, nursing homes, hospices, home health agencies, and other providers in more effectively:
    - (a) determining likely climate impacts (that is, both immediate impacts associated with climate-related disasters and long-term chronic disease implications of climate change) on their patients, residents and consumers so that they can develop plans to mitigate those impacts;
    - (b) understanding exceptional threats that climate-related emergencies (for example, storms, floods, extreme heat, wildfires) present to continuous facility operations (including potential disruptions in patient services associated with catastrophic events as a result of power loss, limited transportation, evacuation challenges, etc.) so they can better address those; and
    - (c) understanding how to take action on reducing their emissions and tracking their progress in this regard.

CMS also requests public comments on the following topics:

- The availability of information, such as analyses of climate change impacts (whether developed internally or collected from outside sources), that hospitals, nursing homes, hospices, home health agencies, and other providers can access to better understand climate threats to their patients, community, and staff.
- The degree to which different provider types currently complete comprehensive climate change risk assessments to better understand risks to their patient populations and the costs incurred due to catastrophic climate events and climate-related chronic disease.
- The degree to which facility efforts to prepare for climate impacts overlap with the work they already complete to meet CMS's Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, and the degree to which related CMS requirements sufficiently (or insufficiently) prepare them for the threats created by climate change and help or hinder these efforts.
- The degree to which hospitals, nursing homes, hospices, home health agencies, and other providers measure and share performance associated with their response to climate-related catastrophes (for example, measuring harm to vulnerable populations as a result of such events, or extent of disruption in service).
- The nature of facility plans for assisting the community and patients to prepare for and recover from climate-related events, as well as the nature of plans for evacuating patients with differing needs, including those with disabilities.
- The degree to which climate change, and climate change linked to health equity, is publicly addressed in strategic plans and objectives in your facility or system, and the degree to which hospital leadership regularly reviews progress on goals related to climate preparedness and mitigation and invests in health professional training on this topic.
- Whether health systems and facilities have time-bound, public aims for GHG emissions reduction, and, if yes, whether those aims relate to direct facility emissions, emissions associated with purchased energy, emissions associated with supply chain or some combination of these.
- The measures that health systems and facilities use to track their progress on GHG emissions reduction and use of renewable energy, as well as the data collection tools that they may use support this tracking.

- The tools and supports that health systems and facilities most heavily rely on to support their efforts to reduce GHG emissions.
- How HHS and CMS can support hospitals, nursing homes, hospices, home health agencies, and other providers in their efforts to more fully prepare for climate change's catastrophic and chronic impacts on their operations and the people they serve, as well as what incentives (for example, recognition, payment, reporting) might assist them in taking more action on climate readiness and emissions reduction.
- Whether accrediting organizations assess facilities' readiness for climate-related threats and their efforts to reduce GHG emissions.

VI. Request for Information: Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

CMS requests comments on key considerations in five specific areas:

- Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Programs – identifying potential approaches for measuring healthcare disparities through measure stratification in CMS quality reporting programs;
- Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting Across CMS Quality Reporting Programs – describing considerations that could inform the selection of healthcare quality measures to prioritize for stratification;
- Principles for Social Risk Factor and Demographic Data Selection and Use – describing several types of social risk factor and demographic data that could be used in stratifying measures for healthcare disparity measurement;
- Identification of Meaningful Performance Differences – describing several strategies for identifying meaningful differences in performance when measure results are stratified; and
- Guiding Principles for Reporting Disparity Results – describing considerations CMS could take into account in determining how quality programs will report measure results stratified by social risk factors and demographic variables to healthcare providers, as well as the ways different reporting strategies could hold healthcare providers accountable for identified disparities.

CMS also invites stakeholders to submit additional comments about disparity measurement or stratification guidelines suitable for overarching consideration across CMS quality programs.

CMS further requests comments on the following topics:

- Overarching goals for measuring disparity that should be considered across CMS quality programs, including the importance of pairing stratified results with overall measure quality programs, including the importance of pairing stratified results with overall measurer 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.
- 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.

- Guiding principles for the use and application of the results of disparity measurement such as providing confidential reporting initially.

