IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BLUE CROSS AND BLUE SHIELD OF FLORIDA, INC., *et al.*, Plaintiffs, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Case No. 24-3609

JOINT APPENDIX
VOLUME 1 OF 1, TABS 1-24

ADMINISTRATIVE RECORD

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ADMINISTRATIVE RULEMAKING RECORD

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3.	83 Fed. Reg. 54982, 55025-26 (Nov. 1, 2018)	0000044-45
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5.	83 Fed. Reg. at 55059	0000078
6.	83 Fed. Reg. at 55064	0000083
7.	83 Fed. Reg. at 55074-75	0000093-94
8.	PCMA Comments	0000503-36
9.	RxAnte Comments	0000625-28
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12.	AmeriHealth Caritas Comments	0000791-800
13.	AHIP Comments	0000802-15
14.	VIVA Health Comments	0000830-36
15.	MMM Holdings Comments	0000849-54
16.	MCS Advantage Comments	0000898-908
17.	WellCare Comments	0000910-32
18.	Humana Comments	0001024-62

19.	UnitedHealth Group Comments	0001075-111
20.	Centene Corp. Comments	0001187-95
21.	Magellan Health Comments	0001209-26
22.	83 Fed. Reg. 16440, 16520, 16521 (Apr. 16, 2018)	0017678-79
23.	84 Fed. Reg. 15680, 15770-74 (Apr. 19, 2019)	0026097-101
24.	84 Fed. Reg. at 15821	0026148

TAB 1

Calendar Year 2025 Advance Notice

In keeping with our commitment to transparency, a summary of the analysis of the candidate measure set that includes the minimum, median, and maximum values for the within-contract variation for the low-income subsidy (LIS)/dual eligible (DE) differences are posted with the 2025 CAI values on CMS's Part C and D Star Ratings website.

Extreme and Uncontrollable Circumstances Policy for the 2025 Star Ratings

Extreme and uncontrollable circumstances such as natural disasters can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide beneficiaries with important medical care and prescription drug coverage. An affected contract is identified based on these criteria:

> (1) Its service area is within an "emergency area" during an "emergency period" as defined in section 1135(g)(1) of the Act;
>
> (2) Its service area is within a geographic area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s); and
>
> (3) A certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance. (See §§ 422.166(i) and 423.186(i).)

We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period extends to another calendar year (§§ 422.166(i) and 423.186(i)).

Under the 25 percent rules at §§ 422.166(i)(2)–(6) and 423.186(i)(2)–(5), contracts with at least 25 percent of their service area in a FEMA-designated Individual Assistance area in 2022 will receive the higher of their measure-level rating from the current and prior Star Ratings years for purposes of calculating the 2025 Star Ratings (thus, for 2025 Star Ratings, affected contracts will receive the higher of their measure-level ratings from the 2024 rating or 2025 rating for the applicable measures). The numeric scores for contracts with 60 percent or more of their enrollees living in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance are excluded from: (1) the measure-level cut point calculations for non-CAHPS measures; and (2) the performance summary and variance thresholds for the reward factor as described at §§ 422.166(i)(9)(i) and (i)(10)(i), and 423.186(i)(7)(i) and (i)(8)(i). As a reminder, starting with the 2026 Star Ratings that covers

the 2024 measurement year for most measures, the 60 percent rule will be removed.[76] Table IV-2 lists the emergency areas affected by emergency declarations first issued in 2023, as defined in section 1135 of the Act, and the exercise of the Secretary's authority under section 1135 of the Act.

Table IV-2. List of Section 1135 Waivers Issued in Relation to the FEMA Major Disaster Declarations

Section 1135 Waiver Date Issued	Waiver or Modification of Requirements Under Section 1135 of the Social Security Act	FEMA Incident Type	Affected State	Incident Start Date
March 27, 2023	Severe Storms, Straight-Line Winds, and Tornadoes	Severe Storms, Straight-line Winds, and Tornadoes	Mississippi	Mar 24, 2023
June 2, 2023	Typhoon Mawar	Typhoon Mawar	Guam	May 22, 2023
August 11, 2023	Wildfires	Wildfires	Hawaii	August 8, 2023
August 30, 2023	Hurricane Idalia	Hurricane	Florida	August 27, 2023
September 12, 2023	Hurricane Idalia	Hurricane	Georgia	August 30, 2023

Table IV-3 lists the states and territories with Individual Assistance designations from the FEMA major disaster declarations.

[76] See CY 2024 final rule (CMS-4201-F) at https://www.federalregister.gov/documents/2023/04/12/2023-07115/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program.

Table IV-3. Individual Assistance Counties and County-Equivalents in FEMA Major Disaster Declared States/Territories

FEMA Declaration	State	FEMA Individual Assistance Counties or County-Equivalents
DR-4697-MS	Mississippi	Carroll, Humphreys, Monroe, Montgomery, Panola, Sharkey
DR-4715-GU	Guam	Guam
DR-4724-HI	Hawaii	Maui
DR-4734-FL	Florida	Charlotte, Citrus, Columbia, Dixie, Gilchrist, Hamilton, Hernando, Hillsborough, Jefferson, Lafayette, Levy, Madison, Manatee, Pasco, Pinellas, Sarasota, Suwannee, Taylor
DR-4738-GA	Georgia	Berrien, Brooks, Cook, Glynn, Lowndes

Changes to Existing Star Ratings Measures for the 2025 Measurement Year and Beyond

CMS solicits feedback on new measure concepts as well as measure updates through the annual Advance Notice and Rate Announcement process. We also provide advance notice regarding measures considered for implementation as future Star Ratings measures. As codified at §§ 422.164(c)(2)(4), 423.184(c)(2)(4), 422.164(d)(2), and 423.184(d)(2), new measures and measures with substantive specification changes must be added or updated through rulemaking and must remain on the display page for at least two years prior to becoming a Star Ratings measure. CMS uses the Advance Notice and Rate Announcement process to announce non-substantive specification changes as described at §§ 422.164(d)(1) and 423.184(d)(1) and to remove measures as described at §§ 422.164(e) and 423.184(e). We describe a number of measure concepts and changes in the Advance Notice. We encourage interested parties to provide comments directly to measure developers during their public comment periods. For example, the National Committee for Quality Assurance (NCQA) and the Pharmacy Quality Alliance (PQA) regularly solicit public comments on new measures, changes to existing measures, and measure retirements. We have also submitted the Initiation and Engagement of Substance Use Disorder Treatment (Part C) and Initial Opioid Prescribing for Long Duration (IOP-LD) (Part D) measures to the 2023 Measures Under Consideration (MUC) list, which includes measures that CMS is considering adopting through future rulemaking.

Future Universal Foundation Star Ratings Measures. As part of the CMS National Quality Strategy and Medicare Value-Based Care Strategy, CMS is committed to aligning a subset of

TAB 2

Florida Blue Communications with the Government

From: CMS PartC&DStarRatings
To: Krizanovic, Aldiana
Cc: Simpson, Hillary; CMS PartC&DStarRatings
Subject: RE: Florida Declaration of Emergency excluded from Advance Notice
Date: Wednesday, February 7, 2024 1:08:43 PM
Attachments: image002.png
image003.png
image004.png

Hi Aldiana,

As you note the Part C and D Star Ratings extreme and uncontrollable circumstance policy identifies an affected contract based on these criteria:
(1) Its service area is within an "emergency area" during an "emergency period" as defined in section 1135(g)(1) of the Act;
(2) Its service area is within a geographic area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s); and
(3) A certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)- designated Individual Assistance area at the time of the extreme and uncontrollable circumstance. (See §§ 422.166(i) and 423.186(i).)

1135 waivers are listed on this page, and these are the 2023 1135 waivers included in the 2025 Advance Notice for use in the 2025 Star Ratings:
https://aspr.hhs.gov/legal/1135-Waivers/Pages/1135-Waivers.aspx

The Part C and D Star Ratings mailbox is not able to answer questions about why an 1135 waiver was not issued for a particular disaster.

Thank you and regards,
Part C & D Star Ratings Team

From: Krizanovic, Aldiana <Aldiana.Krizanovic@bcbsfl.com>
Sent: Wednesday, February 7, 2024 11:23 AM
To: CMS PartC&DStarRatings <PartCandDStarRatings@cms.hhs.gov>
Cc: Simpson, Hillary <Hillary.Simpson@bcbsfl.com>
Subject: Florida Declaration of Emergency excluded from Advance Notice
Importance: High

Greetings,

In the CY 25 Advance Notice, CMS included a list of disaster areas. Even though there was a declaration of emergency (and FEMA assistance) for the flooding that took place in Broward County in April of 2023, it doesn't look like a waiver was issued. CMS did not include this declaration of emergency in the Advance Notice. I am wondering if you can assist us with information regarding why a waiver was not issued for this disaster.

Thank you,
Aldiana Krizanovic
904.655.0188

Below is the information found on this in case it is helpful:

Disaster: Florida Severe Storms, Tornadoes, and Flooding (DR-4709-FL)
Incident Period: Apr 12, 2023 - Apr 14, 2023

Presidential Declaration Date: Apr 27, 2023

Presidential Declaration: https://www.fema.gov/disaster-federal-register-notice/4709-dr-fl-initial-notice
FEMA designation: https://www.fema.gov/disaster/4709
List of 1135 waivers issued: https://aspr.hhs.gov/legal/1135-Waivers/Pages/default.aspx

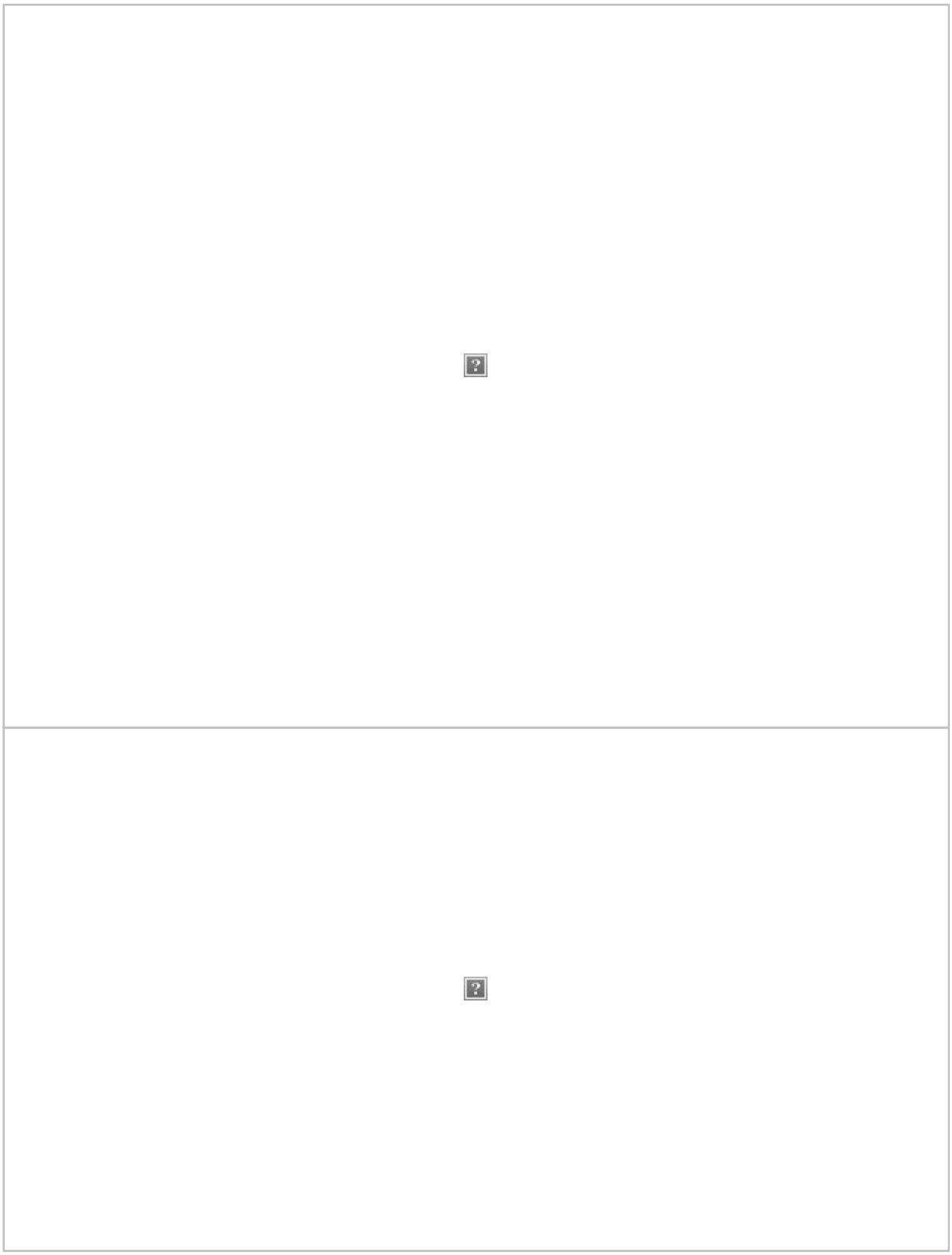
From Draft Rate Notice:

Extreme and Uncontrollable Circumstances Policy for the 2025 Star Ratings

Extreme and uncontrollable circumstances such as natural disasters can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide beneficiaries with important medical care and prescription drug coverage. An affected contract is identified based on these criteria:
(1) Its service area is within an "emergency area" during an "emergency period" as defined in section 1135(g)(1) of the Act;
(2) Its service area is within a geographic area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s); and
(3) A certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)- designated Individual Assistance area at the time of the extreme and uncontrollable circumstance. (See §§ 422.166(i) and 423.186(i).)

We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period extends to another calendar year (§§ 422.166(i) and 423.186(i)). Under the 25 percent rules at §§ 422.166(i)(2)–(6) and 423.186(i)(2)–(5), contracts with at least 25 percent of their service area in a FEMA-designated Individual Assistance area in 2022 will receive the higher of their measure-level rating from the current and prior Star Ratings years for purposes of calculating the 2025 Star Ratings (thus, for 2025 Star Ratings, affected contracts will receive the higher of their measure-level ratings from the 2024 rating or 2025 rating for the applicable measures).

Table IV-2 lists the emergency areas affected by emergency declarations first issued in 2023, as defined in section 1135 of the Act, and the exercise of the Secretary's authority under section 1135 of the Act.



Aldiana Krizanovic, MPH,CPH
Senior Health Policy Consultant
Federal Government Relations

4800 Deerwood Campus Parkway, Jacksonville, FL 32246
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March 1, 2024

Meena Seshamani, MD, PhD
Director, Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-2024-0006; Advance Notice of Methodological Changes for CY 2025 for MA Capitation Rates and Part C and Part D Payment Policies

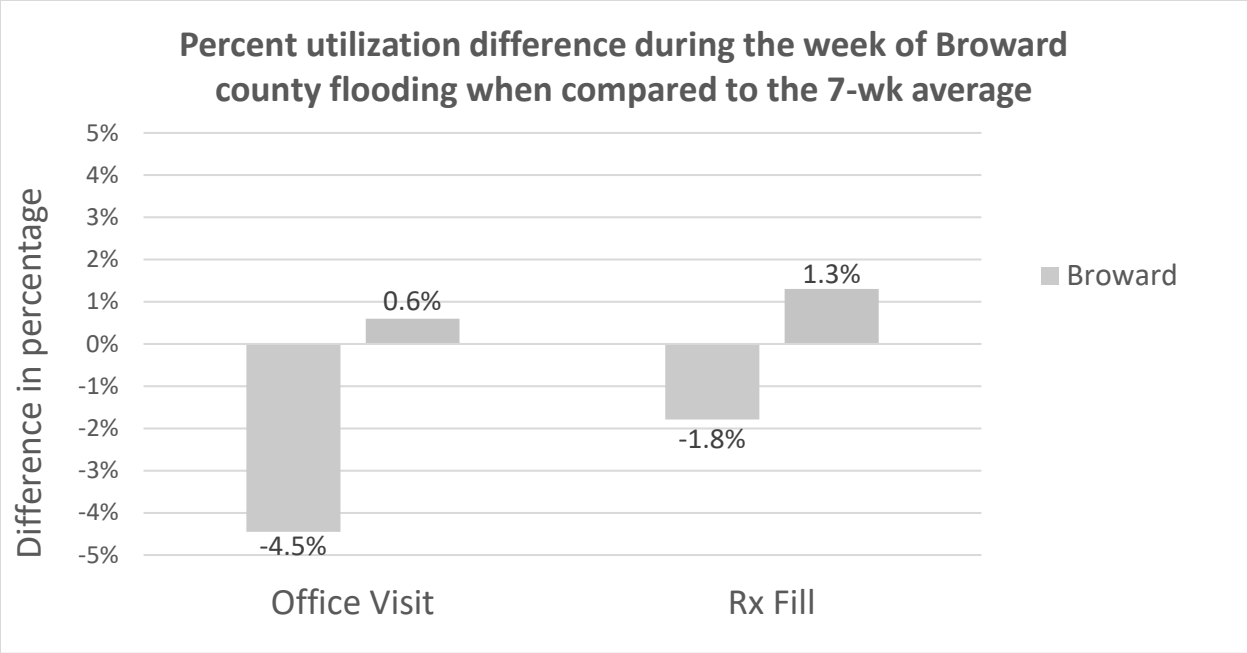
Dear Dr. Seshamani:

Florida Blue thanks you for this opportunity to comment on the Advance Notice of Methodological Changes for CY 2025 for MA Capitation Rates and Part C and Part D Payment Policies that we will refer to as the CY 25 Advance Notice. Florida Blue is a subsidiary of GuideWell, a not-for-profit health solutions company dedicated to serving all Floridians in the pursuit of health. Florida Blue is an independent licensee of the Blue Cross and Blue Shield Association, serving residents and businesses in the state of Florida and a member of AHIP.

We concur with the recommendations made in the BCBSA and AHIP comment letters in response to the CY 25 Advance Notice. However, we would like to take this opportunity to comment on a unique issue impacting Florida specifically related to the disaster adjustment declarations.

In the CY 25 Advance Notice, CMS included a list of disaster areas. Even though there was a presidential declaration of emergency, a FEMA declaration, and a Florida emergency declaration from the Governor's office for the flooding that took place in Broward County in April of 2023, there was not a 1135 waiver issued. Therefore, CMS did not include this declaration in the list of major FEMA declaration disaster areas in the Advance Notice.

A historic flash flood event occurred in Broward County on April 12th, 2023. The purpose of the current analysis shown in the chart below is to examine its impact on utilization including office visit and Rx fills, by comparing the difference of average utilization during the week of flooding April 9th, 2023, vs. the average utilization during the seven weeks before and after flooding (March 19th - May 6th). Our data shows that among members who reside in Broward County, there's a 4.5% drop of office visit and 1.8% drop of Rx fills during the week of flooding when compared to the 7-wk average. Whereas among members who reside in the other areas of Florida, there's a 0.6% increase of office visit and 1.3% increase of Rx fills during the week of flooding when compared to the 7-wk average.



Although the flooding wasn't as severe as originally anticipated when FEMA declared individual assistance designation for Broward, the anticipation of severe flooding likely drove the visit and Rx fill impact we are seeing, based on canceled doctor appointments. We are held to difficult Star thresholds established by the industry. Every gap closure and medication fill can potentially matter for the Star Rating's Program and impact the individual measure scores. Plans should not be disadvantaged by the impact of uncontrollable disasters, whether through active or perceived threats. These circumstances can especially impact senior beneficiaries and their utilization of health care services.

We believe the section 1135 waiver not being issued for the flooding that took place in Broward County is due to a timing technicality per our discussion with HHS where we were told that had this data been available during the immediate post disaster window an 1135 waiver likely would have been issued. We would like to take this opportunity to kindly request this disaster be included in the list of FEMA declared individual assistance designation's in the CY 25 Final Notice of Methodological Changes for CY 2025 for MA Capitation Rates and Part C and Part D Payment Policies so health plans that have members that experienced an interruption to health care services as a result of this disaster declaration are not disadvantaged.

We have provided additional information in the appendix listed below in case you find it helpful.

If you have any questions regarding our comments or require additional data, please contact me or Aldiana Krizanovic, Senior Health Policy Consultant for Federal Government Relations, at 904-655-0188 or aldiana.krizanovic@bcbsfl.com.

Thank you,

Camille Harrison

Camille Harrison
Executive Vice President of Medicare and Chief Innovation and Experience Officer

APPENDIX

List of declarations made for the April 2023 Broward County Flooding:

Disaster: Florida Severe Storms, Tornadoes, and Flooding (DR-4709-FL)
Incident Period: Apr 12, 2023 - Apr 14, 2023

Presidential Declaration Date: Apr 27, 2023
Presidential Declaration:
http://defang.bcbsfl.com/defang.php?url=https://www.fema.gov/disaster-federal-register-notice/4709-dr-fl-initial-notice

FEMA designation:
http://defang.bcbsfl.com/defang.php?url=https://www.fema.gov/disaster/4709

State of Florida Governor's Office emergency declaration:
https://www.flgov.com/2023/04/13/memorandum-executive-order-23-65-emergency-management-broward-county-flooding/

List of 1135 waivers issued:
http://defang.bcbsfl.com/defang.php?url=https://aspr.hhs.gov/legal/1135-Waivers/Pages/default.aspx

From CY 25 Advance Rate Notice:

Extreme and Uncontrollable Circumstances Policy for the 2025 Star Ratings

Extreme and uncontrollable circumstances such as natural disasters can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide beneficiaries with important medical care and prescription drug coverage. An affected contract is identified based on these criteria:

(1) Its service area is within an "emergency area" during an "emergency period" as defined in section 1135(g)(1) of the Act;

(2) Its service area is within a geographic area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s); and

(3) A certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)- designated Individual Assistance area at the time of the extreme and uncontrollable circumstance. (See §§ 422.166(i) and 423.186(i).)