VII. Request for Information: Overarching Principles for Measuring Equity and Healthcare Quality Disparities across CMS Quality Programs

a. Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification across CMS Quality Programs

CMS requests feedback on several systematic principles under consideration to better prioritize measures for disparity reporting across programs:

- Programs may consider stratification, among existing *clinical quality measures for further disparity reporting*, prioritizing recognized measures which have met industry standards for measure reliability and validity.
- Programs may consider measures for prioritization that show *evidence that a treatment or outcome being measured is affected by underlying healthcare disparities* for a specific social or demographic factor. Literature related to the measure or outcome should be reviewed to identify disparities related to the treatment or outcome, and should carefully consider both SRFs and patient demographics. In addition, analysis of Medicare-specific data should be done in order to demonstrate evidence of disparity in care for some or most healthcare providers that treat Medicare patients.
- Programs may consider establishing *statistical reliability and representation standards* (for example, the percent of patients with a SRF included in reporting facilities) prior to reporting results. They may also consider prioritizing measures that reflect performance on greater numbers of patients to ensure that the reported results of the disparity calculation are reliable and representative.
- After completing stratification, programs may consider prioritizing the *reporting of measures that show differences in measure performance* between subgroups across healthcare providers.

b. Identifying Meaningful Performance Differences

CMS also requests feedback on the benefits and limitations of the possible reporting approaches described below:

- *Statistical approaches* could be used to reliably group results, such as using confidence intervals, creating cut points based on standard deviations, or using a clustering algorithm.
- Programs could use a *ranked ordering and percentile approach*, ordering providers in a ranked system based on their performance on disparity measures to quickly allow them to compare their performance to other similar providers.
- LTCHs could be categorized into groups based on their performance using *defined thresholds*, such as fixed intervals of results of disparity measures, indicating different levels of performance.
- *Benchmarking*, or comparing individual results to a state or national average, is another potential reporting strategy.
- Finally, a ranking system is not appropriate for all programs and health care settings, and some programs may *only report disparity results*.

ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: April 27, 2022

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

On April 18, 2022, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule with comment period entitled, "*Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) and Proposed Policy Changes and Fiscal Year 2023 Rates*" (proposed rule).[1]

This memorandum summarizes the proposed 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.

Comments to the proposed rule are due no later than 5:00 pm EDT on June 17, 2022.

[1] Full text of the proposed rule can be found here: https://public-inspection.federalregister.gov/2022-08268.pdf

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

a. Overview of Proposed 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 include 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. Proposals to Suppress Specific Measures for the FY 2023 Program Year

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 proposes 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 proposes 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 is proposing 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 welcomes public comment on this proposal.

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

CMS proposes 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 proposes 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 proposes 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 is proposing 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 proposes 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 proposes 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 is proposing to suppress the CY 2021 HAI measure data to address the impact of the ongoing COVID-19 PHE on HAI incidence

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

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

CMS proposes to use a special rule for FY 2023 scoring. Specifically, CMS proposes 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 proposes 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 proposes 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 invites public comment on the proposals.

c. Retention and Removal of Quality Measures

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

CMS proposes to suppress the HCAHPS and HAI measures for the FY 2023 program year. CMS notes it is not currently proposing to add new measures. CMS notes that if these measure suppression proposals are 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:

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).

d. Previously Adopted Baseline and Performance Periods

i. Proposal to Update 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 is proposing to suppress the HCAHPS and five HAI measures for the purposes of scoring and payment for FY 2023, the agency is proposing several updates to the baseline periods in this proposed rule for the FY 2025 program year. CMS notes it is not proposing to update the baseline periods for certain measures under the Hospital VBP Program that have a 1-year baseline period.

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

CMS proposes 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.

3. Proposal to Update 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 is proposing to use a baseline period of January 1, 2019 through December 31, 2019 for the FY 2025 program year.

e. Performance Standards for the Hospital VBP Program

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

CMS establishes 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 is requesting 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 is also requesting information on the potential future inclusion of these digital CDC NHSN measures in the Hospital VBP Program.

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

Specifically, CMS seeks 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 invites 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. We also seek 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.

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 proposes 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. Proposals to Apply the Measure Suppression Policy to FY 2023 and FY 2024 HAC Reduction Program Years

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

CMS also proposes 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 proposes 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 proposes 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 is proposing 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 proposes 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 is also proposing 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 proposes 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.

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

CMS invites public comment on its proposals including the temporarily 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 proposes 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 invites public comments on the proposal to suppress CY 2021 CDC NHSN HAI Measure data from the FY 2024 HAC Reduction Program year.

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 notes 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 notes 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 requests 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 requests information on the potential inclusion of these digital CDC NHSN measures in the HAC Reduction Program.

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

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

Specifically, CMS seeks 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 invites 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. We also seek 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.

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

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

CMS notes 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.

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. Proposal to resume use 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 is proposing 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.

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 is proposing 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.

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 is modifying 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

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

CMS is seeking 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 is asking 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.