We use the start date of the incident period to determine which year of Star Ratings could be affected, regardless of whether the incident period extends to another calendar year (§§ 422.166(i) and 423.186(i)). Under the 25 percent rules at §§ 422.166(i)(2)–(6) and 423.186(i)(2)–(5), contracts with at least 25 percent of their service area in a FEMA-designated Individual Assistance area in 2022 will receive the higher of their measure-level rating from the current and prior Star Ratings years for purposes of calculating the 2025 Star Ratings (thus, for

2025 Star Ratings, affected contracts will receive the higher of their measure-level ratings from the 2024 rating or 2025 rating for the applicable measures).

Table IV-2 lists the emergency areas affected by emergency declarations first issued in 2023, as defined in section 1135 of the Act, and the exercise of the Secretary's authority under section 1135 of the Act.

Table IV-2. List of Section 1135 Waivers Issued in Relation to the FEMA Major Disaster Declarations

Section 1135 Waiver Date Issued	Waiver or Modification of Requirements Under Section 1135 of the Social Security Act	FEMA Incident Type	Affected State	Incident Start Date
March 27, 2023	Severe Storms, Straight-Line Winds, and Tornadoes	Severe Storms, Straight-line Winds, and Tornadoes	Mississippi	Mar 24, 2023
June 2, 2023	Typhoon Mawar	Typhoon Mawar	Guam	May 22, 2023
August 11, 2023	Wildfires	Wildfires	Hawaii	August 8, 2023
August 30, 2023	Hurricane Idalia	Hurricane	Florida	August 27, 2023
September 12, 2023	Hurricane Idalia	Hurricane	Georgia	August 30, 2023

Table IV-3 lists the states and territories with Individual Assistance designations from the FEMA major disaster declarations.

Table IV-3. Individual Assistance Counties and County-Equivalents in FEMA Major Disaster Declared States/Territories

FEMA Declaration	State	FEMA Individual Assistance Counties or County-Equivalents
DR-4697-MS	Mississippi	Carroll, Humphreys, Monroe, Montgomery, Panola, Sharkey
DR-4715-GU	Guam	Guam
DR-4724-HI	Hawaii	Maui
DR-4734-FL	Florida	Charlotte, Citrus, Columbia, Dixie, Gilchrist, Hamilton, Hernando, Hillsborough, Jefferson, Lafayette, Levy, Madison, Manatee, Pasco, Pinellas, Sarasota, Suwannee, Taylor
DR-4738-GA	Georgia	Berrien, Brooks, Cook, Glynn, Lowndes

From: Goldstein, Elizabeth (CMS/CM)
To: Giles, Tom; Gaillot, Sarah (CMS/CM)
Cc: Krizanovic, Aldiana
Subject: RE: Disaster Relief and Star Ratings Special Consideration Request
Date: Tuesday, March 19, 2024 9:28:00 AM
Attachments: image001.png

Good morning,

Thank you for sharing your concerns. We have reviewed your request.

As you know, for the Part C and D Star Ratings extreme and uncontrollable circumstance, an affected contract must meet the following criteria:

(1) Its service area is within an "emergency area" during an "emergency period" as defined in section 1135(g)(1) of the Act;
(2) Its service area is within a geographic area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s); and
(3) A certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)- designated Individual Assistance area at the time of the extreme and uncontrollable circumstance. (See §§ 422.166(i) and 423.186(i).)

We are required to follow the methodology codified in regulation so cannot make exceptions in how we administer the disaster policy for Star Ratings.

Liz

Liz Goldstein, Ph.D.
Director, Division of Consumer Assessment and Plan Performance
Center for Medicare
Centers for Medicare & Medicaid Services
Elizabeth.goldstein@cms.hhs.gov
410-786-6665

From: Giles, Tom <Tom.Giles@bcbsfl.com>
Sent: Friday, March 8, 2024 6:37 AM
To: Goldstein, Elizabeth (CMS/CM) <Elizabeth.Goldstein@cms.hhs.gov>; Gaillot, Sarah (CMS/CM) <Sarah.Gaillot@cms.hhs.gov>
Cc: Krizanovic, Aldiana <Aldiana.Krizanovic@bcbsfl.com>
Subject: Disaster Relief and Star Ratings Special Consideration Request

Dear Liz and Sarah,

We hope this email finds you well. We are writing on behalf of Florida Blue Medicare. We

have identified a potential STARs performance concern related to Florida natural disasters. We expected the historic flash flood event that occurred in Broward County on April 12th, 2023, to be listed under the list of emergency areas affected by emergency declarations issued in 2023 in the Advance Notice of Methodological Changes for CY 2025 for MA Capitation Rates and Part C and Part D Payment Policies that we will refer to as the CY 25 Advance Notice. Even though there was a presidential declaration of emergency, a FEMA declaration, and a Florida emergency declaration from the Governor's office for the historic flash flooding that took place in Broward County, there was not a section 1135 waiver issued. Therefore, CMS did not include this declaration in the list of major FEMA declaration disaster areas in the CY 25 Advance Notice.

We inquired about the section 1135 waiver with HHS and were informed that the State of Florida did not request a section 1135 waiver or an official public health emergency declaration most likely because they did not need outside resources to handle the disaster. This decision did not take into consideration the impact this disaster declaration would have on health care utilization, health plans and beneficiaries, and that they would be disadvantaged by the impact of uncontrollable disasters, whether through active or perceived threats. We did a thorough examination of our Broward population utilization during the flooding period and noticed a significant reduction compared to the rest of our population, suggesting that members may have canceled appointments or delayed seeking care in light of the anticipated flooding.

HHS examined our data and found it compelling, stating that if they had it at the time of the presidential declaration, a waiver would likely have been issued because it shows a clear interruption to health care utilization especially to senior beneficiaries. HHS informed us that at this time, since there is not an active presidential declaration, that we could not formally request a section 1135 waiver. However, they advised us, with their support, to reach out to your office to ask for special consideration for our issue given these unique circumstances.

Please see the attached letter we submitted to CMS in response to the CY 25 Advance Notice citing this issue and additional context for your review. Our data shows that among members who reside in Broward County, there's a 4.5% drop of office visit and 1.8% drop of Rx fills during the week of flooding when compared to the 7-wk average. Whereas among members who reside in the other areas of Florida, there's a 0.6% increase of office visit and 1.3% increase of Rx fills during the week of flooding when compared to the 7-wk average.

We would like to respectfully ask that CMS take these circumstances into consideration when assessing our plan's quality performance for CY 2023 so we are not penalized through our star ratings for circumstances outside of our control and treat the Broward County FEMA disaster declaration as you would those listed in the CY 25 Advance Notice, despite a formal section 1135 waiver not being due to an oversight by the State.

We greatly appreciate your time and attention to this important issue. If you would like to schedule a call for us to discuss this issue in greater detail or need additional data from us, please let me know.

We look forward to hearing from you!

Thomas E. Giles
Vice President, Government Relations

tom.giles@floridablue.com
(o) 202.904.2417 **(c)** 202.568.1306

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Washington DC 20005
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From: CMS PartC&DStarRatings
To: Neal, Leigh Anne
Cc: Graf, Thomas; Bowers, Lee; CMS PartC&DStarRatings
Subject: RE: Plan Preview#2 Florida Blue Medicare/Blue Cross Blue Shield of Florida
Date: Tuesday, September 17, 2024 9:05:14 AM
Attachments: image001.png
image002.png

We have reviewed your request again. We are unable to apply the extreme and uncontrollable circumstances adjustment codified at §§ 422.166(i) and 423.186(i) as your contracts do not meet the requirements to receive this adjustment.

Thank you,

Part C and D Star Ratings Team

From: CMS PartC&DStarRatings <PartCandDStarRatings@cms.hhs.gov>
Sent: Wednesday, September 11, 2024 8:33 AM
To: Neal, Leigh Anne <LeighAnne.Neal@bcbsfl.com>
Cc: Graf, Thomas <Thomas.Graf@bcbsfl.com>; Bowers, Lee <Lee.Bowers@bcbsfl.com>; CMS PartC&DStarRatings <PartCandDStarRatings@cms.hhs.gov>
Subject: RE: Plan Preview#2 Florida Blue Medicare/Blue Cross Blue Shield of Florida

Confirming receipt.

Part C & D Star Ratings Team
Medicare Drug Benefit and C&D Data Group (MDBG)
PartCandDStarRatings@cms.hhs.gov



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From: Neal, Leigh Anne <LeighAnne.Neal@bcbsfl.com>
Sent: Wednesday, September 11, 2024 7:52 AM
To: CMS PartC&DStarRatings <PartCandDStarRatings@cms.hhs.gov>
Cc: Graf, Thomas <Thomas.Graf@bcbsfl.com>; Bowers, Lee <Lee.Bowers@bcbsfl.com>

Subject: Plan Preview#2 Florida Blue Medicare/Blue Cross Blue Shield of Florida

Contract ID #: H1035, H5434 and R3332

Good morning,

We are writing to bring to your attention an ongoing concern regarding the identification of our contracts for disaster relief in Plan Preview 2. As previously discussed with CMS, we had raised an issue following the April 2024 CY 2025 Advance Notice regarding the exclusion of Florida's Broward County declaration of emergency from the list of major FEMA declaration disaster areas.

To recap, the declaration was issued by the President, FEMA, and Governor's office in response to the flooding that occurred in Broward County on April 12, 2023. Despite the absence of an 1135 waiver, our plan data indicates a decline in utilization for doctor visits and prescription refills during this emergency. Although the flooding may not have been as large scale as initially anticipated, the perceived threat of the flooding was sufficient to result in canceled doctor visits and limited access to prescription medications. We believe that plans should not be unfairly penalized in this unique situation, and that CMS should consider classifying Broward County among the disaster declaration counties. Given the significance of every point in meeting the star thresholds, we believe the matter warrants further evaluation.

We respectfully request that CMS re-evaluate this unique situation and consider making a one-time exception to the Part C and D Star Ratings extreme and uncontrollable circumstance provision. This exception is necessary to ensure that our plan receives accurate performance measurement ratings in the Star Program, particularly since important medical care and prescription drugs for our members were impacted by the disaster. To facilitate the re-evaluation, we have attached our original issue submission and CMS's initial response for your reference. Please let us know if any additional information is required or if there are further steps we need to take.

We appreciate your attention to this matter, and we look forward to your response. Thank you for your time and consideration.

Sincerely,

Leigh Anne Neal
VP of Quality Florida Blue Medicare
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November 27, 2024

VIA E-MAIL & U.S. MAIL

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator Brooks-LaSure,

Blue Cross and Blue Shield of Florida, Inc. and Florida Blue Medicare, Inc. (collectively "Florida Blue Medicare")[1] respectfully seek adjustments for the 2025 Medicare Advantage Star Ratings ("Star Ratings") applicable to its MA-PD and PDP contracts due to extreme and uncontrollable circumstances, specifically the record-breaking rainfall and resulting flooding that occurred in Broward County on April 12, 2023, which in turn caused disruptions to plan utilization within the affected member population. Broward County is a service area that was served by these Medicare Advantage and Prescription Drug Plan contracts (collectively the "Plans") at the time of the flooding. Prior efforts to obtain recognition of these extreme events and an adjustment from CMS have been denied.[2]

The record-breaking flooding that occurred in April 2023 in Broward County prompted emergency declarations by both the Florida Governor and President Biden, who declared Broward County a major disaster area on April 28, 2023. On that same day, the Federal Emergency Management Agency ("FEMA") announced that federal disaster assistance had been made available to affected individuals in Broward County. As a direct result of that emergency event, including member hesitancy and apprehension in the hours leading up to it—especially among our senior beneficiaries—Florida Blue Medicare's measures that factor into its Star Ratings were impacted significantly. Typically, these impacts would be ameliorated by a waiver authorized by the Secretary pursuant to Section 1135(b) of the Social Security Act ("Section 1135").[3] In this case, however, despite the emergency declarations by both the Governor's office and the President in response to the flooding, the Secretary did not declare a Public Health Emergency under the Public Health Service Act ("PHSA"),[4] which is a prerequisite to a Section 1135 waiver. And because the

[1] Both companies are subsidiaries of GuideWell Mutual Holding Corporation and independent licensees of the Blue Cross and Blue Shield Association.
[2] Relevant correspondence is appended to this letter for your convenience.
[3] 42 U.S.C. § 1320b-5.
[4] 42 U.S.C. § 247d(a).

Secretary did not issue a Section 1135 waiver, CMS did not include Broward County in the list of major FEMA declaration disaster areas in its Advance Notice of Methodological Changes for Calendar Year 2025 for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies. As a result, Florida Blue Medicare's Plans did not receive the "extreme and uncontrollable circumstances" adjustment in its 2025 Star Ratings.[5]

Had the Broward County declared emergency been included in the calculation for Florida Blue Medicare's Star Ratings, the change would have had a material impact on the final ratings, as follows:[6]

> H1035 (HMO): approximately 18% of the applicable population was considered impacted by Hurricane Idalia in the current calculation; adding Broward County adds another approximately 8% of impacted members bringing the total for H1035 to 26%. The estimated revised calculation would move the contract from the current 3.5 stars to 4.0 stars. Moreover, if the plan were rated as a 4.0 then it would be eligible for a reward factor adjustment that, based on current percentile ratings across all MA-PD plans, would likely result in a final score of 4.5.
>
> S5904 (PDP): approximately 22% of the applicable population was considered impacted by Hurricane Idalia in the current calculation; adding Broward County adds another approximately 4% of impacted members bringing the total for S5904 to 26%. The estimated revised calculation would move the contract from the current 2.5 stars to 3.0 stars.

Star Ratings are designed to reflect a plan's quality and must be based on complete, accurate, and reliable data.[7] This objective methodology helps ensure that all plans can be evaluated on equal terms, promoting transparency and accountability across Medicare Advantage plans. The extreme and uncontrollable circumstances adjustment is intended to help Medicare Advantage and Part D plans avoid impacts to their Star Ratings due to factors beyond their control, such as disruptions due to severe weather events, which can affect their ability to deliver services or meet performance targets.

The April 2023 weather-related emergency in Broward County is exactly the type of event for which a Star Ratings adjustment is necessary. For example, Florida Blue Medicare's utilization data shows that during the relevant timeframe there were substantial declines in doctor visits and prescription refills by members. We respectfully submit that CMS's refusal to make an adjustment in this situation places form over substance. The requirement that a Section 1135 waiver be granted frustrates Star Ratings objectivity by arbitrarily inserting multiple layers of subjectivity into the calculation. Requiring a Section 1135 waiver be issued in order for Florida Blue Medicare to receive an adjustment for unforeseen circumstances is especially arbitrary where, as here, those circumstances were recognized by both the Governor and the President as an emergency, and it

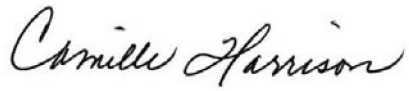
[5] 42 CFR §§ 422.166(i) and 423.186(i).
[6] Florida Blue Medicare's BlueMedicare LPPO (Contract No. H5434), was also affected, but not to a degree that the star rating would have changed absent other adjustments to Star Ratings calculations; BlueMedicare RPPO (Contract No. R3332) was also affected, but that contract was not renewed by Florida Blue Medicare.
[7] 83 Fed. Reg. 16440, 16521 (Apr. 16, 2018)

was only because the Secretary did not declare a Public Health Emergency that a Section 1135 waiver was not granted.

Florida Blue Medicare respectively requests that CMS re-evaluate this unique situation and adjust Florida Blue Medicare's Star Ratings accordingly by treating Broward County as if it were included in the Advance Notice of Methodological Changes for Calendar Year 2025 for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies and allowing the recalculation to occur for purposes of calculating revised Star Ratings for 2025 for its Plans and for all subsequent related calculations and payments.

Because time is of the essence, should Florida Blue Medicare not receive an assurance within 30 days of the date of this letter that its Star Ratings will be adjusted to account for the impacts of the April 2023 emergency weather event in Broward County, it will consider taking legal action.

Sincerely,



Camille Harrison
Executive Vice President, Medicare & Chief Innovation & Experience Officer

cc: Meena Seshamani, MD, PhD
Alisha Pieraccini, Senior Vice President, Florida Blue Medicare
Tom Giles, Vice President, Government Relations

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-12-12
Baltimore, Maryland 21244-1850



Center for Medicare

December 20, 2024

Camille Harrison
EVP, Medicare & Chief Innovation & Experience Officer
Florida Blue
4800 Deerwood Campus Parkway
Building 100, 8th Floor
Jacksonville, Florida 32246-8243

Dear Camille Harrison:

Thank you for your letter regarding Florida Blue Medicare and adjustments for the 2025 Medicare Advantage Star Ratings due to the flooding that occurred in Broward County, Florida on April 12-14, 2023. As you know, the Part C and D Star Ratings extreme and uncontrollable circumstances policy is codified at 42 CFR §§ 422.166(i) and 423.186(i). Per these regulations, a contract must meet all of the following criteria to qualify as an "affected contract" and be eligible for adjustments:

> (1) Its service area is within an "emergency area" during an "emergency period" as defined in section 1135(g)(1) of the Social Security Act (the Act);
>
> (2) Its service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s); and
>
> (3) A certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

Contracts must meet all of the codified criteria to qualify for adjustments for extreme and uncontrollable circumstances. As you note, the HHS Secretary did not issue a section 1135 waiver for the flooding that occurred in Broward County in April 2023 for the incident period that went from April 12 - 14, 2023. As such, this flooding was not a qualifying disaster for purposes of the extreme and uncontrollable circumstances adjustment and was not included in the list of qualifying disasters in the Announcement of Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. Florida Blue Medicare's contracts did not receive the extreme and uncontrollable circumstances adjustment in

their 2025 Star Ratings since they did not qualify for an adjustment per the rules codified at §§ 422.166(i)(1) and 423.186(i)(1).

Per § 422.504(o) all MA organizations are required to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the restoration of business operations following disruptions to business operations, which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences.

Again, thank you for your letter. I value your feedback and look forward to working with you to maintain a strong Medicare program so that our nation's Medicare beneficiaries can continue to have a wide range of high-quality health care choices.

Sincerely,

Cheri Rice

Cheri Rice
Deputy Center Director
Center for Medicare

TAB 3

83 Fed. Reg. 54982, 55025-26 (Nov. 1, 2018)

(5) Data Integrity

At §§ 422.164(g)(1)(iii) and 423.184(g)(1)(ii), CMS codified a policy to make scaled reductions to the Star Ratings for a contract's Part C or Part D appeals measures because the relevant Independent Review Entity (IRE) data are not complete based on the Timeliness Monitoring Project (TMP) or audit information. The reduction is applied to the measure-level Star Ratings for the applicable appeals measures. We propose adding an additional regulatory provision at §§ 422.164(g)(1)(iii)(O) and 423.184(g)(1)(ii)(M) that would assign a 1-star rating to the applicable appeals measure(s) if a contract fails to submit TMP data for CMS's review to ensure the completeness of their IRE data. We believe it is appropriate to assume that there is an issue related to the performance when the MA organization or Part D plan sponsor has refused to provide information for the purposes of our oversight of the compliance with the appeals requirements. Our proposal to modify measure-specific ratings due to data integrity issues is separate from any CMS compliance or enforcement actions related to a sponsor's deficiencies; these rating reductions are necessary to avoid falsely assigning a high star to a contract, especially when the MA organization or Part D sponsor has refused to submit data for us to evaluate performance in this area and to ensure that the data submitted to the IRE are complete.

(6) Review of Sponsors' Data

At §§ 422.164(h)(1) and 423.184(h)(1), CMS proposes to codify a policy regarding the deadlines for an MA organization or Part D plan sponsor to request CMS or the IRE to review a contract's appeals or CMS to review a contract's Complaints Tracking Module (CTM) data. For example, information regarding the Part C and Part D appeals process is available to MA organizations and is updated daily on the IRE website. Additionally, sponsors can access the Part D Appeals Reports under the Performance Metrics pages in HPMS. To allow enough time for the IRE to make any necessary changes to ensure the accuracy of a contract's measure score, we are proposing that requests for CMS or the IRE to review contract data must be received no later than June 30 of the following year in order to have time to use accurate information in the Star Ratings calculations (for example, changes to contract year 2018 appeals data must be made by June 30, 2019 for the 2020 Star Ratings). Reopenings are not taken into account under this proposed deadline for corrections to the IRE data. When the decision is evaluated for purposes of the appeals measures, if a reopening occurs and is decided prior to May 1, the revised determination is used in place of the original reconsidered determination. If the revised determination occurs on or after May 1, the original reconsidered determination is used.

Similarly, we propose that any requests for adjustments following CMS's CTM Standard Operating Procedures for the complaints measures be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data (for example, changes to contract year 2018 complaints data must be made by June 30, 2019 for the 2020 Star Ratings).

e. Extreme and Uncontrollable Circumstances

Extreme and uncontrollable circumstances such as natural disasters can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide them with important medical care and prescription drug coverage. These circumstances may negatively affect the underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program, all without fault on the part of the MA organization or Part D plan sponsor. We propose to adjust the Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance or measurement period. CMS is also concerned that certain natural disasters and emergencies may interfere in plans' abilities to provide services for their enrollees. In this rule, we describe proposed policies for identifying affected contracts and adjusting the Star Ratings measures. These policies are largely the same as those described in the 2019 final Call Letter, with the substantive exception of eliminating the difference-in-differences adjustment for survey data. The difference-in-differences adjustment showed no consistent, negative impact of extreme and uncontrollable circumstances on the 2019 Star Ratings; therefore, we are eliminating this adjustment to simplify the methodology for calculating Star Ratings in cases of extreme and uncontrollable circumstances. We propose to codify a series of special rules for calculation of the Star Ratings of certain contracts in certain extreme and uncontrollable circumstances in paragraph (i) of §§ 422.166 and 423.186.

We propose that the adjustments be tailored to the specific areas experiencing the extreme and uncontrollable circumstance in order to avoid over-adjustment or adjustments that are unnecessary. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. To ensure that the Star Ratings adjustments focus on the specific geographic areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and are not applied to areas sustaining little or no adverse effects, our proposal is to target the adjustments to specific contracts and to further specify and limit the adjustments.

(1) Identification of Affected Contracts

In paragraph (i)(1) of §§ 422.166 and 423.186, we propose to identify MA and Part D contracts affected by extreme and uncontrollable circumstances during the performance or measurement period that may have affected their performance on Star Ratings measures or their ability to collect the necessary measure-level data. These ''affected contracts'' would be the contracts eligible for the adjustments specified in this proposed rule to take into account the effects of the extreme and uncontrollable circumstances. For an MA or Part D contract to be considered an affected contract under our proposal, the contract would need to meet all of the following criteria:

- The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in Section 1135(g) of the Act.
- The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).
- A certain minimum percentage (25 percent for measure star adjustments or 60 percent for exclusion from cut point and Reward Factor calculations) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

We propose to identify an area as having experienced extreme and uncontrollable circumstances if it is within an ''emergency area'' and ''emergency period'' as defined in section 1135(g) of the Act, and also is

within a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act, and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s) (*https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx*). Major disaster areas are identified and can be located on FEMA's website at *https://www.fema.gov/disasters.* To ensure the policy is applied to those contracts most likely to have experienced the greatest adverse effects, we propose to narrow it to apply to contracts with a certain minimum percentage of enrollees residing in an area declared as an Individual Assistance area because of the disaster declaration. Individual Assistance includes assistance to individuals and households, crisis counseling, disaster case management, disaster unemployment assistance, disaster legal services, and the disaster Supplemental Nutrition Assistance Program. We focus on enrollees residing in counties eligible for Individual Assistance because of a major disaster, because most Star Ratings measures are based on services provided directly to beneficiaries in their local area. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. Therefore, we believe adjustments to the Star Ratings are most appropriately targeted to contracts serving beneficiaries who were eligible for individual and household assistance because of the disaster declaration.

For adjustments, at least 25 percent or 60 percent of the enrollees under the contract must reside in Individual Assistance areas identified because of the extreme and uncontrollable circumstances. This ensures that the adjustments are limited to contracts that we believe may have experienced a real impact from the extreme and uncontrollable circumstance in terms of operations or ability to serve enrollees. In calculations for the 2019 Star Ratings, we observed that contracts tend to have either very few enrollees impacted or most of their enrollees impacted due to the nature of contracts either covering a broad region or a localized area. If 1 out of 4 enrollees was impacted during the period of the year when the disaster hit, we believe there is a small chance that scores may have been impacted. The selection of the exclusion of numeric measures scores from contracts with 60 percent or more enrollees impacted from the determination of the cut points is conservative in case scores are impacted in contracts where a clear majority or all of the enrollees are impacted. Using the Individual Assistance major disaster declaration as a requirement for the extreme and uncontrollable event policy also ensures that the policy applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings.

We propose that contracts that do not meet the definition of an ''affected contract'' would not be eligible for any adjustments based on the occurrence of the extreme and uncontrollable circumstances. However, meeting the criteria to be an affected contract is not sufficient for all the adjustments we propose.

(2) CAHPS Adjustments

For CAHPS, we propose two different types of special rules for affected contracts: exemption from having to administer the CAHPS survey or adjustments to the Star Ratings on the CAHPS measures if the affected contract must administer the CAHPS survey. CAHPS measures are based on a survey conducted early in the year in which the Star Ratings are released that is, the year before the year to which the Star Ratings are applicable. For example, the CAHPS survey in early 2019 will be used for the 2020 Star Ratings, which are released in late 2019, before the annual coordinated election period for 2020.

We propose at §§ 422.166(i)(2)(i) and 423.186(i)(2)(i), that an MA and Prescription Drug Plan contract, even if it is an affected contract, must administer the CAHPS survey unless the contract demonstrates to CMS that the required sample for the CAHPS survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster in the prior calendar year and requests and receives a CMS approved exception. We believe that displacement of a substantial number of the contract's enrollees would make it practically impossible to contact the required sample for the CAHPS survey. For an affected contract that receives the exemption from administering the CAHPS survey, we propose at 422.166(i)(2)(iii) and 423.186(i)(2)(iii) that the affected contract would receive the prior year's CAHPS measure stars (and corresponding measure scores).

For other affected contracts, we propose an adjustment to the CAHPS scores and Star Ratings based on the administered survey and the percentage of enrollees in the affected contract that reside in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance. We propose that affected contracts with at least 25 percent of enrollees residing in Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure (including the annual flu vaccine measure). For example, for the 2022 Star Ratings for affected contracts, we would take the higher of the 2021 Star Ratings or the 2022 Star Ratings for each CAHPS measure. The affected contract would receive the CAHPS measure score for the corresponding Star Rating year chosen. We propose the 25 percent threshold to avoid including contracts with very few enrollees impacted. The measure-level scores for contracts with very few enrollees impacted should not be adversely affected by these extreme and uncontrollable circumstances. If a small percentage of enrollees were impacted by an extreme and uncontrollable circumstance, it should not have a significant impact on measure scores.

(3) HOS Adjustments

For the HOS survey, we propose to follow similar procedures as CAHPS but due to the follow-up component of HOS, the adjustment would be to the Star Ratings for the year after the completion of the follow-up HOS survey that is administered 2 years after the baseline HOS survey. For example, the 2022 Star Ratings are based on data collected from April through June 2020 and reflect experiences over the past 12 months. The data collected in 2021 will be used for the 2023 Star Ratings, so responses may reflect the impact of 2020 extreme and uncontrollable circumstances and thus, those circumstances may have an impact on the 2023 Star Ratings.

As described at proposed § 422.166(i)(3)(i), an MA contract, even if it is an affected contract, must administer the HOS surveys the year after the extreme and uncontrollable circumstance unless the contract demonstrates to CMS that the required sample cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster during the measurement period and requests and receives a CMS approved exception. For an affected contract that receives the exemption from administering the HOS survey, we propose at paragraph (i)(3)(iii) that the affected contract would receive the prior year's HOS and

TAB 4

83 Fed. Reg. at 55052-54

• We first estimated the costs of additional telehealth benefits that are to be transferred from supplemental benefits to basic benefits. Using the 2019 submitted bid information, we estimated that $0.09 per member per month (pmpm) would be transferred. We computed $0.09 by examining and averaging the largest organizations' telehealth benefits, particularly under the category ''Web and Phone Based Technology.'' The reason for basing estimates on the largest organizations is that only the largest organizations included the category ''Web and Phone Based Technology'' as a separate line item in their bids. The other organizations had multiple, non-telehealth benefits, in the same line as the telehealth benefits, and so we were not able to distinguish the costs between telehealth and non-telehealth for the smaller organizations. Information from the 2018 Medicare Trustees Report [34] shows that the applicable medical-inflation trend that should be applied to the $0.09 pmpm is 5.2 percent per year; the average trend can be derived from information in Table IV.C3 of this report.

• We applied the pmpm amounts to the projected MA enrollment for the years 2020 through 2029. The source of the projected MA enrollment is Table IV.C1 of the 2018 Medicare Trustees Report.

• We assumed that 15 percent of the additional telehealth benefits would be considered capital and infrastructure expenses. As discussed in the preamble, these expenses are excluded from the Medicare Trust Fund payments for additional telehealth benefits. We obtained the 15 percent assumption by subtracting the 85 percent required Medical Loss Ratio (MLR) from 100 percent. We used the MLR as a proxy for the medical share of provider payments.

• We applied the average rebate percentage of 66 percent, which is based on the expected submitted bid information, including expected enrollment and expected average Star Ratings.

• We applied a factor of 86 percent to the calculation, which represents the exclusion or the backing out of the Part B premium.

• However, per OMB guidance, ordinary inflation should be carved out of estimates, while medical inflation, which outpaces ordinary inflation (as well as enrollment growth), may be retained. The source of the ordinary inflation is Table IV.D1 of the 2018 Medicare Trustees Report. It is 2.6 percent per year for each of the years 2020 through 2029.

Combining these six factors, we calculated the net costs to the Medicare Trust Fund to be $6.1 million in 2020, $6.5 million in 2021, $6.9 million in 2022, $7.3 million in 2023, and $7.7 million in 2024. We calculated the net costs to the Medicare Trust Fund for years 2025 through 2029 to be $8.2 million, $8.5 million, $9.0 million, $9.5 million, and $9.9 million, respectively. The calculations of impact for 2020 through 2029 are summarized in Table 6. The total cost for all 10 years is found in the right-most column of Table 6, titled ''Net Costs.''

BILLING CODE 4120–01–P

[34] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.*

BILLING CODE 4120–01–C

TABLE 5: CALCULATIONS OF NET COSTS PER YEAR TO THE MEDICARE TRUST FUND FOR ADDITIONAL TELEHEALTH BENEFITS

Year	Enrollment (thousands)	PMPM Cost	Number of Months per Year	Gross Amount ($ in millions) (A)	Infrastructure Costs (B)	Average Rebate Percentage (C)	Backing out of Part B Premium (D)	Net Cost ($millions) (A * (1-B) * (1-C) * (D) * (E))	Ordinary Inflation (F)	Net Costs ($millions) (A * (1-B)) * (1 - C) * (D) (E)/ (1+(F))^(year-2019)
2020	21,995	0.09	12	25.0	15%	66%	86%	6.2	2.6%	6.1
2021	22,873	0.10	12	27.3	15%	66%	86%	6.8	2.6%	6.5
2022	23,739	0.10	12	29.8	15%	66%	86%	7.4	2.6%	6.9
2023	24,584	0.11	12	32.5	15%	66%	86%	8.1	2.6%	7.3
2024	25,395	0.12	12	35.3	15%	66%	86%	8.8	2.6%	7.7
2025	26,198	0.12	12	38.4	15%	66%	86%	9.5	2.6%	8.2
2026	26,986	0.13	12	41.6	15%	66%	85%	10.2	2.6%	8.5
2027	27,737	0.14	12	44.9	15%	66%	85%	11.0	2.6%	9.0
2028	28,455	0.14	12	48.5	15%	66%	85%	11.9	2.6%	9.5
2029	29,101	0.15	12	52.2	15%	66%	85%	12.8	2.6%	9.9
Raw Total										79.6

b. Savings for Enrollees Due to Decreased Travel Time to Providers

Additional telehealth benefits will save enrollees the cost of traveling to providers. Currently, original Medicare telehealth benefits are used to bring healthcare services to MA enrollees, including those in rural locations. Stakeholders have informed CMS that MA enrollees like the use of telehealth services to reduce travel times and have greater access to providers that may not otherwise be available.

The analysis assumes a replacement of some face-to-face provider visits with telehealth visits and no additional increase in overall provider visits. Although, as discussed later in this section, there are studies suggesting the possibility of increased provider visits due to ease of access of telehealth, these studies are mainly theoretical and furthermore suggest methods to curb the unwanted increase in visits; it might therefore, be very reasonable to assume that there is no increase. Another important point to bear in mind is that increased telemonitoring does not cost the enrollee extra time. Once a system is set up to electronically transfer medical measurements, the enrollee does not have to spend extra time for this transmission. A provider will only intervene if a medical measurement indicates the possibility of an adverse medical event. However, in such a case, the expected adverse medical event might be resolvable with a phone call or medication adjustment and is less costly time-wise than an actual face-to-face provider visit.

An additional concern with this estimation is that it does not take into account that the current MA program already has certain telehealth benefits, such as phone hotlines and telemonitoring. Therefore, it is not accurate to estimate the effect of telehealth in general without differentiating the former allowance of telehealth and the new allowances afforded by this provision.

We believe that the primary driver of telehealth savings is not the authority under the law to use it, but rather, increased availability of telehealth technology and implementation. For example, although current MA guidelines allow some telehealth services as supplemental benefits, only the largest plans have provided specific, line item data on it in their bid submissions.

Another example, illustrating that availability, not authority under the law, is the primary driver of telehealth savings, is found in national usage of telehealth. Although telehealth has always been allowed by commercial plans, it is rapidly increasing now because of increased availability and ease of implementation. Studies continually point to the growth potential for using telehealth; these studies emphasize that telehealth is not being used where it could be and that the issues are feasibility and availability.[35]

Thus, allowing plans to offer additional telehealth benefits, or reclassify their current supplemental telehealth benefits as basic benefits, would not, by itself, increase telehealth usage. Rather, the increased telehealth usage comes when telehealth technologies are readily available and easy to implement. The goal of this provision is to foster an atmosphere where both commercial and MA plans will be equally interested in the increasingly accessible technology and seek to incorporate it in their offerings.

In summary, we acknowledge the possibility that the estimates below, assuming no increase in provider visits and not taking into account current telehealth practices, may have elements of overestimation. Because of our uncertainties, we invite industry comments on our analysis.

To estimate the impact on enrollee travel time, we need four estimates:

- *Average travel time and average travel distance per visit:* While it is difficult to estimate the savings in reduced travel time quantitatively, since distances from enrollees to providers vary significantly, to estimate the travel time to providers we use a former CMS standard that providers should be located within 30 minutes or 30 miles of each enrollee. While this standard has since been replaced by a more sophisticated measurement of access, we can use it as a proxy. The former CMS standard was used because it is formulated simply in terms of time (one-half hour) and miles (30 miles) and does not differentiate among provider types. The current standards for access involve sophisticated algorithms, which involve more than two parameters (time and mileage), and additionally differ by geographic location and provider types. Therefore, the current standards were not suitable. We therefore assume that the midpoint, 15 minutes or 0.25 hour, represents the typical travel time to providers per enrollee visit.[36] We similarly believe that 15 miles (one-half of 30 miles) is the average travel distance per provider visit. We note the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment. CMS estimates cost per hour for enrollees using the occupational title ''All Occupations'' (occupation code 00–0000) from the BLS, with a mean wage of $24.34/hour. Thus, the net savings per enrollee per telehealth visit to providers would be $17.57 ($24.34 hourly wage * 0.25 minutes travel time * 2 (round trip) + 15 miles * 2 (round trip) * 18 cents a mile (cost of gasoline for medical transportation [37])). This is summarized in Table 7.
- *Average number of visits per enrollee:* The Center for Disease Control (CDC) estimates that in 2014, 65-year-olds and older average 5.89 visits per person.[38]
- *Number of MA enrollees:* Table IV.C1 of the 2018 Medicare Trustees Report provides the projected MA enrollment.
- *Percent, per year, of provider visits that are telehealth:* Ideally, we would like an estimate on the number of total visits and telehealth visits for 65-year-olds. However, these data are not available. Therefore, we use the best available proportions. We proceed as follows.

The CDC website cited above estimates 885 million provider visits in 2014. This is an aggregate number over all age groups; the 885 million was not broken out further by age group.

Absent information on the proportion of telehealth visits among total visits by 65-year-olds to providers, we use general averages (across all age groups) with the understanding that some accuracy is lost. The Statista website suggests 22 million telehealth visits in 2014.[39] This implies that 2.49 percent (22/885) of all physician visits were for telehealth.

Inferring growth rates from the numbers on the Statista website, the projected low and high growth rate for telehealth services is 1.089 percent and 1.22 percent respectively. Other

[35] See *https://www.ncbi.nlm.nih.gov/pubmed/23406075.* Also see Harry Wang, Director Health and Mobile Product Research, Parks Associates ''Virtual Health Care will revolutionize the Industry If we let it'', Forbes, 2014, accessible at *https://www.forbes.com/sites/ciocentral/2014/04/03/virtual-health-care-visits-will-revolutionize-the-industry-if-we-let-it/#4ee9a9e97c25.*

[36] This would result in 30 minutes (2 * 15 minutes) roundtrip. The following article using independent sources estimates 37 minutes, which is close to our estimate: *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1130.*

[37] *https://www.irs.gov/newsroom/standard-mileage-rates-for-2018-up-from-rates-for-2017.*

[38] *https://www.cdc.gov/nchs/products/databriefs/db292.htm.*

[39] *https://www.statista.com/statistics/820756/number-of-telehealth-visits-in-us/.*

TAB 5

83 Fed. Reg. at 55059

3. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560–562, 422.566, 422.629–634, 438.210, 438.400, and 438.402)

Proposed changes to the appeals and grievances provisions at §§ 422.629 through 422.634 focus on creating MA and Medicaid appeal and grievances processes that are unified for D–SNPs that also have comprehensive Medicaid managed care contracts (or are the subsidiary of a parent organization or share a parent organization with the entity with a comprehensive Medicaid managed care contract). The proposal addresses appeals at the plan level. Currently, Medicaid and MA appeals and grievance processes differ in several key ways. These differences hinder a streamlined grievance and appeals process across Medicare and Medicaid managed care sectors and create unnecessary administrative complexity for plans that cover dual eligible individuals for both Medicare and Medicaid services. Our proposed revisions would allow enrollees in a D–SNP that is also a Medicaid managed care plan through which the enrollees get Medicaid coverage to better understand the grievance and appeals processes and generally receive a resolution of their grievances and appeals more quickly.

There are six areas where this provision will have an impact.

- Certain Medicare Parts A and B benefits that the D–SNP has tried to terminate would be provided during the pendency of the integrated appeal at the plan level. This is estimated in detail below. The cost to the Medicare Trust Fund and beneficiaries (in the form of cost sharing) is $0.4 million in 2021 and $0.5 million in 2022–2024, growing modestly due to expected enrollment growth, to $0.6 or $0.7 million in the next few years.
- Applicable integrated plans' grievance policies and procedures and grievance notices would be updated. As discussed in the Collection of Information section, there would be a one-time first year cost of $18,790 for updates of applicable integrated plans' policies and procedures on grievances and an annual savings of $270,103 reflecting savings from Medicare and Medicaid grievance consolidation). Thus, there would be an annual savings of $0.3 million.
- Notice templates for the unified appeals for use by applicable integrated plans would be created by CMS, which is estimated to be a one-time negligible cost of about $1,000 for the work of Federal employees.
- Subregulatory guidance on integrated grievance and appeals would be developed by CMS staff, which is estimated to be a one-time negligible cost of about $2,000.
- Applicable integrated plans' appeals policies and procedures and appeals notices would be updated to comply with the unified appeals requirements, which is estimated to be a one-time negligible cost of $9,395 (4 hours per contract * 34 contracts * $69.08, the hourly wage of a business operations specialist).
- Enrollees of applicable integrated plans who wish to receive a copy of their appeal case file would request that plans send it to them at plan expense, which we estimate to cost about $38,637 annually.

The aggregate cost of this provision is $0.2 million a year. Industry would save $0.3 million each year in reduced services because grievances in Medicare and Medicaid are unified. However, this $0.3 million savings would be offset by an increase in cost of $0.5 million reflecting increased services. The $0.5 million cost (as well as the 0.3 million savings) are ultimately borne by the Medicare Trust Fund in the form of payments and beneficiaries in the form of increased cost-sharing.

We present details on these six areas in the sections that follow.

a. Furnishing Medicare Parts A and B Services During the Pendency Of Appeals

One of the provisions related to appeals integration may marginally impact the ways MA sponsors bid for their D–SNPs, which could marginally impact Medicare spending. We propose that the existing standards for continuation of benefits at § 438.420 apply to applicable integrated plans for Medicare benefits under Parts A and B and Medicaid benefits in our proposed integrated appeals requirements at § 422.632. Under our proposal, and as is applicable to Medicaid managed care plans currently, if an applicable integrated plan decides to stop or reduce a benefit that the enrollee is currently authorized to receive, the enrollee could request that the benefit continue to be provided at the currently authorized level while the enrollee's appeal is pending through the integrated reconsideration. Currently, MA plans in general are not required to provide benefits pending appeal, whereas in Medicaid it has been a long-standing feature.