IV. Key Proposed Medicare Quality Data Reporting Policies

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

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

CMS proposes 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.

ii. Proposed Global Malnutrition Composite Score eCQM

Currently, CMS quality reporting programs do not include quality measures that specifically address malnutrition. In response, CMS proposes 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.

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

CMS proposes to adopt the 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 proposes 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.

iv. Proposed 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 proposes 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 proposes 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.

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

CMS proposes 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.

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

CMS proposes 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 proposes 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 proposes 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.

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

CMS proposes 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 proposes 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 proposes 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.

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

i. Proposal to Adopt a Patient Safety Exception to the Measure Removal Policy

CMS proposes 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*.

1. Proposal to Begin 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 proposes 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.

2. Proposal to Begin Public Display of the 30-Day Unplanned Readmissions for Cancer Patients Measure

CMS proposes 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.

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

i. Proposed 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 notes that all 50 states and several localities host PDMPs.

CMS proposes 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 proposes 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 proposes 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 proposes 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 invites public comment on these proposed changes and exclusions, as well as whether to include Schedule V or other drugs in this measure.

ii. Proposed 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 proposes to revise descriptions to reflect this change.

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 proposes 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 proposes 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 proposes 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 proposes that eligible hospitals and CAHs would report on this measure by attesting to certain criteria and use the capabilities of CEHRT.

iv. Proposed 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 proposes 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 proposes a new AUR Surveillance measure, in which the eligible hospital or CAH is actively engaging with the NHSN to submit AUR data. CMS proposes to require eligible hospitals and CAHs to report this measure beginning with the EHR reporting period in CY 2023. However, CMS also proposes 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 proposes that this measure must be calculated by reviewing all patient records.

v. Proposed 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 proposes to consolidate these options into two options to incentivize eligible hospitals and CAHs to move towards submitting production data. Specifically, CMS proposes 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 proposes 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 proposes 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.

vi. Proposed 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 proposes to require the Query of PDMP measure. In response, CMS proposes 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 proposes 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 proposes 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 proposes to reduce the points associated with the Provide Patients Electronic Access to Their Health Information measure.

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

viii. Proposed 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 proposes to align the eCQM reporting requirements for the Medicare Promoting Interoperability Program with similar requirements under the Hospital IQR Program. Specifically, CMS proposes 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 proposes 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.

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 invites 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?

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

CMS is proposing 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 seeks 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?

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 seeks 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 will 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 requests 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.

2. Inclusion in the LTCH QRP Measure Set

CMS requests 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 requests 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 will not be responding 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 requests 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.

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 requests feedback on potential data reporting formats for this measure.

vi. RFI on the Patient Access to Health Information Measure

CMS seeks 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 seeks 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?

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 revises the hospital and CAH CoPs for infection prevention and control and antibiotic stewardship programs. In particular, CMS proposes 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 this proposed rule until April 30, 2024. Specifically, CMS proposes 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. This proposed rule allows 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 proposes 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 proposes 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 establishes new reporting requirements to address future PHEs related to epidemics and pandemics. Specifically, CMS proposes 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 proposes to require reporting of specific data elements to CDC NHSN or other CDC surveillance systems.

CMS proposes 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 proposes that data reporting would be required in a standardized format providing person-level information and on a daily basis, unless specified otherwise.

* * *

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: April 20, 2022

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

On April 18, 2022, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule with comment period entitled, "*Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation (CMS-1771-P)".*[1]

This memorandum summarizes proposed policy changes relating to rural hospitals. **Comments to the proposed rule are due no later than June 17, 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 is proposing to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period to be used for the demonstration extension period.

b. CAH infection prevention and control CoP requirements

CMS is proposing 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 proposes 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] https://public-inspection.federalregister.gov/2022-08268.pdf

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.

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

CMS is proposing 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 is proposing to expand the Query of PDMP measure to include Schedule II, III, and IV drugs beginning with the CY 2023 EHR reporting period. CMS is also proposing 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. CMS is proposing 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. CMS is proposing 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. CMS is proposing to institute public reporting of certain Medicare Promoting Interoperability Program data beginning with the CY 2023 EHR reporting period. CMS is proposing to modify the scoring methodology for the Promoting Interoperability Program beginning in the CY 2023 reporting period.

CMS is also proposing the adoption of 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 is proposing 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.

II. Rural Referral Centers (RRCs)

a. Proposed 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 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 is proposing 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 1.8251 (national--all urban) or the median CMI value (not transfer-adjusted) for urban hospitals.

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)

a. Proposed 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 is proposing 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 is proposing 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 is proposing 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.

CMS is also proposing 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 proposes 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.

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

a. Proposed 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 is proposing 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.

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 proposes 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.