It is our expectation that the new integrated appeals provisions will result in an increase in expenditures by applicable integrated plans for Medicare covered services because they will be required to continue coverage for services during the pendency of the reconsideration request, or first-level appeal under our proposal.

The estimate of impact of this continuation is based on calendar year (CY) 2016 appeal metrics, which are then trended to CY 2021.

The assumptions, sources and calculations are summarized in Tables G5 and G6 in this rule and further clarified as follows.

The first step in this estimation is to determine the number of applicable reconsiderations per 1,000 beneficiaries enrolled in integrated plans affected by this provision. Given the similarity of population characteristics, the reconsideration experience for the Medicare-Medicaid Plans (MMPs) participating in the Financial Alignment Initiative was used as a proxy for the applicable integrated plans. In 2016, MMP enrollees were impacted by 1,232 reconsiderations for services which were resolved adversely or partially favorably to the beneficiary. The corresponding MMP enrollment in 2016 was 368,841, which implies a rate of 3.3 applicable reconsiderations per 1,000 in 2016.

Then we projected D–SNP enrollment impacted by the unified procedures to grow from 150,000 in 2018 to 172,000 (150,000 * 1.145) in 2021 based on the estimated enrollment growth for all D–SNPs during the period of 14.5 percent. Applying the MMP appeal rate of 3.3 per 1,000 to the projected 2021 enrollment in applicable integrated plans of 172,000 results in an estimated 568 (172,000 * 3.3/1,000) service reconsiderations for the applicable integrated plans in 2020.

The next step is to determine the average level of benefit subject to the appeals. Table 1 in the report Medicare Part C QIC Reconsideration Data for 2016 [47] contains data on the number and benefit amounts by service category for the second level appeals filed in 2016. Analysis of these data resulted in an estimated per-appeal benefit value of $737 for 2016. The determination of this value took into account that some services would not be subject to the regulatory extension of coverage due to the existence of immediate review rights (inpatient hospital, skilled nursing facility, and home health), other benefits would likely have been rendered already (emergency room, and ambulance), and other services are not

[47] *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/IRE.html.*

TAB 6

83 Fed. Reg. at 55064

TABLE 13: COST PER PDP SPONSOR PER QUARTER FOR TRANSMITTING CLAIMS DATA

PDP Size in Enrollees	Number of Sponsors	Cost per Quarter per Sponsor for Transmission of Claims Data
Above 5 million	1	$26,500
1 million – 5 million	6	$17,500
100,000 – 1 million	11	$10,500
Under 100,000	45	$10,500

To complete the annual impact analysis we need an estimate of proportions for each plan size that would request data. For example, we are certain that the 1 PDP sponsor with over 5 million enrollees will request data. Thus the annual burden for that plan size is 1 * 4 quarters X $26,500 per quarter = $106,000. Similarly, if we assume that all six PDP sponsors with enrollments between 1 and 5 million would request data then the annual burden is 6 sponsors * 4 quarters * $17,500 per quarter per sponsor = $420,000. If we assume that only three-quarters of these six sponsors request data then the annual burden would be 0.75 * $420,000 = $315,000. In the absence of any other basis for the decision, it is reasonable to assume that the proportion goes down as the size goes down. In the absence of data, we could use a descent of simple fractions (1, three-fourths, one-half, one-fourth). Note, that 50 percent of plans with under 100,000 enrollees have under 10,000 enrollees. It is very unlikely that such plans would have the resources to use the data. Thus an assumption that only 50 percent of plans under 100,000 request data is reasonable. However, we consider multiple scenarios. Table 14 presents for a variety of scenarios of proportions and their total impact. The average of the five scenarios is $1.5 million while the median is $1.3 million. The range of impacts is $0.8 million–$2.9 million. For purposes of E.O. 13771 accounting we are listing the impact as $1.5 million annually, with a $0.2 million one-time cost in the first year. We do not trend this estimate by year since the number of PDP sponsors has remained at 63 since 2015.

TABLE 14: ANNUAL BURDEN OF PROVIDING CLAIMS DATA TO PDP SPONSORS

Scenario Label	Proportion of sponsors with over 5 million enrollees requesting data	Proportion of sponsors with 1 - 5 million enrollees requesting data	Proportion of sponsors with 100,000 – 1 million enrollees requesting data	Proportion of sponsors with under 100,000 enrollees requesting data	Aggregate annual burden based on Costs provided in Table 13
A	100 percent	75 percent	50 percent	33 percent	$1.3 million
B	100 percent	100 percent	75 percent	50 percent	$1.8 million
C	100 percent	50 percent	33 percent	25 percent	0.9 million
D	100 percent	100 percent	100 percent	100 percent	$2.9 million
E	100 percent	100 percent	50 percent	0 percent	$0.8 million

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We do not anticipate any further burden. It is most likely that the PDP sponsor would exclusively use the data. In the event that downstream entities are shared any data they are already bound in their contracts by all Medicare regulations including the regulations of this provision. Even if there would be a need to modify contracts to address the regulatory requirements of using such data, it would require at most one hour of work of a GS–12 or GS–13 staff member and one hour of review by a GS–15. A total of 2 hours of work by Federal employees would have a burden significantly less than $1,000. Hence, we are not further scoring this negligible impact.

5. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

We are proposing some measure specification updates. These type of changes are routine and do not have an impact on the highest ratings of contracts (that is, overall rating for MA–PDs, Part C summary rating for MA-only contracts, and Part D summary rating for stand-alone prescription drug plans). Hence, there will be no, or negligible, impact on the Medicare Trust Fund.

We are also proposing some adjustments for disasters. The proposed policy would make adjustments to take into account the potential impact on contracts when there are extreme and uncontrollable circumstances affecting them. This policy is in response to the multiple disasters in 2017 and 2018, including several hurricanes and wildfires. We are proposing a policy to permit an adjustment to Star Ratings when extreme and uncontrollable circumstances occur during the performance period or measurement period for MA and Part D plans.

We are also proposing enhancements to the current methodology to set Star Ratings cut points. The intent of the changes is to increase the stability and predictability of cut points from year to year. This proposal is consistent with the CMS goal to increase transparency. We believe this provision would also have minimal impact on the highest ratings of contracts. Specifically, simulations of the proposal using the 2018 Star Ratings show that the QBP

TAB 7

83 Fed. Reg. at 55074-75

the enrollee may receive the specified Part B service(s) through an in-person visit or through electronic exchange.

(3) Identify, in the MA plan's provider directory required at § 422.111(b)(3)(i), any providers offering services for additional telehealth benefits and in-person visits or offering services exclusively for additional telehealth benefits.

(4) Comply with the provider selection and credentialing requirements provided in § 422.204, and, when providing additional telehealth benefits, ensure through its contract with the provider that the provider meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service.

(5) Make information about coverage of additional telehealth benefits available to CMS upon request. Information may include, but is not limited to, statistics on use or cost, manner(s) or method of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the requirements of this section.

(d) *Requirement to use contracted providers.* An MA plan furnishing additional telehealth benefits may only do so using contracted providers. Coverage of benefits furnished by a non-contracted provider through electronic exchange may only be covered as a supplemental benefit.

(e) *Bidding.* An MA plan that fully complies with this section may include additional telehealth benefits in its bid for basic benefits in accordance with § 422.254.

(f) *Cost sharing.* MA plans offering additional telehealth benefits may maintain different cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange.

§ 422.156 [Amended]

■ 9. Section 422.156 is amended in paragraph (b)(1) by removing the phrase ''the quality improvement projects (QIPs) and''.

■ 10. Section 422.162 is amended in paragraph (a) by adding the definitions of ''Absolute percentage cap'', ''Cut point cap'', ''Guardrail'', ''Mean resampling'', ''Restricted range'', and ''Restricted range cap'' in alphabetical order to read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Absolute percentage cap is a cap applied to non-CAHPS measures that are on a 0 to 100 scale that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage as compared to the prior year's cut point.

* * * * *

Cut point cap is a restriction on the change in the amount of movement a measure-threshold-specific cut point can make as compared to the prior year's measure-threshold-specific cut point. A cut point cap can restrict upward movement, downward movement, or both.

* * * * *

Guardrail is a bidirectional cap that restricts both upward and downward movement of a measure-threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point.

* * * * *

Mean resampling refers to a technique where measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchal clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values.

* * * * *

Restricted range is the difference between the maximum and minimum measure score values using the prior year measure scores excluding outer fence outliers (first quartile −3*Interquartile Range (IQR) and third quartile + 3*IQR).

Restricted range cap is a cap applied to non-CAHPS measures that restricts movement of the current year's measure-threshold-specific cut point to no more than the stated percentage of the restricted range of a measure calculated using the prior year's measure score distribution.

* * * * *

■ 11. Section 422.164 is amended by adding paragraphs (f)(1)(v), (g)(1)(iii)(O), and (h) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(f) * * *

(1) * * *

(v) CMS will exclude any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(O) CMS will reduce a measure rating to 1 star for the applicable appeals measure(s) if a contract fails to submit Timeliness Monitoring Project data for CMS's review to ensure the completeness of the contract's IRE data.

* * * * *

(h) *Review of sponsors' data.* (1) A request for CMS or the IRE to review a contract's appeals data must be received no later than June 30 of the following year.

(2) A request for CMS to review a contract's Complaints Tracking Module (CTM) data must be received no later than June 30 of the following year.

■ 12. Section 422.166 is amended by revising paragraph (a)(2)(i) and adding paragraph (i) to read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for three years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first three years in the program.

* * * * *

(i) *Extreme and uncontrollable circumstances.* In the event of extreme and uncontrollable circumstances that may negatively impact operational and clinical systems and contracts' abilities to conduct surveys needed for accurate performance measurement, CMS will calculate the Star Ratings as specified in paragraphs (i)(2) through (10) of this section for each contract that is an affected contract during the performance period for the applicable measures.

(1) *Identification of affected contracts.* A contract that meets all of the following criteria is an affected contract:

(i) The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.

(ii) The contract's service area is within a county, parish, U.S. territory or

tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).

(iii) As specified in paragraphs (i)(2) through (10) of this section, a certain minimum percentage (25 percent or 60 percent) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

(2) *CAHPS adjustments.* (i) A contract, even if an affected contract, must administer the CAHPS survey unless exempt under paragraph (i)(2)(ii) of this section.

(ii) An affected contract will be exempt from administering the CAHPS survey if the contract completes both of the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in paragraph (i)(1)(iii) of this section in the prior calendar year.

(B) Requests and receives a CMS approved exception.

(iii) An affected contract with an exception defined in paragraph (i)(2)(ii) of this section will receive the contract's CAHPS measure stars and corresponding measure scores from the prior year.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the contract will receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure.

(3) *HOS adjustments.* (i) An affected contract must administer the HOS survey unless exempt under paragraph (i)(3)(ii) of this section.

(ii) An affected contract will be exempt from administering the HOS survey if the contract completes the following:

(A) Demonstrates to CMS that the required sample for the survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to the FEMA-designated disaster identified in (i)(1)(iii) of this section during the measurement period.

(B) Requests and receives a CMS approved exception.

(iii) Affected contracts with an exception defined in paragraph (i)(3)(ii) of this section will receive the prior year's HOS and Healthcare Effectiveness Data and Information Set (HEDIS)-HOS measure stars and corresponding measure scores.

(iv) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract will receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HOS and HEDIS–HOS measure.

(4) *HEDIS adjustments.* (i) An affected contract must report HEDIS data unless exempted under paragraph (i)(4)(ii) of this section.

(ii) An affected contract will be exempt from reporting HEDIS data if the contract completes the following:

(A) Demonstrates an inability to obtain both administrative and medical record data that are required for reporting HEDIS measures due to a FEMA-designated disaster in the prior calendar year.

(B) Requests and receives a CMS approved exception.

(iii) Affected contracts with an exception defined in paragraph (i)(4)(ii) of this section will receive the prior year's HEDIS measure stars and corresponding measure scores.

(iv) Affected contracts that do not have an exception defined in paragraph (i)(4)(ii) of this section may contact National Committee for Quality Assurance (NCQA) to request modifications to the samples for measures that require medical record review.

(v) For an affected contract with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance, the affected contract will receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each HEDIS measure.

(5) *New measure adjustments.* For affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, CMS will apply a hold harmless provision by comparing the result of the contract's summary and/or overall rating with and without including all of the applicable new measures. If the ''with'' result is lower than the ''without'' result, then CMS will use the ''without'' result as the final rating.

(6) *Other Star Ratings measure adjustments.* (i) For all other measures except those measures identified in this paragraph (i)(6)(ii) of this section, affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance will receive the higher of the previous or current year's measure Star Rating and then use the corresponding measure score.

(ii) CMS will not adjust the scores or Star Ratings for the following measures, unless the exception in paragraph (i)(6)(iii) of this section applies.

(A) Part C Call Center—Foreign Language Interpreter and TTY Availability.

(B) Part D Call Center—Foreign Language Interpreter and TTY Availability.

(iii) CMS will adjust the measures listed in paragraph (i)(6)(ii) of this section using the adjustments listed in paragraph (i)(6)(i) of this section for contracts affected by extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study.

(7) *Exclusion from improvement measures.* Any measure that reverts back to the data underlying the previous year's Star Rating due to the adjustments made in paragraph (i) of this section will be excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract.

(8) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating will come from the current year unless any of the exceptions described in paragraphs (i)(2)(ii), (i)(3)(ii), and (i)(4)(ii) of this section apply.

(9) *Cut points for non-CAHPS measures.* (i) CMS will exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(9)(i) of this section will be used to assess all affected contracts' measure Star Ratings.

(10) *Reward Factor.* (i) CMS will exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of

TAB 8

PCMA Comments

PCMA

December 21, 2018

Filed electronically at https://www.regulations.gov

Mr. Alex M. Azar, II
HHS Secretary
Department of Health and Human Services
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Ms. Seema Verma
CMS Administrator
Centers for Medicare & Medicaid Services
Attention: CMS–4185–P
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Baltimore, MD 21244–8013

RE: Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS–4185–P)

Dear Secretary Azar and Administrator Verma:

PCMA appreciates the opportunity to comment on the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly, Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021; Policy and Technical Changes proposed rule (hereafter referred to as "NPRM" or "proposed rule") as published in the Federal Register (83 FR 54982) on November 1, 2018.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the exchanges established by the Affordable Care Act.

While we support some of the proposals in the NPRM, we also have concerns with some proposals, including elements around the Part D access to Medicare Parts A and B claims data, Star Ratings program, exceptions timeframes for Part D drugs, and preclusion list requirements. In this comment letter, we largely focus on those provisions for which we have concerns. Below is a summary of our recommendations, followed by a detailed discussion of the issues in the order that they appear in the NPRM.

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PCMA

Executive Summary

Part D Access to Medicare Parts A and B Claims Data. While PCMA supports finalizing the permissible uses as proposed, it encourages CMS to reaffirm and leave open flexibility for other uses of Parts A and B data. PCMA further urges CMS to clearly provide that claims data otherwise permissibly obtained by Part D plans are not subject to limits, and to retract its recent Paperwork Reduction Act (PRA) collection regarding claims data requests and not to adopt an attestation requirement regarding the use of this data. Finally, PCMA recommends that CMS provide itself with flexibility to not have to amend the rules every time it seeks to change the data set, and that CMS make the claims data available as close as possible to real time.

Part D Prescription Drug Plan Quality Rating System. PCMA opposes the CMS addition of a frequency component to the MPF Price Accuracy Measure. PCMA supports the CMS recommendation for the updates to the improvement measures and recommends future changes to the improvement measures using a logarithmic scale. Finally, PCMA suggests future updates to the D02 Appeal Auto-Forward measure to be introduced in the CY2020 Call Letter to account adequately for enrollment size.

Improving Clarity around Exceptions Timeframes for Part D Drugs. While PCMA appreciates the efforts to improve clarity particularly regarding tolling of exceptions requests, PCMA urges CMS to provide clear, consistent timeframes that are the same in both the pending new appeals chapter and the rules set forth in the NPRM.

Preclusion List Requirements for Prescribers in Part D. In light of the numerous ongoing unanswered questions regarding implementation of the Preclusion List, PCMA strongly urges CMS to delay implementation of the Preclusion List requirements until January 1, 2020. As an alternative to such a delay, CMS could commit to exercising enforcement discretion against Medicare plans until January 1, 2020 for such plans that make a good faith effort to comply with the Preclusion List requirements.

We look forward to engagement with CMS on these and other issues to help advance the agency's goals with respect to implementing certain provisions of the Bipartisan Budget Act of 2018 (BBA) and reducing unnecessary regulatory complexity to help ensure the Medicare Part D program meets the needs of beneficiaries.

Our detailed comments follow below.

* * * *

PCMA

A. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153) (pp. 55015 – 55017)

Proposal: This provision seeks to implement a provision of the BBA entitled "Providing Prescription Drug Plans with Parts A and B Claims Data to Promote the Appropriate Use of Medications and Improve Health Outcomes." This statutory provision allows Part D plan sponsors, beginning in plan year 2020, to request extracts of Medicare claims data about their enrollees. In its proposal to implement this provision, CMS notes that it identifies options and alternatives to its proposed policies and "strongly" encourages comments on its proposed policies and alternatives. (p. 55016)

We summarize the key elements of the CMS proposal and then comment on each aspect.

1. Permissible Purposes

CMS proposes that the "full range of activities for which plan sponsors would need Medicare claims data" is:

- To optimize therapeutic outcomes through improved medication uses;
- To improve care coordination to prevent adverse health outcomes; or
- To execute certain "health care operations" or "fraud and abuse or compliance activities" under the HIPAA privacy regulations.

CMS requests comments on whether there would be any additional purposes for which plan sponsors ***should*** be allowed to use Medicare claims data under this section.

2. Impermissible Purposes

Per the BBA, CMS also proposes that plan sponsors ***not*** be permitted to use Medicare claims data from CMS for any of the following purposes:

- To inform coverage determinations (CDs) under Medicare Part D;
- To conduct retroactive reviews of determinations related to medically accepted indications (MAIs);
- To facilitate enrollment changes to a different Part D plan or MA-PD offered by the same parent organization; and/or
- To inform marketing of benefits.

PCMA

3. *Data Protection*

CMS states that it is "committed to ensuring beneficiary-level data is protected by strict privacy and security requirements" and is proposing to require that plan sponsors contractually bind relevant contractors to requirements under the section. CMS states its belief that Medicare claims data under this section is "protected health information" and plan sponsors are "business associates" under the HIPAA privacy rules, and that CMS therefore is not proposing any additional limitations on their use of the Medicare claims data. (p. 55016)

CMS requests comments on whether additional limitations should be placed on the data. CMS also proposes to require that plan sponsors attest that they will adhere to the permitted uses and limitations on the use of the Medicare claims data and requests comment on the proposed attestation.

4. *Process and Minimum Data Set*

Regarding the process for requesting the Medicare claims data from CMS, the agency proposes to accept data requests on an ongoing basis beginning January 1, 2020 and that requests may be submitted without an end date. CMS proposes to not allow plan sponsors to request data for subsets of their enrolled beneficiary populations.

In developing its minimum data set, CMS proposes that the data access limits would be consistent with the HIPAA privacy rule's "minimum necessary" concept. CMS states that data from all seven claim types – inpatient, outpatient, carrier, durable medical equipment, hospice, home health and skilled nursing facility – would be required to carry out the permitted uses of the data under the BBA. CMS believes that information on all Parts A and B services provided to a patient, along with the dates on which the services were furnished, would support care coordination and quality improvement activities. The claims information also would provide "insight into the services or procedures that resulted in a patient receiving a certain prescription drug, and the particular care setting in which the drug was prescribed" in order to help plan sponsors promote the appropriate use of medication and improve health outcomes for their enrollees. (p. 55017)

CMS proposes to include the following data elements/fields: enrollee identifier, diagnosis and procedure codes, dates of service, place of services, provider numbers and claim processing and linking identifiers/codes. Any proposed changes to these elements would be established through rulemaking.

PCMA

5. Time Span

Regarding the time span of the data, CMS states that only the most current data is relevant. CMS proposes to provide the Medicare claims data for items and services furnished to beneficiaries who are enrolled in a Part D plan offered by the sponsor "at the time of the disclosure." The data would be provided quarterly with a three-month lag from the last day of the last month of the prior quarter. In addition, it could take up to two months to process and ship the data extracts. Thus, the first claims data extract would be available to plan sponsors ***no earlier than August 15, 2020***. The quarterly releases would occur on a specified release date for all eligible plan sponsors. CMS requests comment on the proposed frequency and content for the proposed data releases.

Discussion: We provide below specific comments on each topic addressed by CMS regarding Part D plan sponsor access to Parts A and B claims data under the BBA. Initially, however, we note our major concern that the restrictions on access and use of this data as proposed not only significantly limit the value of the claims data to Part D sponsors for the purposes established under section 50354 of the BBA, but also are inconsistent with other ongoing regulatory obligations of Part D sponsors. As we note below, there are numerous examples where CMS currently allows Part D sponsors to access Parts A and B claims data which would seemingly conflict with the proposed impermissible uses.

Thus, we strongly urge CMS, in the final rule, to clarify that the "permissible" and "impermissible" uses in the final rule under § 423.153 apply *only* to data obtained under that section and do not preempt any other plan use of such data that is otherwise required and/or obtained through other permissible avenues. It is clear from the plain statutory language of the BBA that the intended permissible and impermissible restrictions apply only for purposes of the "four corners" of the new section of law, and not to other areas of Part D where such data use may be ongoing.

In addition, we encourage CMS to reassess its implementation strategy to assure that this proposal does not inadvertently restrict Part D plan sponsor's other, less restricted access to claims data.

1. Permissible Purposes

As noted above, our chief concern is that CMS may be reading the changes made by the BBA outside of the context in which they were enacted. In other words, while PCMA expresses no objection to the permissible uses proposed in this rule (which reflect the permissible uses delineated by Congress), we encourage CMS to clarify that such uses are only relevant for purposes of implementing this section. Further, to the extent the agency feels it has the flexibility to expand permissible uses, we would support such expansion.

***PCMA Recommendation*: PCMA supports finalizing the permissible uses as proposed, but encourages CMS to reaffirm and leave open flexibility for other uses of Parts A and B claims data outside of this particular section.**

2. Impermissible Purposes

Frankly, we believe that the impermissible purposes limits are very constraining and in fact fully undermine the usefulness of the claims data to Part D sponsors, particularly the restrictions on not using the data for CDs or retroactive reviews of MAIs. While we understand that this language emanates from the BBA, we believe it renders the claims data under this section as basically of very little value for many required and important plan functions.

We provide below some examples of scenarios where Part D plan sponsors have access to Medicare claims data where the limits vary significantly from those proposed under § 423.153.

- 2019 Call Letter.[1] The final 2019 Call Letter included detailed guidance on the use of Best Available Information where Part D plans make Part B vs. Part D coverage determinations for immunosuppressants and inhalable durable medical equipment (DME) supply drugs. (pages 255-257) The basic thrust of the 2019 Call Letter is that Part D sponsors are responsible for determining whether immunosuppressants used for Medicare-covered transplants are covered under Part B. In order to help reduce reliance on conflicting information, CMS announced the launch of a new web portal to provide additional enrollee information. The portal, called the Additional Beneficiary Information Initiatives (ABII), is to be populated with Medicare-covered transplant data derived from Medicare FFS claims. Even beyond the ABII web portal, the Call Letter establishes CMS' expectations on how Part D plans should perform due diligence to ensure Part D does not pay for Part B drugs. Simply put, Part D plans that do not have access to medical claims are held accountable in audits for drugs used for MAI. Because of this accountability, plans must be able to use this data for these coverage determination purposes.

- MTM Demonstration. Under the ongoing MTM demonstration being conducted by the Center for Medicare & Medicaid Innovation, participating Part D plan sponsors are allowed to access Part A and Part B claims data that they need to implement the demonstration. While plans do not have access to all Medicare

[1] HPMS Memo, "Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 2, 2018. Available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf

FFS claims data, there are no restrictions similar to those in this NPRM on how such data is used by plans internally (e.g., the data can be used for determinations about how well interventions are working).

- Data Provided by Enrollee or Prescriber Directly. Enrollees and prescribers are not banned from providing Medicare claims data to Part D sponsors (although prescribers would generally need the approval from the patient to do so). Indeed, with the recent launch of the Blue Button 2.0 option, it is more likely that beneficiaries will be in a position to provide such data to the plan sponsor. It will be very important that plans continue to be able to use such claims data in any permissible fashion, as they currently do and as intended by initiatives such as Blue Button 2.0 which declares on its Medicare web page that one of its key purposes is for beneficiaries to "share your health information with…anyone you choose."

In light of the lack of flexibility and contracting restrictions placed on Part D plan sponsors under this proposed rule, we further request that CMS clarify that for purposes of audits and reviews, Part D plan sponsors will not be penalized for failure to take into account Parts A and B claims data that is excluded from permissible uses. In particular, given that Part D plan sponsors are explicitly prohibited from conducting retroactive reviews of determinations related to MAIs, we ask that CMS clarify that, Part D plan sponsors will not be penalized for failing to implement MAI and other restrictions, even if the plan sponsor has this data on hand.

***PCMA Recommendation*: PCMA urges CMS to clearly provide that claims data permissibly obtained by Part D plans other than under this section are not subject to these limits and that nothing in this proposed rule in any way limits other regulatory requirements on plan use of claims data. CMS also must clarify how the permissible and impermissible use of this claims data will be taken into account for purposes of audits and other reviews.**

3. Data Protection

We do not believe that any additional limits should be placed on the data. However, we strongly oppose the requirement that plan sponsors must attest that they will adhere to the permitted uses and limits on the use of the Medicare claims data. In light of all the uncertainties and overlap in uses of the data as noted above, it is unreasonable to seek such attestation, which would likely result in the unintended consequences that no plan sponsors would seek any data under this section since they could not necessarily ensure that the data came from this authority with these limits, in contrast to data coming under other authority with fewer restrictions.

CMS recently released a PRA (CMS-10691, OMB 0938-TBD) collection to allow a PDP sponsor to submit a request to CMS for claims data for its enrollees and to attest that it will adhere to the permitted uses and limitations on the use of the Medicare claims data. This request, based on *proposed* regulations, is irregular given that the comment period on the proposed regulations is still pending. We are particularly concerned that CMS appears to be moving forward in favor of a problematic attestation process without the time and consideration for public comment.

***PCMA Recommendation*: PCMA urges CMS retract its recent PRA collection and not to adopt an attestation requirement regarding the use of the data obtained under this section as such a requirement would be unreasonable in light of all the other plan obligations relating to use of data.**

4. Process and Minimum Data Set

PCMA does not have any comments on the proposed process, and agrees with the proposed minimum data set. However, we believe CMS should leave some flexibility in terms of future changes to the data set and not necessarily require all future changes to go through rulemaking. In our dynamic and rapidly changing world of health care data sets, we do not think CMS should establish an arbitrary barrier to access to future data that may be added to Medicare claims data sets. One possible approach would be to require a regulatory change if a data set is proposed to be eliminated, but not if one is to be added.

***PCMA Recommendation*: PCMA recommends that CMS provide itself with flexibility to not have to amend the rules every time it seeks to change the data set.**

5. Time Span

Simply put, six-month old data is not helpful to improving therapeutic outcomes. As CMS notes, one of the permissible use of the data under the BBA is to optimize therapeutic outcomes. However, for data to be useful in that regard, the six-month delay would defeat that purpose. Rather, data needs to be made available as close as possible to a real-time basis. We urge CMS to expedite the timing to the greatest extent possible.

***PCMA Recommendation*: PCMA recommends that CMS make the claims data available as close as possible to real time.**

PCMA

B. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§ 423.182 et. seq.) (pp. 55018 – 55028)

Measure-Level Star Ratings

CMS is proposing an enhanced cut point methodology for data collected during the 2020 measurement year and associated 2022 Star Ratings. PCMA appreciates that CMS took into account the ongoing comments from Part D plans and PBMs, and from the RAND technical expert panel (TEP) as to the need to address the volatility of Star Rating measure cut points. PCMA supports the overarching goals of the Star Ratings program as articulated by CMS and looks forward to improvements that will help the program better align with the stated goals.

While we strongly support the efforts to establish new methodologies for ensuring that cut points more closely match with industry averages, PCMA has a number of questions and comments about the two methodologies proposed. As CMS finalizes the methodologies for 2020, we encourage CMS to further refine the methodologies based on our comments below.

a. Resampling. With mean resampling, CMS proposes that measure-specific scores for the current year's Star Ratings be randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm would be done 10 times, each time leaving one of the 10 groups out. The method would result in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure would be calculated using the 10 values. (p. 55020)

   The description that CMS has provided about the new methodology is relatively brief and limited to the language above. With such minimal information, PCMA and its member companies do not have a clear understanding as to whether the resampling methodology will address the impact of outliers. Under one reasonable interpretation, our understanding is that the methodology could lead to the outlier contracts being included in 9 of the 10 times that the hierarchical clustering algorithm is done, leading to a greater impact on the overall cut point calculation. While this interpretation may not be accurate, the proposed regulation does not provide enough information to provide necessary clarity. Thus, PCMA asks that CMS:

   - Provide additional clarity on the resampling methodology, including modeling the impact of cut points and detailed technical specification; and
   - Consider whether the resampling methodology actually leads to outlier contracts having greater influence as described above.

PCMA has identified two alternate cluster methodologies that we believe CMS should consider:

1. One algorithm is *k*-means clustering with outlier removal as described by Guojun Gan and Michael Kwok-Po Ng in *Pattern Recognition Letters*. The *k*-means clustering is one of the oldest and most commonly used clustering methodologies; however, it is sensitive to noisy data and outliers. Gan and Ng propose the KMOR (*k*-means clustering with outlier removal) algorithm by extending the *k*-means algorithm for outlier detection. Given a desired number of clusters *k*, the KMOR algorithm partitions the dataset into *k* + 1 groups, which include k clusters and a group of outliers that cannot fit into the *k* clusters. Unlike most existing clustering algorithms with outlier detection, the KMOR algorithm assigns all outliers into a group naturally during the clustering process.[2]

2. A second algorithm is clustering with outlier removal (COR) algorithm as described by Hongfu Liu, et al in *Proceedings of ACM SIG on Knowledge Discovery and Data Mining*. According to Liu, et al, the original space is transformed into the binary space via generating basic partitions in order to define clusters. Only part of the problem can be handled by k-means optimization. To provide a more integrated solution, an auxiliary binary matrix is introduced so that COR completely and efficiently addresses the problem via a unified k-means optimization.[3]

b. Measure-specific caps in both directions to provide guardrails. CMS proposes establishing a guardrail for measures that have been in the Part C and D Star Ratings program for more than 3 years. The proposed guardrail of 5 percent would be a bi-directional cap that restricts movement both above and below the prior year's cut points. A 5 percent cap restricts the movement of a cut point by imposing a rule for the maximum allowable movement per measure threshold; thus, it allows a degree of predictability.

   In general, PCMA supports the addition of measure-specific caps in both directions to provide guardrails. We offer the following observations intended to enhance the CMS proposal:

   1. It appears that the 5 percent figure was selected randomly, when improvement varies differently across years and individual measures. For some Star Rating measures the 5 percent limit could be too high, yet for others measures it could

[2] Guojun Gan and Michael Kwok-Po Ng, "k-means clustering with outlier removal," *Pattern Recognition Letters*, March 8, 2017. 90 (2017) 8-14. Accessible at https://arxiv.org/pdf/1801.01899.pdf
[3] Hongfu Liu, Jun Li, Yue Wu and Yun Fu, "Clustering with Outlier Removal," *Proceedings of ACM SIG on Knowledge Discovery and Data Mining,* 1997. Accessible at http://www.math.uconn.edu/~gan/ggpaper/gan2017kmor.pdf



be too low. With the current measure cut points, changes of 2 to 3 percent are significant on some measures. We do not believe that one absolute number will address the issue and suggest instead that CMS should consider whether to set different cut point caps for individual measures. One proposal that CMS should consider for a more appropriate guardrail would be establishing a threshold limit for cut point movement of not more than two times the industry average movement.

2. CMS proposes a 5 percent restricted range cap, defined as (0.05) * (maximum value – minimum value) only for measures that are not scored on a 1 to 100 scale. This percent restricted range cap may be more appropriate than the 5-percentage point absolute cap for all measures, including those scored on a 1 to 100 scale.

3. CMS proposes that the measure-specific caps would apply to measures that have been in the Part C and D Star Ratings program for more than three years. PCMA is concerned that new measures are often where the most fluctuation occurs. Part D plan sponsors need the ability to work with providers to improve performance on new Star Rating measures, and it is challenging to provide appropriate feedback and incentives with such fluctuation. Some guardrails should also be established for new measures, although we acknowledge that new measures will present different challenges. One option is to extend the weighting of 1 for new metrics from 1 to 2 years, at the end of which time period threshold limits would be applied at no more than two times the industry average movement until metric specific guardrails can be established.

PCMA has an additional concern which reinforces the need for guardrails. While we are supportive of the CMS proposal for policy to adjust the methodology for Star Ratings for affected Medicare Advantage and Part D plans in the event of extreme and uncontrollable circumstances (discussed later in these comments), PCMA recognizes that the repeated removal of certain contracts has an impact on the overall cut point thresholds and may lead to incremental volatility. CMS should be mindful of the impact of such excluded contracts. We believe that the Extreme and Uncontrollable Circumstances proposal reinforces the need for meaningful and effective guardrails.



c. Effective date. Finally, PCMA's understanding from review of the NPRM is that the cut point methodology changes would be implemented for CY2020. We strongly encourage CMS to confirm that the change is for CY2020; we would oppose delaying the cut point methodology change to occur with the updated Star Rating measures in 2022.

PCMA Recommendation: PCMA supports CMS's efforts to establish new cut point methodologies. We encourage CMS to further refine the methodologies based on our comments, including: a) provide additional clarity on resampling methodology; b) consider whether the proposed methodology does actually lead to outlier contracts having greater influence and consider two alternate methodologies; c) establish measure-specific caps rather than 5 percent for all measures; and, d) implement measure-specific caps for measures that have been in use for less than three years. In addition, PCMA asks that CMS confirm that the changes are to be implemented for CY2020.

Updating Measures

PCMA is providing comments on two existing Star Rating measures for which CMS is proposing modifications to the following existing measures to take effect in 2022 and 2023 Star Ratings. (pp. 55021 – 55024)

a. Medicare Plan Finder Price (MPF) Accuracy (Part D). (additional detail p. 55021 - 55022): CMS indicates that the new measure will be a Display Measure for 2020 and 2021, and then will become a new Star Rating measure in 2022 in place of the current MPF measure. The new measure will include the Price Accuracy Index (magnitude difference) and Claims Percentage Index (percentage of PDEs with total PDE cost higher than total MPF cost). CMS will use $0.01 rather than $0.005 to identify claims to be included in the Claims Percentage Index. The new MPF Star Rating measure will have weight of 1 in 2022 Star Ratings.

   PCMA continues to strongly advocate that the frequency of price changes is not an appropriate measure of concern to beneficiaries. Beneficiaries are impacted when the pricing data available on the MPF is significantly different than the price charged at POS and reflected in the PDE data. In the past several years, Part D plan performance remained consistently strong on the MPF Price Accuracy magnitude calculation. Nearly 100 percent of MA and PDP plans scored 98 (4 Stars) and 99 (5 Stars) on the measure.

In addition to our previous comments as summarized below, PCMA believes that price change frequency is already addressed in the current Star Rating measure. While in theory, a small change would not bring down the current MPF rating; in practice, price changes occur in high volume with thousands of claims for each drug. Because the current calculation incudes a sum of all differences, even a small or moderate difference between MPF and PDE data, multiplied by thousands of claims, is already reflected in the current MPF score.

The frequency of pricing differences between the data available on the MPF and the price reflected in the PDE data is due to established CMS timelines for MPF updates. Files are prepared and submitted by a Part D plan according to the CMS-issued calendar and guidelines which do not allow submissions outside the specified bi-weekly schedule. CMS posts files two weeks after submission which are then displayed on MPF for two weeks. When a beneficiary views drug pricing data on MPF, the data are typically between 19 to 31 days old. Pricing data for the MPF display are based on a single reference/proxy NDC and are compared to an expanded list of NDCs on the PDEs. Drug costs vary by NDC, even those with same strength or dosage form, and drug prices can change daily. This variability leads to unavoidable inconsistencies between a Part D plan's submitted price and the price on the claim or PDE record.

Rather than continue to evaluate Part D plan sponsors negatively when the timing construct creates a situation where MPF pricing information will never be 100 percent accurate, it would be more reasonable for CMS to consider an alternative approach. Specifically, CMS should include language on the MPF that indicates that the pricing data may be up to two weeks old and thus may not reflect the prices that beneficiaries experience at the time a prescription is dispensed.

PCMA continues to urge CMS to convene a group of experts, including representatives from Part D plan sponsors and PBMs, to develop appropriate improvements in the measure. We believe that by working together we can develop more meaningful approaches to beneficiary protections, as well as provide more accurate information on drug pricing.

CMS should also reconsider whether frequency is an appropriate component to be added to the MPF Price Accuracy measure. If a frequency measure must be used, CMS should revise frequency calculations to ensure that the measure is relevant to beneficiaries and does not include price differences of less than or equal to something in the range $0.50 – $1.00. The de minimis amount of $0.01 does not account for all rounding errors. PCMA member companies have data samples to demonstrate the impact of rounding errors to share with CMS as appropriate.

If CMS is to move forward with the change to the MPF Star Rating measure, CMS should provide national averages and/or updated cut points with the new methodology to allow Part D plan sponsors an opportunity to estimate their Star Ratings. CMS has not yet published any industry benchmarks (e.g. industry plan performance) or Star Rating measure thresholds for the new measure methodology. With no reference point for historical performance or industry performance to put the new MPF composite calculations in context, Part D plan sponsors cannot predict Star Ratings measure thresholds.

b. **Improvement Measures (Part C and D)**. CMS proposes modifying the improvement measures to exclude from the improvement calculation any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year.

PCMA supports the current recommendation and urges CMS to continue to adapt the Quality Improvement Star Rating methodology to both encourage underperforming contracts to meet CMS standards and reward high-achieving contracts to strive for further excellence.

PCMA encourages CMS to consider future changes to the Quality Improvement (QI) measures to ensure alignment with the stated goals of the Stars Ratings program. We recommend CMS use a logarithmic scale to evaluate year-over-year performance improvement. For example, a revised calculation formula could be: log (10 x (absolute value (year-over-year change))) = Improvement Change Score. Unlike the linear scale, the log scale accommodates the law of diminishing returns and reduced improvement opportunity. Additionally, CMS should review the measures that are included as a part of the QI measure calculation to ensure that: (1) performance improvement on these measures is under control of the plan; and (2) that performance has not topped out on these measures, resulting in little to no opportunity to improve performance.

In addition to the measure updates proposed by CMS, PCMA suggests a measure update for CMS to include with new measure changes to be introduced in the CY2020 Call Letter, D02 Appeal Auto-Forward. The current specifications for D02 Appeal Auto-Forward do not adequately account for enrollment size. A plan with less than 2,703 beneficiaries will drop at least one star with only one auto-forward or missed turnaround time for the entire year. A goal of 100 percent timely turnaround is the desired standard, but PBMs supporting a number of Part D plan sponsors see a major discrepancy between small and large plans. Because PCMA believes the impact of these misses should be scaled more equitably, we request that CMS

consider either raising the minimum enrollment or excluding plans that have fewer than two auto-forwards for the contract.

***PCMA Recommendation*: 1) PCMA continues to oppose the CMS addition of a frequency component to the MPF Price Accuracy Measure. CMS should convene a group of experts to assess the most appropriate measurement of MPF Price Accuracy to reflect performance information that is both meaningful to beneficiaries and accurate. If CMS moves forward with the change to the MPF Star Rating measure, it should provide national averages and/or updated cut points with the new methodology to allow Part D plan sponsors an opportunity to estimate their Star Ratings. 2) PCMA supports the CMS recommendation for the updates to the improvement measures and recommends future changes to the improvement measures using a logarithmic scale as described above. 3) PCMA suggests future updates to the D02 Appeal Auto-Forward measure to be introduced in the CY2020 Call Letter to account adequately for enrollment size.**

Data Integrity

CMS is proposing an additional provision that would assign a 1-star rating to applicable appeals measures if a contract fails to submit Timeliness Monitoring Project (TMP) data for CMS' review to ensure completeness of their IRE data.

PCMA supports CMS' efforts to ensure data integrity. However, PCMA is concerned that the additional change effectively modifies the appeals Star Ratings measure from a timeliness measure to a timeliness and data integrity measure. Indeed, the proposed change has the effect of modifying the measure significantly. As PCMA has indicated previously, PCMA remains opposed to the use of audit data that CMS uses to assess data integrity for these measures, as audit data is not a reflection of quality. Additionally, CMS needs to recognize that the TMP auditor holds the Part D plan sponsors to a short timeframe similar to the Part D Program Audit, yet the results are not shared with plan sponsors until December, nine months later.

The timing of the TMP is exceptionally burdensome. TMP occurs at the same time that the departments being tested are completing the Part D reporting process and responding to the Part D data validation audits. All three efforts evaluate the same coverage determination and redetermination data. This situation presents an opportunity to apply the requirements of Executive Order 13771 – Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs. We believe our recommendation would fulfill the star ratings integrity goal, be less burdensome for Part D plan sponsors, and save the Part D program the amounts CMS would otherwise pay for the TMP audit.

Specifically, PCMA recommends that CMS eliminate the TMP audit. In its place, CMS should modify the Part D Reporting Requirements and Technical Specifications for the Coverage Determination and Redetermination reports. Currently, CMS collects a summary report for these requirements. PCMA recommends that CMS instruct Part D sponsors to report this data in a detail file layout, similar to what CMS collects for the MTM report. Further, we recommend that CMS adopt the Part D Program Audit CDAG file layout for the universe with the highest number of fields (ECDER). Instead of quarterly subreports, CMS should instruct plan sponsors to report in the aggregate for the entire contract year.

Part D plan sponsors already have to pay an independent data validation auditor to confirm the accuracy and completeness of the reporting process. This includes sampling a subset of cases to confirm that the data reported is consistent with the adjudication of the coverage determination or redetermination. The data validation auditors provide their reports directly to CMS. CMS has already proposed to use the data validation results in section 423.186(a)(2)(ii). CMS could choose to align the data validation audit instructions and methodology so that the independent auditors also cover the activities undertaken in the TMP. PCMA member companies experience is that the process is almost identical where coverage determination and redetermination timeliness is concerned. This approach would cover the validation of the Appeals Auto-forward measure compared to the IRE data.

Finally, PCMA asks that CMS clarify whether the 2018 or the 2019 cycle results will be used for the 2020 Star Ratings measure.

***PCMA Recommendation*: PCMA recommends that CMS consider future changes to eliminate the TMP audit and use alternate existing reports as described above.**

Review of Sponsors' Data

CMS proposes to codify policy regarding the deadlines for an MA organization or a Part D plan sponsor to request CMS or the IRE to review a contract's appeal or for CMS to review a contract's Complaint Tracking Module (CTM) data. CMS is proposing that requests for CMS or the IRE to review contract data must be received by June 30 of the following year in order to have time to use accurate information in the Star Ratings calculations. CMS is also proposing that any requests for adjustments following CMS' CTM Standard Operating Procedures for the complaints measures be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data.

PCMA is generally supportive of the proposal. However, PCMA is opposed to June 30 as the deadline for review. PCMA recommends that CMS select a date aligned with the end of the first plan preview of Star Ratings performance metrics (usually occurring in the second or third week



of August). This later date would allow plans to fully respond to all appeals and complaints information and still allow CMS time to incorporate this data into the Star Ratings.

***PCMA Recommendation*: While PCMA is generally supportive of establishing deadlines; however, PCMA recommends that CMS select a date aligned with the end of the first plan preview of Star Ratings performance metrics.**

Extreme and Uncontrollable Circumstances

CMS proposes a policy to adjust the methodology for Star Ratings for affected Medicare Advantage and Part D plans in the event of extreme and uncontrollable circumstances, such as hurricanes. The proposed policy for extreme and uncontrollable circumstances is similar to the one implemented for the 2019 Star Ratings.

PCMA is supportive of the proposal and of CMS efforts to address the impact on beneficiaries and Star Ratings measures. However, we are concerned that the criteria outlined by CMS that greater than 25 percent of total membership must be in the impacted service area is biased against larger contracts serving populations spread across multiple regions. PCMA recommends that CMS develop a method that adjusts for impacted membership in a more representative manner at the enrollee level. One suggested alternative would be for enrollees identified as living within the impacted geographic area be removed from the measurement calculation. This alternative would ensure that all affected contracts receive an adjustment that is commensurate with the level of impact to the plan performance and would maintain an approach consistent with other exclusion criteria used in Star Ratings measures. This approach would also ensure that Star Ratings performance is representative of performance during the measurement period.

In addition, PCMA encourages CMS to provide additional industry visibility within the published quality data when an adjustment is made for extreme and uncontrollable circumstances. Such information would allow Part D plan sponsors a better understanding of marketplace performance and reduce questions to CMS.

PCMA also asks CMS to consider the implications of applying the methodology year-over-year as some regions unfortunately face consecutive years of natural disasters. With some regions, we are concerned that 2017 data could be continued to be pulled forward each year and be used in the 2022 Star Ratings program. PCMA does not have a specific alternative but recommends that CMS consider the implications of ongoing and repeated extreme and uncontrollable circumstances.

***PCMA Recommendation*: While PCMA supports CMS efforts to address the impact of extreme and uncontrollable circumstances on beneficiaries and Star Rating measures, CMS should develop a method that adjusts for impacted membership in a more representative manner at the enrollee level.**

Additional Comments

In addition to our comments on the NPRM, PCMA also offers comments on recent reports that appear to communicate that PDPs offer a lower level of quality than MA-PDs on the 2019 Star Rating measures. Based on 2019 Part C and D Star Rating data released by CMS, it was widely reported that enrollment in PDPs with 4+ stars was reduced in 2019 compared to 2018. The number of PDP contracts with 4+ stars decreased from 28 in 2018 to 16 in 2019. If enrollees remain in these plans, this reduction would result in 3 percent of beneficiaries enrolled in these plans, compared to 47% in 2018. Further, enrollment in PDPs with 3 and 3.5 stars would increase from 44% in 2018 to 90% in 2019.[4] While the numbers reported were accurate, CMS should communicate on the Medicare Plan Finder that the decrease in PDPs with 4+ stars was in part due to higher cut points for PDPs vs. MA-PDs on a number of Star Rating measures.

For example, on the Medication Adherence for Diabetes Medication (D10) measure, the 2019 MA-PD cut points were 85 for 5-star and 78 to <81 for 3-star; for PDPs, the same cut points were 88 for 5-star and 84 to <86 for 3-star. While the differences between MA-PD and PDP vary among the difference in measures, PCMA believes that CMS should make clear that the change across PDP performance is due in a significant part to the changes and differences in cut points. Because of the cut point issues, specifically outliers not being addressed, PDPs were even more drastically impacted in 2019 Star Ratings than MA-PDs.

[4] Avalere, CMS 2019 Star Ratings Remain Stable for MA-PD Plans; Shift for PDPs, October 19, 2018. http://avalere.com/expertise/managed-care/insights/cms-2019-star-ratings-remain-stable-for-ma-pd-plans-shift-for-pdps

PCMA

C. Improving Clarity of Exceptions Timeframes for Part D Drugs (§§ 423.568, 570, and 572) (pp. 55028- 55029)

Background: CMS proposes to change the Part D adjudication timeframes related to exception requests where the prescriber's supporting statement has not been received by the plan sponsor. Specifically, CMS would limit the time an exception request can be held open in pending status while the plan sponsor tries to obtain the supporting statement. CMS notes the importance of the supporting statement as the reason that the adjudication timeframes for coverage determinations (CDs) do not begin until the supporting statement is received by the plan. CMS then notes that, under current guidance, "plans are instructed not to keep an exception request open indefinitely" and "to apply a reasonableness standard for holding the request open pending receipt of the prescriber's supporting statement." (p. 55028) CMS cites Chapter 18 as instructing plans that if they do not receive the statement in a reasonable period of time, they should make their determination on whatever evidence exists.

CMS notes that it has received input from stakeholders that there should be more certainty in the time frame applied to the exceptions process. Benefits of a fixed period include having "the effect of more timely submission of supporting statements by prescribers once they become familiar with the fixed timeframe in which plans must issue a decision based on an exceptions request." (p. 55028) Thus CMS is proposing as follows:

- For an exception request, the plan must notify the enrollee (and prescriber as appropriate) of its decision no later than 72 hours (24 hours for expedited request) of receipt of the supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

CMS is not proposing any change to the existing timeframes for issuing decisions, except for an outside limit to the timeframe where the supporting statement is not timely received. CMS acknowledges that if a supporting statement is received late in the adjudication time period (e.g., on the 12th day), the plan sponsor will have less time to conduct its review. In other words, it appears that, if supporting documentation arrives on day 14, the plan must make and communicate its decision *on that same day*. CMS believes the shortened timeframe is mitigated by "the value in having greater certainty in the process by establishing a maximum timeframe for notifying the enrollee of the plan sponsor's decision" (p. 55028) If the plan sponsor does not have clinical support to approve the exception request, the plan then issues the standardized denial notice (including the reason for the denial, the documentation needed, and the enrollee's appeal rights).

Discussion: We set forth below the comments PCMA just filed on October 22 on the proposed new appeals chapter to replace Chapter 18 of the Prescription Drug Manual (hereafter, the "Proposed New Appeals Chapter"). We are struck by a number of potential inconsistencies in



that chapter and the proposed new rule, including effective date (2019 or 2020?), time to conduct review once the supporting statement is received, and whether 14 days tolling timeframe is an absolute maximum. We hope these comments provide useful context for the comments we provide below.

Excerpt from PCMA comments filed with CMS on October 22 on the proposed New Appeals Chapter to replace Chapter 18 of the Prescription Drug Manual (and Chapter 13 of the Medicare Managed Care Manual):

> ***7. 40.5.4 – Adjudication Time Frames for Coverage Determinations Involving an Exception (p. 31)***
>
> *For exception requests, CMS permits plans to "toll" the timeframe until it receives the prescriber's supporting statement, and now notes that it does not believe the tolling should exceed 14 calendar days. We appreciate CMS defining the acceptable upper limit on tolling time (subject of course to the specific facts of the situation).*
>
> *As it currently stands, the tolling process is administratively burdensome for plans, confusing to beneficiaries and prescribers, and does not consistently add value for beneficiaries, as it is in their best interests to have accurate, well-informed coverage decisions made as early in the process as possible, reducing the need for unnecessary appeals. Thus, we recommend that CMS consider guidance that would allow the use the concept of "tolling" for more information whenever there is insufficient information to make an informed decision. Below are some examples where tolling would be appropriate:*
>
> - *Plans have to ascertain whether the appellant is seeking to satisfy coverage criteria or asking for an exception to UM criteria, even though typically the beneficiary is unaware of the difference and would select whichever path is most likely to lead to an approval.*
> - *Plans have to define (in detail) when a supporting statement is 'valid' such that an exception cannot be tolled, regardless of whether the supporting statement sufficiently demonstrates medical necessity (see also the related discussion in section B(2) below).*
> - *Plans can toll only for exceptions (14 days) and not when the appellant is looking to satisfy coverage criteria or prior authorization.*
> - *Plans can toll CDs and IRE appeals but not plan level appeals, even when it only becomes clear the beneficiary is seeking an exception at the redetermination level (e.g., at the CD level, it appears the appellant is trying to satisfy PA criteria, but upon redetermination, the appellant asks the plan to waive the criteria due to medical necessity).*
>
> *We would appreciate anything CMS can do to reduce burden, make the process more clear, consistent, and easily understood for all involved, and shift the focus from administrative minutia onto obtaining sufficient information and making well informed coverage decisions. We believe extending the tolling concept in the instances noted above would be a reasonable step to help accomplish these goals.*
>
> *Finally, we also would appreciate clarification on implementation of tolling. Specifically, although CMS articulates that 14 days is a reasonable time for tolling the adjudication time frame (as outreach is performed to gain a supporting statement), we do not*

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> *understand the 14-day tolling timeframe to be a definitive time frame that requires the plan to auto-forward the case to the IRE if the plan occasionally misses the time frame. In other words, while plans should not routinely leave cases open longer than 14 days trying to get a statement, if plans do not get the information by day 14, they should follow current guidance which is to deny for lack of a statement and issue appeal rights.*

We appreciate CMS' efforts to provide a clear, consistent timeframe for exceptions. However, the proposal, in the NPRM, while directionally helpful, appears inconsistent with the "New Appeals Chapter" proposed by CMS on October 1, which states that CMS is targeting January 1, 2019, as the draft date for the new guidance.[5] The areas of inconsistency include:

- Effective date. 2019 or 2020?
- 14 days absolute. Whether the 14 days tolling limit is an absolute maximum.
- Tolling count. Whether the time period to address the exception request (24 / 72 hours) must be concluded in the 14 days or whether it only needs to be triggered in that timeframe.

We strongly urge CMS to issue one set of clear guidance (presumably both a revised New Appeals Chapter and a rule) where the documents are aligned and consistent, and which both provide as follows for each of the points above:

- Effective date. We would of course appreciate having these improvements effective as soon as possible. That said, we are concerned about having one set of requirements effective during the 2019 year and another set effective 2020. We particularly seek to avoid audits where part of the year is under one construct and another part of the year is under another. CMS should consider making the changes effective 90 days after the New Appeals Chapter is released, and then allowing plans to phase in the new protocols with compliance effective as of January 1, 2020.

[5] CMS, HPMS Memo, "2019 Program Audits," December 4, 2018. Accessible at https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2019ProgramAuditHPMSMemo.pdf.
Based on recent updated guidance issued on HPMS, we understand that the target date is now February 1, 2019. Specifically, CMS notes: "On October 1, 2018, CMS released a draft consolidation of Chapter 13 of the Medicare Managed Care Manual and Chapter 18 of the Prescription Drug Benefit Manual into one comprehensive guidance document. CMS has reviewed industry comments on the proposed guidance and does not anticipate significant changes for the final which we expect will be released in February 2019. Although CMS sees the changes put forth in the updated guidance as a reduction in burden for the industry, CMS will ensure sponsors have an opportunity to implement the updates within their organization before auditing any changes to compliance standards. Upon release of the finalized guidance, CMS will provide detail on how and when any audit compliance standards will be affected."



- 14-day absolute. Our preference would be for CMS to build in some flexibility on whether the 14-day period for additional support can be extended. If so, the rules will need to address the impact of any such extension on tolling. In any event, the rules need to be very clear on how this would work.

- Tolling count. In no event should CMS proceed with the proposal under which if a plan gets the information on the 14th day, it must make the decision by the 14th day. This will increase denials and errors because it will not be possible for plans to make decisions fast enough. We urge CMS to clarify that the decision process must begin within the 14 days but not require that it be completed in that time frame. One way to achieve this would be to provide that the plan must begin the adjudication timeline of 72 hours (or 24 hours for expedited requests) on the date that the prescriber statement is received or when tolling expires on the 14th calendar day, whichever comes first.

Finally, CMS may want to consider other alternatives that would be easier to implement, which would be to replace tolling altogether in favor of fixed processing timeframes. For example:

- All standard requests – including prior authorization, step therapy, and exception requests – would have a 7-day maximum timeframe for completion to ensure weekends and holidays do not prevent successful outreach. Tolling would no longer be permitted.

- All expedited cases would have a 24-hour timeline requirement unless the request is received with insufficient information to arrive at a decision. In the case of insufficient information, the due date would be extended to a maximum of 7 days from time of receipt of the request.

***PCMA Recommendation*: PCMA urges CMS to accomplish its goal of improving the clarity of exception timeframes by providing clear, consistent timeframes that are the same in both the Proposed New Appeals Chapter and the rules set forth in the NPRM. In no event should CMS adopt the shortened outside limit to the time frame where the supporting statement is received late in the adjudication period.**

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D. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§ 422.222 and 423.120(c)(6)) (pp. 55029 – 55037)

Proposal: At the outset, and as detailed in our comments on the "Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule" (82 FR 56336), PCMA commends CMS for retracting its previous proposal (as set forth in a 2015 Interim Final Rule) for mandatory prescriber enrollment in Part D. Such a requirement would have resulted in a significant decline in the number of eligible prescribers, harming beneficiary access and driving up programmatic costs, and with limited impact on safeguarding the program.

While PCMA generally supports the concept of a "Preclusion List" as a way to ensure beneficiary safety and safeguard the program, PCMA is concerned by CMS' proposed implementation of the new Preclusion List requirements, which, if implemented without revisions and clarifications, could unnecessarily increase complexity in the Part D program, expose Medicare beneficiaries to problematic prescribers and uncertainty in their access to needed prescriptions, and perpetuate a cycle where there is insufficient time to implement complex new requirements that pose substantial operational challenges. Particularly in light of the numerous changes to the Preclusion List proposed in this NPRM, along with the additional changes and uncertainty emanating from the recent HPMS guidance on precluded prescribers and subsequent FAQ,[6] we urge CMS to delay implementation of the Preclusion List until it can fully address these concerns, and the many other issues raised by stakeholders. Assuming that the issues and inconsistencies can be addressed in a meaningful way, we believe a January 1, 2020 effective date across the board for all requirements would be appropriate.[7]

As an alternative to a total delay, CMS could (in coordination with its auditors including its recovery audit contractors, or RACs) exercise enforcement discretion for the 2019 plan year for good faith efforts to implement the Preclusion List rules as currently in place for 2019. In particular, CMS could announce that it will refrain from sanctioning plans that fall short regarding implementation of the Preclusion List requirements until CY 2020.

[6] CMS, HPMS memo, "Preclusion List Requirements," November 2, 2018. Accessible at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-Week1-Nov-1-2.html?DLPage=2&DLEntries=10&DLSort=1&DLSortDir=descending. *See also* CMS, "Prelusion List Requirements Frequently Asked Questions (FAQs)," December 14, 2018.

[7] Indeed, on December 6, 2018, PCMA formally filed a request with CMS for a delay in implementation of the Preclusion List until January 1, 2020. See Exhibit B.



Discussion: Our comments on specific issues raised by the proposed rule are set out below.

a. PCMA supports many of the changes to the Preclusion List in the FY 2020 NPRM but is concerned that multiple and varying effective dates will lead to confusion and beneficiary harm.

In the proposed rule, CMS expands upon and clarifies the "precluded provider" provisions finalized in the CY 2019 MA/Part D Policy & Technical Rule. In many cases, PCMA is supportive of these clarifications. Specifically, PCMA supports efforts by CMS to: (1) shorten the Preclusion List appeal timeframe from nine months to five months; (2) place providers and prescribers on the Preclusion List after their first level of appeal; and (3) prohibit beneficiary appeals of payment denials due to Preclusion List placement. In each of these cases, CMS has taken common sense steps to reduce administrative burden on Medicare Advantage Organizations (MAOs) and Part D plan sponsors (hereafter, Medicare plans), ensure precluded providers and prescribers are not continuing to provide care and/or prescribe medications after bad behavior is already established, and take into account the best interests of beneficiaries. However, rather than making corrections to the Preclusion List policies and delaying the effective date of all of the policies until January 1, 2020, CMS is proposing to take the unusual step of implementing the Preclusion List in a three-step, phased-in process. Such a disjointed rollout could be extremely problematic for Medicare plans, providers, and beneficiaries.

As we understand the framework being proposed, CMS would phase in the Preclusion List in the following timeframe: (1) beginning on January 1, 2019, the Preclusion List will go into effect *without* any of the proposed reforms introduced in the NPRM; (2) 60 days following publication of the final CY 2020 rule, Medicare plans will be required to implement the new consolidated appeals provisions; and (3) finally, any other changes made in the 2020 NPRM will not go into effect until January 1, 2020.

At the outset, we are unaware of any precedent for such a phased-in rollout of such a major policy in the MA and Part D programs, presumably because such an approach is ill-advised: it saddles Medicare plans with managing multiple deadlines and effective dates despite long-term planning already underway, and it introduces a changing set of rules for providers, prescribers, and beneficiaries so that at any point in time the rules for the Preclusion List are changing and uncertain. Beneficiaries, for one, will face confusion as the rules under which their provider and/or prescriber may or may not be placed on the Preclusion List change throughout the benefit year. Likewise, they may be particularly confused as to whether they have appeal rights, with the issue not addressed for 2019 but then apparently at least partially not allowed as of 2020. Such disruption could lead to gaps in care, disappointment and displeasure with their Medicare plans, and frustration with providers.

For the convenience of CMS, we have included as Exhibit A a chart which illustrates many of the varying effective dates, inconsistencies and issue gaps when the 2019 final rule, the

November 2 HPMS guidance, the December 14 FAQ, and the 2020 NPRM provisions are compared. We believe this chart underscores the range of areas where clear, consistent and implementable CMS guidance is needed.

***PCMA Recommendation*: In light of the flaws in the Preclusion List identified to date by CMS as well as by the industry, the effective date of the program should be delayed until it can be implemented in a seamless and coherent fashion. PCMA strongly urges CMS to delay implementation of the Preclusion List requirements until January 1, 2020. As an alternative to such a delay, CMS could commit to exercising enforcement discretion against Medicare plans until January 1, 2020 for such plans that make a good faith effort to comply with the Preclusion List requirements.**

b. A January 1, 2019 effective date is not feasible in light of numerous unanswered questions regarding implementation of the Preclusion List.

Based on past experience since provider enrollment was first proposed in 2015, PCMA does not believe CMS' proposal to implement any of the Preclusion List requirements on January 1, 2019 is realistic. Implementing these requirements in a rushed manner will challenge MAOs and Part D plan sponsor operations and cause potential harm to beneficiary access. In addition to a delay in the effective date of the rule, more clarity is needed in order for successful implementation. It will be critical for CMS to release clear guidance that takes into account the range of operational issues that stakeholders have discussed with them over this time period, including the detailed points specific to precluded prescribers. CMS must provide all needed guidance, and *then* provide ample time for implementation. We are particularly concerned by last minute guidance released by the agency in the form of a FAQ just two weeks prior to the implementation date of the Preclusion List addressing for the first time many questions that the industry has been asking for a very long time. As discussed below, not only does this new FAQ require substantive changes by plans just two weeks before "launch" date, but it also raises a number of novel and unanswered questions. Below we highlight some of the key open issues underlying our concerns:

1. Beneficiary Notice. In the NPRM, CMS proposes (effective January 1, 2020 – although the agency is "recommending" plans to adopt the policy earlier) that MAOs and Part D plan sponsors send a notification to a beneficiary within 30 days of their provider being added to the preclusion list. Following notification, beneficiaries would have 60 days to locate another provider, before their claims are denied. While PCMA supports beneficiary notification, this proposed policy leaves open several unanswered questions, particularly regarding beneficiaries who receive services during the "gap," including:

    - Assuming a January 1st release of an initial Preclusion List, what is a plan to do if on day 89 following the publication of the preclusion list, a beneficiary receives a service from their provider who is included on the Preclusion List



for which they have no pharmacy claims history? Based on the language of the December 14 FAQ, is it correct that this beneficiary who has an established relationship with this provider but has no claims history may never receive notification from the plan about the provider's placement on the Preclusion List?

- Does the 90-day clock begin to run again for this beneficiary?
- Is it CMS' intention that a provider or prescriber identified on January 1, 2019, as meeting the severely negative qualification of preclusion could provide services to a Medicare beneficiary for close to 6 months following inclusion on the Preclusion List? In other words, as we understand the situation, if CMS releases the preclusion list on January 1, plans have until February 1 to notify beneficiaries, at which time claims begin to be denied on April 1. However, if a beneficiary sees a provider placed on the initial exclusion list on March 28, a new 90-day clock would arguably begin to run, under which the plan would be given 30 days to contact the beneficiary (April 28), and then claims would not be denied until June 28th.
- Given ongoing Patients over Paperwork initiatives at the agency, why are beneficiary notices required to be mailed, and not allowed to be emailed where the beneficiary has indicated that electronic communication is his or her preferred method of communication?

2. Prescriber Notice. Are Medicare plans required to notify providers and prescribers of inclusion on the Preclusion List? The NPRM revises paragraph (c) (6) (IV) (B) to note that a plan "must ensure that reasonable efforts are made to notify the prescriber," yet does not identify what these "reasonable efforts" are. Adding to further confusion, the November 2 HPMS memorandum entitled "Preclusion List Requirements"[8] states that plans "may" notify providers included on the Preclusion List, while the December 14 FAQ affirmatively states that Medicare plans "should notify precluded prescribers that they can no longer treat plan enrollees…" . What standard should plans follow? Given that CMS has already notified the prescriber (and in the case of an MA plan, the plan has already sent a network termination letter), we urge CMS to clarify that Part D plan sponsors are not required to notify the prescriber because such notification would be duplicative and costly. Particularly in light of the ongoing Patients over Paperwork initiative at CMS, we urge the agency to remove this redundant requirement.

[8] Ibid

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3. Beneficiary Appeal Rights. In the NPRM, CMS notes that it is updating the regulatory text to confirm that if payment is denied because the prescriber or provider is on the Preclusion List, the affected beneficiary would not have the right to appeal that denial. Later, in the December 14 FAQ, CMS introduced new confusion by declining to inform beneficiaries of their lack of appeal rights and stating that "an enrollee always has the right to seek a coverage decision from the plan if there's a question regarding coverage for an item, service or drug.": We remain very concerned in this regard including with respect to the following:

   - Will enrollees be permitted to appeal the denial of a claim (due to a provider's placement on the Preclusion List) during CY 2019 given that beneficiary appeals were not addressed in the 2018 rule applicable to CY 2019? If so, how does CMS intend to notify beneficiaries of the change in policy for CY 2020?
   - While we understand that the beneficiary cannot appeal the provider's status of preclusion, we had understood, based on longstanding conversations with the agency, that they cannot appeal the Medicare plan's denial of a claim due to preclusion. We would ask CMS to confirm this understanding. Is it CMS' intention that the determination of a provider's preclusion is a "coverage decision" subject to standard appeal rights?
   - While we understand that a beneficiary who received the notice that the provider was excluded but continued to use that provider could not appeal the denial of that claim, what about the beneficiary who for some reason was not sent a notification?
   - We understand CMS does not intend to add language to the sample notification letter advising the beneficiary that appeal rights will not apply when a claim is denied due to the precluded prescriber programs. We urge CMS to rethink this decision in light of the beneficiary confusion that could result from such a failure to notify.

4. Content for Member Notice. In the November 2nd HPMS memo and again on December 14th, CMS included a Sample Beneficiary Notice that conflicts in many places with existing guidance, and in other cases leaves open new questions, including:

   - The Instructions note that plans must "ensure reasonable efforts" are made to notify the provider of a beneficiary who was sent a notice. CMS does not define what "reasonable efforts" are. Elsewhere, and as noted above, the associated HPMS memo uses different language, stating that plans "may" notify providers.
   - The sample notice says for stand-alone Part D plans to insert the 1-800-Medicare number but then it leaves the "hours of operation" configurable – should this just be the standard hours for 1-800-Medicare? Or is CMS

wanting stand-alone Part D enrollee to call only if they need assistance finding another prescriber, but then intend for enrollees to call plans at the plan number for further questions regarding the status of their prescriptions? In other words, by including the language below, did CMS mean for there to be two numbers for stand-alone Part D plans?

- Please call 1-800-Medicare (1-800-633-4227) (TTY users should call 1-877-486-2048) if you need assistance finding another provider. If you have further questions regarding the status of your prescription(s), please call <Customer/Member> Service at <phone number> (TTY/TDD users should call <TTY/TDD number>). We are available from <hours of operations>.

5. Treatment of Pharmacies. There still appears to be conflicting language as to whether the precluded provider process applies *only* to the prescriber or if it could *also* apply to the pharmacy as the provider entity that would be represented as the Service Provider ID within the prescription claim. In particular, the "preclusion list" is defined differently for Part C (42 CFR 422.222) and Part D (42 CFR 423.120(c)) purposes, including "individuals and entities" for Part C purposes, but only "prescribers" for Part D purposes (although the preamble says there is only one list for both). Outstanding questions include:

   - Can CMS provide additional clarification as to whether or not pharmacies can be placed on the Preclusion List?
   - If CMS does intend to permit pharmacies be placed on the Preclusion List, does it intend to amend its existing regulations which rely on the word "individuals?"
   - In its December 14th FAQ, CMS states that Part D plans are expected to remove precluded pharmacies from their network, but provides no additional information including the necessary rulemaking for such a decision to be made. The FAQ merely references "future rulemaking" but meanwhile we are not aware of any current authority which would allow such termination.

6. PDE Claim Forms. There are a number of PDE issues emanating from the above uncertainties. Based on information on the December 14th FAQ, we understand CMS intends to provide guidance on these issues at some point in the future. It is critical that CMS provide this guidance as soon as possible, as there is significant concern that there will not be sufficient time to implement the new guidance. For example, for an enrollee who did not receive the notice, where there is a 90-day period before the claim rejects, what are the requirements regarding PDE edits and whether CMS will pay for the PDE? Will a new PDE edit be created to reject PDEs submitted for providers on the Preclusion List? Given that guidance is still forthcoming, will CMS consider exercising enforcement discretion for CY 2019 in light of the ongoing delays in providing this information?

7. Preclusion List File and Layout. There are also numerous outstanding questions with regard to the preclusion list file and file layout. For example, are Medicare plans going to be limited to the number of users granted access to the CMS preclusion list? PBMs, as subcontractors who are delegated to process and pay claims and others need access to this file. In its December 14th FAQ, CMS states that the agency will not grant access to the Preclusion List to PBMs. We urge CMS to reconsider this position or otherwise to facilitate this process so that such access can be done both timely and systematically. One alternative that we recommend CMS seriously consider would be to make the preclusion list public.

   Other file and layout questions include:

   - Are Part D plan sponsors to utilize the "claim reject date" and not the "effective date" field as the relevant field for the date when claim rejections begin? Is the "claim reject date" the relevant date for when CMS validates the PDE?
   - What does a provider record look like when they are reinstated on the file? How does it compare to the original provider record?
   - Will reinstatement dates be provided for each preclusion effective date?
   - How far in advance of a provider being reinstated will the date be provided on the file?
   - Are any of the fields conditionally required? For example, for a prescriber, is date of birth required? For business, is EIN required?
   - Is there a communication process for questionable data records? For example, for missing required fields such as an NPI, missing effective dates, etc.

8. Interaction with other Federal Programs and regulatory authority to deny Part B drug claims from precluded prescribers under Part C. In the December 14th FAQ, CMS provides additional details on interactions with other Federal programs, including Medicare Part B and Medicaid. New questions include:

   - In the FAQ, CMS states that the Preclusion List applies only to Parts C and D and that Part B claims processing will follow its normal process. Is CMS referring to Part B fee-for-service claims or MA claims processing? The preclusion regulation does not appear to give MA or MA-PD plans the authority to deny payment of Part B pharmacy prescriptions written by a precluded provider. The Part C regulation addresses precluded providers, but does not address Part B prescribers. Per the regulation, "an MA organization must not make payment for a **health care item or service furnished by an**

individual or entity that is included on the preclusion list."[9] Consequently, if a beneficiary comes to the pharmacy counter with two prescriptions from a precluded prescriber – one for a Part D drug and one for a Part B drug – does CMS intend that the pharmacy should reject one prescription (Part D) and fill the other prescription (Part B)?

- The FAQ also states that the Preclusion List is not applicable to Medicaid. In cases where Medicaid is the primary payer for a drug for a dually-eligible individual, is the pharmacy to fill a prescription for a drug prescribed by a precluded prescriber? What if the drug is covered by Part D, but the cost-sharing is covered by Medicaid?
- CMS also needs to address how the FAQ applies to Medicaid-Medicare Plans (MMPs) with a three-way contract. Specifically, in a MMP, the enrollee has one insurance card and thus will be extremely confused if the MMP rejects their Part D drugs due to preclusion but then pays for the Medicaid drug from the same prescriber.

***PCMA Recommendation*: In light of numerous unanswered questions regarding the operation of the Preclusion List, and given the limited timing available prior to the proposed effective date of January 1, 2019, CMS should delay implementation of the effective date until January 1, 2020. As an alternative to a full delay, CMS could commit to exercising enforcement discretion with respect to plans until January 1, 2020 for plans that make a good faith effort to comply with the rule.**

Thank you for the opportunity to provide comments. We look forward to working with you on the ongoing efforts to improve Part D.

Sincerely,

Wendy Krasner

Wendy Krasner
Vice President, Regulatory Affairs

cc: Kristin Bass, Senior Vice President, Policy and Federal Affairs, PCMA
Demetrios Kouzoukas, Principal Deputy Administrator & Director of the Center for Medicare, CMS
Cheri Rice, Deputy Director, Center for Medicare, CMS

Attachments

Exhibit A	Chart of inconsistencies to day for preclusion list
Exhibit B	PCMA letter dated December 6 to CMS requesting delay in precluded prescriber effective date

[9] 42 CFR § 422.222(a)(1)(i) [emphasis added.]

PCMA

EXHIBIT A: Chart of Inconsistencies To Date for Preclusion List

Issue Area	Inconsistency/Lack of Clarity	Impact
Beneficiary Notification	90-day notification timeframe could result in a precluded provider providing services to an enrollee for close to 6 months following inclusion on the Preclusion List. Guidance does not permit electronic notification	• FY 2019 implementation date and FY 2020 phase in of notification policy will result in beneficiary confusion and harm access. • Timeframe could expose enrollees to "bad" providers for nearly 6 months after identification. • Lack of plan flexibility in claim rejection date hurts programmatic operations.
Prescriber Notification	November 2nd HPMS memo notes that Part D plans *may* notify providers of beneficiary receipt of Notification Letter; the NPRM, FAQ, and Sample Member Notice tasks Part D plans with making "reasonable efforts" to notify providers.	• Inconsistent guidance will result in some providers receiving notification, and others not receiving notification. As a result, future prescribing practices could be impacted.
Beneficiary Appeal Rights	Proposed rule does not make clear whether or not a beneficiary can appeal the denial of a claim due to provider inclusion on Preclusion List. If appeals are permitted, do those rights begin in 2019 or 2020?	• FY 2019 implementation date and FY 2020 phase in of appeals policy will result in beneficiary confusion and harm access. • Lack of clarity of beneficiary ability to appeal denial of claim due to provider inclusion on Preclusion List will result in beneficiary confusion and complaints.

Treatment of Pharmacies	Conflicting language in MA and Part D regulations raise questions as to whether or not pharmacies can be placed on Preclusion List.	• Whether or not a significant group of providers can be placed on a Preclusion List is critical information for timely implementation. • If pharmacies can be placed on the Preclusion List Type 2 NPIs need to be addressed. Type 2 NPIs, which would be assigned to pharmacies or other "non-people" are not permitted, in fact, they are currently rejected at adjudication and CMS rejects the PDE. Is it CMS's intention to allow Type 2 NPIs? If this is the case, adjudication and PDE logic will need to be modified to accommodate Type 2 NPIs.
File Layout	Proposed rule does not address how PBMs and other sub-contracting providers will receive access to the Preclusion List in a timely manner. Numerous questions remain about the file layout, including the roles of the "effective date" and "claim reject date" fields.	• Lack of direct PBM access to the Preclusion List will slow the notification process and result in significant delays. • Unclear reporting fields in the File Layout could lead to errors.
Other Federal Programs	The proposed rule does not address interactions with other Federal programs, including Medicaid and Medicare Part B.	• Inconsistencies among Federal programs will result in beneficiary confusion. • Precluded prescribers may be able to prescribe some drugs (Part B, for example) but not others (including with respect to enrollees in MMPs).

PCMA

December 6, 2018

Submitted via email to demetrios.kouzoukas@cms.hhs.gov and Kimberly.Brandt1@cms.hhs.gov

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Ms. Kimberly Brandt
Principal Deputy Administrator for Operations
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Re: Request for Extension of Provider Preclusion Implementation Date

Dear Principal Deputy Administrators Kouzoukas and Brandt:

As noted in our previous and ongoing comments to the agency on this issue, PCMA commends CMS (both the Centers for Medicare and for Program Integrity) for its attention to implementing a commonsense solution to provider enrollment and reducing the risk of fraud and abuse in the Medicare Part D program. However, we are increasingly concerned with CMS' ongoing implementation of its "Preclusion List" requirements which, if implemented without revisions and clarifications, could unnecessarily increase complexity in the Part D program, expose Medicare beneficiaries to problematic providers/prescribers, and perpetuate a cycle where there is insufficient time to implement complex new requirements that pose substantial operational challenges. As such, PCMA is writing today to request that CMS reassess the effective date of the enforcement of the Preclusion List, major parts of which are currently scheduled for implementation on January 1, 2019. **As detailed below, we believe extending the effective date until January 1, 2020, would better ensure implementation is seamless for CMS, plans, and beneficiaries.**

As you know, in the CY 2019 MA/Part D Policy & Technical Final Rule, CMS finalized a new approach to provider enrollment that adopts a Preclusion List, in lieu of mandatory provider enrollment. Unless delayed, beginning January 1, 2019, CMS will publish a list of precluded providers and direct plans to begin denying claims submitted by these providers and prescribers. Notably, in its recently published CY *2020* MA/Part D Policy & Technical Proposed Rule, CMS made a number of significant changes to the Preclusion List requirements, some of which are effective in 2019, and others that do not take effect until 2020.

At the outset, we are unaware of any precedent for such a phased-in rollout of such a major policy in the MA and Part D programs, presumably because such an approach is ill-advised: it saddles Medicare plans with managing multiple deadlines and effective dates despite long-term planning already underway, and it introduces a changing set of rules for providers, prescribers, and beneficiaries so that at any point in time the rules for the Preclusion List are changing and uncertain. Beneficiaries, for one, will face confusion as the rules under which their provider and/or prescriber may or may not be placed on the Preclusion List change throughout the benefit year. Likewise, they may be particularly confused as to whether they have appeal rights, with the issue not addressed for 2019 but then made clear that they are not allowed as of

PCMA

2020. Such disruption could lead to gaps in care, disappointment and displeasure with their Medicare plans, and frustration with providers.

Other open issues on provider preclusion include:

- CMS has yet to clarify, despite multiple calls with agency staff, at which point a plan can begin rejecting claims submitted by a precluded provider. In addition, as currently written, a prescription written by a precluded provider/prescriber could be filled for up to six months following placement on the list due to multiple and additive notification timeframes.
- CMS' regulation, guidance, and preamble language conflict as to whether or not plans are responsible for notifying providers/prescribers as to their placement on the Preclusion List
- In a November 2, 2018 HPMS memo, CMS included a Sample Beneficiary Notice that conflicts in many places with existing guidance and in other cases leaves open new questions.

We are less than a month away from the implementation date, and Part D plans and PBMs simply do not have what they need to effectively implement the Preclusion List requirements as intended by CMS. Indeed, our members tell us that even if we had all of the necessary information today (which we do not), it already will be virtually impossible to meet the deadline, comply with other CMS requirements for the new plan year, and ensure that all systems work as needed on January 1 for the new plan year. Moreover, even if CMS is able to resolve all of the outstanding issues identified in this letter prior to the start of the 2019 plan year, we urge the agency to consider how it will approach enforcement in light of the expedited implementation deadline and difficulties identified so far.

PCMA and its members support the Preclusion List as long as CMS provides enough time and the right tools to make sure it works properly. We are very concerned, however, that in its current state these requirements will have a detrimental impact on beneficiary access to needed drugs while placing unachievable administrative and systems burdens on Part D plans and PBMs, unnecessarily running up program costs.

Thus, we urge CMS to postpone the implementation date for the rule to January 1, 2020, to allow CMS to issue necessary guidance with sufficient time for plans to implement any and all new requirements.

Thank you in advance for your consideration of this request. Please let me know if we can provide you with any further information.

Sincerely,

Wendy Krasner

Wendy Krasner
Vice President – Regulatory Affairs

cc: Alec Alexander, Deputy Administrator and Director, CMS/CPI
Kristin Bass, Senior Vice President, Policy and Federal Affairs, PCMA

TAB 9

RxAnte Comments

December 21, 2018

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-4185-P,
P.O. Box 8013,
Baltimore, MD 21244-8013

Re: Comments to Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

RxAnte is a leading analytics and clinical services organization focused on providing solutions to improve medication use. Founded by nationally recognized subject matter experts in the areas of medication adherence, advanced analytics, and population health, RxAnte's individual and collective experience spans academia, state and federal government, and industry. The RxAnte team has authored and contributed to over 200 published papers in peer-reviewed journals on the causes and consequences of medication non-adherence, statistical methods related to measuring and predicting medication use, and evaluations of adherence-related interventions. As a core component of our solution, RxAnte partners with MAPD and PDP plans (currently 8.5M lives under management) to improve their Star Rating performance by improving medication use among their membership.

RxAnte commends CMS for the release of the Proposed Rule outlining changes to Medicare and Medicaid Programs for Years 2020 and 2021, and appreciates the efforts CMS is taking to gather and incorporate stakeholder opinions to help shape the program and Star Rating technical specifications.

In order to provide thoughtful, data-driven feedback on the proposed rule, RxAnte convened an internal team of subject matter experts to include statisticians, clinicians, policy leaders, and strategic account consultants engaging with MAPD health plans. We tested the impact of recommended methodologies in light of the proposed rule using 2017-2019 Part D CMS Stars for MAPD and PDP plans, and also our client MAPD health plan data for the prior 3 years.

Overall, RxAnte supports CMS efforts in revisiting the Star Rating cut point methodology for non-CAHPS measures. Consistent with other comments cited, we would prefer cut points that are stable, predictable, and free from the undue influence of outliers. RxAnte urges CMS to consider that plans reallocating resources away from measures where they are already high-performing could be a *positive* outcome, enabling those plans to focus resources where they could provide the most benefit. Creating predictability in measure cut points would allow plans to prioritize and allocate resources toward improving Star Ratings and calibrate their investment in accordance with what is needed to attain excellent performance. However, RxAnte appreciates the challenge faced by CMS with regard to balancing this desire for predictability with the intent of the cut point methodology, which is to create score groupings that accurately reflect true performance.

It is with these challenges and opportunities in mind that RxAnte provides feedback on several specific sections within the proposed rule:

1. **Mean resampling.** In general, RxAnte supports incorporating into the Star Rating cut point methodology an approach that increases the stability of cut points and reduces the impact of

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outliers. In order to examine the impact of the mean resampling approach, we performed an analysis using this technique on the 2018 and 2019 Stars for MAPD for the three Part D medication adherence measures. We then compared the changes in cut points from 2018 to 2019 Stars using both the current method and the mean resampling method. (We were able to recreate the cut points using the current method for 11 of the 12 cut points.) In eight of the 11 cases, the magnitude of change was the same. Of the remaining three, the magnitude of the change was smaller once and larger twice. Overall, we found that mean resampling had little impact on the cut points, may lead them to be raised more often than lowered, and could run counter to the goal of creating greater stability. Thus, we encourage CMS not to proceed with incorporating mean resampling as a method for calculating cut points.

2. **Guardrails.** As stated above, RxAnte supports the consideration of approaches to increase the stability of measure cut points year over year. In order to examine the impact of the guardrail approach, we tested what the impact of 3% and 5% guardrails would have been for Star Rating years 2017 to 2018 and 2018 to 2019 for the three Part D medication adherence measures. (We did not include Star Rating years 2014-2016 since the year over year changes are not representative of the movement we would expect to see moving forward, given the improved population performance for these Part D measures.) A summary of our findings is below.

Population	Star Years	Impact of 5% guardrail	Impact of 3% guardrail
MAPD	2017 to 2018	No impact	No impact
	2018 to 2019	Restricted the movement of 1 cut point (2-Star cut point)	Restricted the movement of 4 cut points (two 2-Star cut points, one 3-Star, one 4-Star)
PDP	2017 to 2018	No impact	Restricted the movement of 2 cut point (one 3-Star cut point, one 5-Star)
	2018 to 2019	Restricted the movement of 3 cut points (all 2-Star cut points)	Restricted the movement of 4 cut points (three 2-Star cut points, one 3-Star)

Based on this analysis, we agree that the incorporation of guardrails would improve cut point stability year over year. While a 3% guardrail would create the greatest stability, we are concerned that it could also lead to a future scenario where CMS would have to "correct" for artificially decreased movement in the cut points created by the guardrail, creating greater overall frustration. Thus, we concur with the CMS recommendation to incorporate a 5% guardrail for cut point changes from one year to the next. Though this will still allow for a significant year over year change, it will provide a slight improvement in stability for cut points in future years.

3. **Extreme and uncontrollable circumstances.** RxAnte supports making Star Rating calculation adjustments in extreme and uncontrollable circumstances. We have previously performed analyses that demonstrate how these circumstances can have a negative impact on medication adherence and commend CMS for considering adjustments to Star Ratings accordingly.

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- Our analysis examined the influence Hurricane Irma had on medication adherence in a Medicare population. We used a study period between August and October 2017, and defined the pre-period as 25 days prior to and the post-period as the 25 days after landfall (9/10/2017). In this study of 419,139 member-therapies, 211,673 (51%) were geographically located in FEMA affected counties. Average medication supply was significantly reduced for Irma-impacted zip codes post-landfall (-0.9%; SD = 0.4; p<. 05) and was higher than the change seen in non-impacted zip codes (-0.4%; SD = 0.4). Higher-latitude areas experienced significantly less pre vs. post supply disruption on average (-0.8%; SD= 0.4; p<0.05) versus lower latitudes (-1.2%; SD=0.4). Our results suggest naturally occurring disasters can negatively influence adherence rates in affected geographies, specifically by reducing the amount of drug supply patients have on hand directly before and after such an event. Our findings also suggest that the impact of such extreme and uncontrollable circumstances may be highly concentrated to certain zip codes or counties, and may not rise to the level of a state-level state of emergency. We are unclear on whether criteria #s 1 and 2 require a state-level declaration of emergency to qualify selected geographies and contracts as eligible for adjustment. If so, this may be too restrictive. Rather, we find that criteria #3 (minimum percentage of enrollees residing in a FEMA-designated Individual Assistance Area) is most applicable to accurately identify the impact of an uncontrollable event.

4. **Measure specification updates.** RxAnte supports the measure specification updates as described, and further encourages CMS to make measure implementation guides publicly available. We've found that the Star Rating Technical Notes allow for variable implementation interpretation for some measures.
   - RxAnte identified a recent example in working with health plan clients to improve performance on the Statin Use in Persons with Diabetes (SUPD) measure. The Technical Notes for this measure describe the age criteria as 40-75 years of age and do not include a description of how to determine enrollment. Upon further dialogue with CMS, we've learned that the CMS SUPD definition uses member months in calculating the numerator and denominator for the measure, from when a member turns 40 years of age until the month before the member turns 75 years of age. Each episode of enrollment is considered separately when determining numerator and denominator inclusion and exclusion criteria for each measure. Notably, these criteria differ from the PQA measure manual specifications for the measure. We expect this inconsistency has created variability in how this measure is coded and how quality improvement efforts are executed within the industry. An example of the type of implementation guidance that could be useful can be found in the Patient Safety Report User Guide, though this document is currently only accessible via plan sponsors or pharmacy benefit managers (PBMs).

5. **Telehealth**. RxAnte supports the inclusion of telehealth as a basic benefit starting in 2020. As stated, this may assist in remote medication management for patients taking multiple medications and may improve accessibility to opioid addiction treatment for affected individuals in rural communities.

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Again, RxAnte appreciates the opportunity to comment and commends CMS for releasing the Proposed Rule outlining changes to Medicare and Medicaid Programs for Years 2020 and 2021. We are available for follow-up clarifications or questions or other practical assistance if requested.

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TAB 10

BCBSA Comments

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4800
www.BCBS.com

December 21, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Submitted via the Federal Regulations Web Portal, http://www.regulations.gov

RE: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS-4185-P)

Dear Administrator Verma:

The Blue Cross Blue Shield Association ("BCBSA") appreciates the opportunity to provide comments on the Proposed Rule: "Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021" as issued in the Federal Register on Nov. 1, 2018 (83 Fed. Reg. 54982)

BCBSA is a national federation of 36 independent, community-based, and locally operated Blue Cross and Blue Shield companies (Plans) that collectively provide healthcare coverage for one in three Americans. For more than 80 years, Blue Cross and Blue Shield companies have offered quality healthcare coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid. Blue Cross Blue Shield (BCBS) Plans participate in Medicare Advantage, Medicare Part D, and many also contract with CMS as Medicare Administrative Contractors.

In this rule, the Centers for Medicare and Medicaid Services (CMS), proposes multiple provisions and we would like to highlight several recommendations, which are discussed in more detail, along with other topics in our detailed comments.

We recommend CMS:

- **Provide flexibility for plans to explore the full potential of telehealth**: We support CMS' implementation of new statutory flexibility to provide additional telehealth benefits and offer recommendations to ensure plans have the ability to design these benefits in a way that maximizes beneficiary access and satisfaction as well as potential cost-savings;

- **Create certainty for preclusion list requirements**: BCBSA supported CMS' policy as finalized in the 2019 Final Rule to replace the burdensome provider and prescriber enrollment requirements with the preclusion list. However, multiple guidance documents over the past six months with confusing and contradictory requirements have left plans confused and unsure of how to properly implement this program. BCBSA recommends that CMS delay the effective date of the preclusion list requirements for at least one year and looks forward to working with CMS to develop clear guidance that will lead to effective implementation; and
- **Continue to advance transparency in the Star Rating Program, restore cut points, and ensure fair adjustments for natural disasters.**

In addition, CMS proposed significant changes to the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) audit process. We will submit detailed comments on these provisions before the extended comment deadline of April 30, 2019 and we look forward to analyzing the new underlying data on the "Fee-for-Service (FFS) Adjuster" study that CMS will soon release. BCBSA is committed to working with the Administration to find solutions that ensure accurate MA risk adjustment and payments and an effective RADV methodology. However, we remain concerned with proposals that fail to achieve actuarial equivalence, include flawed methodologies that are applied retroactively, and create a process that lacks needed transparency. We look forward to working with the Administration on our shared commitment to ensuring Medicare beneficiaries have access to the enhanced benefits, care coordination, and financial protections provided by MA and ensuring continued strong public-private partnerships between CMS and plans to best serve Medicare beneficiaries.

Thank you for the opportunity to provide detailed comments and recommendations. We would be pleased to discuss our comments with you at your convenience. Questions regarding these comments may be directed to Jane.Galvin@bcbsa.com.

Sincerely,

Kris Haltmeyer
Vice President, Legislative & Regulatory Policy
Office of Policy & Representation

DETAILED COMMENTS ON MEDICARE AND MEDICAID PROGRAMS; POLICY AND TECHNICAL CHANGES TO THE MEDICARE ADVANTAGE, MEDICARE PRESCRIPTION DRUG BENEFIT, PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE), MEDICAID FEE-FOR-SERVICE, AND MEDICAID MANAGED CARE PROGRAMS FOR YEARS 2020 AND 2021 (CMS-4185-P)

Section A: Implementing the Bipartisan Budget Act of 2018 Provisions

Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits

Issue #1: Ability to Offer Additional Telehealth Benefits

In the past, Medicare Advantage (MA) plans have been limited in how they may deliver telehealth services, since only the limited services payable under Part B of traditional Medicare could be included in the MA basic benefit bid. Any additional telehealth services provided by plans had to be offered as supplemental benefits and funded through the use of rebate dollars and/or supplemental premiums paid by enrollees. The Bipartisan Budget Act of 2018 (BBA 2018) changed this and allows MA plans to provide "additional telehealth benefits" to beneficiaries enrolled in their plans as of plan year 2020 and treat them as basic benefits for purposes of an organization's bid submission and subsequent payments by CMS. CMS proposes to implement this new statutory authority and to continue authority for MA plans to offer supplemental benefits not covered by original Medicare via remote access technologies and/or telemonitoring.

Recommendation #1:

BCBSA supports implementation of this new statutory authority expanding telehealth benefits in MA. Rather than a substitute for in-office visits, we encourage CMS to consider telehealth services as an enhancement to MA benefits and services that will enrich access and convenience for beneficiaries. We caution CMS against unnecessary guardrails that would limit the types of visits or providers who can offer these services.

Following the BBA, there are now three distinct sets of telehealth benefits available to plans. Since the "additional benefits" authorized by the BBA must be included in bids as part of the basic benefit package paid by CMS, Plans request guidance from CMS in the Final Rule and/or the upcoming CY 2020 Advance Notice and Call Letter to ensure there is consistency in Plan administration, bidding, and payments as to benefits that are included in the bid versus those offered as supplemental benefits.

Rationale #1:

Following the changes enacted in the BBA, plans must now address three distinct sets of telehealth benefits when designing their benefit structures and bids:

- Telehealth services payable by original (fee-for-service) Medicare under section 1834(m)

- Telehealth services allowed to be covered as "additional telehealth benefits" under the BBA and included in the basic benefit package
- Telehealth services not covered by original Medicare and only available to plans as supplemental benefits.

While we appreciate the flexible interpretation of "additional telehealth benefits" as described below, we reiterate the importance of guidance to ensure plans have clarity and follow consistent rules. In particular, it is critical that the third set of benefits (those not covered by original Medicare and only available as supplemental benefits) are clearly defined and commonly understood so that premiums can be compared fairly across plans and plans are not mistakenly charging supplemental premiums or allocating rebate dollars to services that should be covered under the basic bid.

We would like to take this opportunity to draw CMS' attention to several recent studies that illustrate the value of telehealth, including cost-savings and increased beneficiary access and convenience:

- A 2017 study published in the *Journal of Medical Internet Research* (JMIR) showed the cost-saving potential of telemedicine. After comparing data of almost 60,000 visits, researchers found that "rural health center, urgent care center, emergency department, and primary care visits were estimated to be $36, $153, $1,735, and $162 more expensive than virtual visit episodes, respectively, including medical and pharmacy costs."
- A report published in *American Family Physician* in 2017 showed that 78 percent of family physicians believed that telemedicine improved access to care and 68 percent of those surveyed believed that the technology improved continuity of care. Fifty-three percent of respondents, however, believed that lack of reimbursement for telehealth was one of the main barriers preventing more family physicians from adoption.
- In a 2018 report on the barriers to and benefits of telemedicine reimbursement published by the Centers for Medicare & Medicaid Services (CMS), the agency wrote that "more than 75 percent of all U.S. counties are considered mental health shortage areas, and half of all U.S. counties have no mental health professional at all." The study goes on to mention how telemedicine can be used to treat substance use disorders and provide acute, non-urgent care for Medicare beneficiaries if Congress were to relax the restrictions imposed by section 1834(m) of the Social Security Act.
- A study published by the *Journal of the American Medical Association* (JAMA) in November 2018 found that annual telehealth visits among the commercially insured increased from 206 in 2005 to about 202,300 in 2017. Researchers found that this massive increase was most likely driven by increased payer coverage for direct-to-consumer telemedicine. The researchers broke telehealth encounter data up into three categories – telemental health, primary care, and all other specialty visits. They found that telemental health telemedicine usage was markedly higher in areas with psychiatrist shortages and in states with more parity reimbursement between telemedicine and in-person health. The study found that the growth of primary care telemedicine was not

necessarily due to physician shortages and suggested that more consumers are turning to telemedicine for primary care as a matter of convenience.

Issue #2: Definition of "Clinically Appropriate Services"

The BBA limits these authorized "additional telehealth benefits" to services that are identified for the applicable year as clinically appropriate to furnish through electronic exchange. The statute does not specify who or what entity identifies the services. CMS proposes to interpret this provision broadly by not specifying the Part B services that an MA plan may offer as additional telehealth benefits for the applicable year, but instead allowing plans to determine which services each year are clinically appropriate to furnish in this manner.

CMS solicits comments on whether they should place any limitations on what types of Part B items and services can be additional telehealth benefits provided under this authority.

Recommendation #2:

BCBSA supports CMS' proposed interpretation of "clinically appropriate services". We agree with CMS that using the list of Medicare telehealth services payable by original Medicare under section 1834(m) without the geographic limitations would be unnecessarily restrictive and not in line with Congressional intent for MA flexibility. Therefore, we also do not believe CMS should place any limitations on the types of Part B items and services that can be additional telehealth benefits.

Rationale #2:

The proposed interpretation provides maximum flexibility for plans; they are in the best position to identify services that are clinically appropriate to furnish via telehealth based on the current standards of care.

Issue #3: Beneficiary Notification

CMS proposes two methods in which MA plans would need to notify beneficiaries about additional telehealth benefits:

- Plans would be required to use their Evidence of Coverage (EOC) to advise enrollees that they may receive the specified Part B service(s) either through an in-person visit or through electronic exchange; and
- Plans would have to use their provider directory to identify any providers offering services for additional telehealth benefits and in-person visits or offering services exclusively for additional telehealth benefits.

CMS states that these notifications in the EOC and provider directory are important to ensure choice, transparency, and clarity for enrollees who might be interested in taking advantage of additional telehealth benefits.

Recommendation #3:

BCBSA disagrees with CMS' proposal to require plans to identify providers who offer telehealth services in their MA provider directory. Plans already face significant challenges ensuring that these directories are accurate and up-to-date, and adding this additional element creates an additional burden.

We support the inclusion of information about services covered by telehealth in the EOC and request that CMS provide sample language.

Rationale #3:

The way in which plans manage the delivery of telehealth services may vary – some Plans use a separate vendor who manages access to telehealth services separate from the traditional plan provider network while others use providers in their established network and still others employ a hybrid approach.

Most importantly, experience suggests that some providers tailor their use of telehealth to the most appropriate patients and/or clinical conditions. Therefore, a directory that indicates that a particular provider offers telehealth can be misleading if the service is not appropriate for a particular beneficiary or condition. BCBSA believes that plans should be allowed to identify telehealth providers in their directories, but not required to do so.

Issue #4: <u>Network Adequacy</u>

CMS asks for comments on the impact, if any, additional telehealth benefits should have on MA network adequacy policies. Specifically, CMS indicates that they will look for the degree to which additional telehealth benefit providers should be considered in the assessment of network adequacy (including for certain provider types and/or services in areas with access concerns) and any potential impact on rural MA plans, providers, and/or enrollees.

Recommendation #4:

CMS should not add additional telehealth benefits to network adequacy standards but should view access to telehealth as an expansion of network adequacy where available, especially for those members who prefer this service rather than an in office visit or consultation, especially where access can be enhanced in certain geographic areas or for certain types of visits such as those for mental health or counseling.

Rationale #4:

Current network adequacy standards for MA plans are very prescriptive with numerical standards for provider types in a given county. BCBSA is encouraged by recent statements from Secretary Azar and others that MA plans should have more flexibility as to network adequacy which we greatly support.

Telehealth should be viewed as an enhancement to a Plan's traditional network of providers and should be viewed as a value-added capability and a means for allowing greater access and flexibility for beneficiaries to access services.

Issue #5: Provider Selection and Credentialing

CMS proposes that MA plans offering additional telehealth services must comply with existing provider selection and credentialing requirements. Further, when providing additional telehealth benefits, plans must ensure through their provider contracts that providers meet and comply with applicable state licensing requirements and other state laws.

Recommendation #4:

BCSBA supports this proposal.

Rationale #4:

BCBSA agrees with CMS that plans that provide additional telehealth services should follow the same provider selection and credentialing requirements as for non-telehealth providers.

Dual Eligible Special Needs Plans (D-SNPs)

Issue #1: New Definitions

The Bipartisan Budget Act of 2018 (BBA) permanently reauthorized D-SNPs and also required them to meet certain minimum criteria for Medicare and Medicaid integration for 2021 and subsequent years. In this rulemaking, CMS proposes new definitions for the terms "dual eligible special needs plans", "fully integrated dual eligible special needs plan", and "highly integrated dual eligible special needs plan". With these changes, CMS intends to consolidate multiple statutory and regulatory references to a D-SNP and clearly define in §422.2 the minimum requirements for a D-SNP.

In order to meet the BBA's integration requirements, CMS proposes that by Jan. 1, 2021, a D-SNP must satisfy one or more of the following criteria for the integration of Medicare and Medicaid benefits:

1) Meets the additional state Medicaid agency contracting requirement at proposed §422.107(d) of this proposed rule that surpass the minimum requirements in current regulations at §422.107(c);
2) Is a highly integrated dual eligible special needs plan (HIDE SNP); or
3) Is a fully integrated dual eligible special needs plan (FIDE SNP).

CMS proposes that a HIDE SNP would be a type of D-SNP offered by an MA organization that has, or whose parent organization or another entity that is owned and controlled by its parent

organization has, a capitated contract with the Medicaid agency in the state in which the D-SNP operates that includes coverage of LTSS, behavioral health services, or both, consistent with state policy. CMS further notes that because a FIDE SNP covers comprehensive Medicaid benefits, including LTSS and behavioral health services, any FIDE SNP would also be a HIDE SNP, but not all HIDE SNPs would qualify to be FIDE SNPs. CMS proposes to interpret the phrase "consistent with state policy" as allowing CMS to permit certain carve-outs where consistent with or necessarily to accommodate state policy, except where specifically prohibited.

Recommendation #1:

BCBSA appreciates CMS' work to clarify and consolidate references as well as proposing a new definition of a highly-integrated dual eligible (HIDE) SNP. We do not recommend that language around "arranging" for benefits be further defined by CMS.

Rationale #1:

BCBSA believes that MA plans are in the best position to define the terms around "arranging" for benefits. Individual plans and the variety of subcontractors with whom they utilize to provide benefits may have varying definitions which must be considered. MA plans should be able to determine the flexibility needed by an enrollee or group of enrollees that is most beneficial to improve access.

Issue #2: <u>D-SNPs and Contracts with States</u>

CMS is proposing to make changes to the regulation to more clearly articulate the requirements of the contract between the D-SNP and the state Medicaid agency, while also incorporating the changes required by the BBA. CMS is also adding language describing the new minimum contracting requirement under the BBA (i.e., that D-SNPs meet additional state Medicaid contracting requirements). Specifically, CMS proposes to require that any D-SNP that is not a FIDE SNP or HIDE SNP be subject to a new contracting requirement: to notify the state Medicaid agency of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk FBDE enrollees, as determined by the state Medicaid agency.

Recommendation #2:

BCBSA recommends these definitions be finalized.

Rationale #2:

The proposals by CMS are consistent with ensuring better care for D-SNP members.

Issue #3: <u>Eligibility of Partial-Benefit Dual Eligible Individuals for D-SNPs</u>

CMS considered proposing limits on the enrollment of partial-benefit dual eligible individuals in D-SNPs, since there are no Medicaid services that the D-SNP is integrating or coordinating on

their behalf. CMS did not propose any limits on enrollment in this rule, but solicits comments on the topic

Recommendation #3:

BCBSA does not believe it is necessary for CMS to engage in rulemaking on this issue and should leave states to define eligibility requirements.

Rationale #3:

While partial dual members typically do not meet the requirements for enrollment into a D-SNP and therefore exclusion of these members is consistent with MA plans' practices, we do not believe CMS should propose any additional rulemaking as it is preferable for states to define eligibility requirements.

Issue #4: Suspension of Enrollment for Non-Compliance with D-SNP Integration Standards

CMS proposes to impose enrollment sanctions for D-SNPs that are non-compliant with the integration requirements during plan years 2021 through 2025, rather than initiating outright termination or other sanction or enforcement options.

Recommendation #4:

BCBSA agrees with CMS' interpretation of the BBA provision.

Rationale #4:

We agree with CMS that the enrollment sanction authority will be less disruptive to beneficiaries and plans than contract or plan termination.

Issue #5: Unified Grievance and Appeals Procedures

The BBA directs the Secretary to establish new procedures that unify, to the extent feasible, Medicare and Medicaid grievance and appeals processes for D-SNPs.

CMS developed goals to guide the development of proposals to implement the unified grievance and appeals provisions, which include: adopting provisions that are most protective of the enrollee; reducing burden on beneficiaries (and those assisting them), plans, states, and providers; and maintaining state flexibility and minimizing disruption by building on existing rules and policies.

To implement this requirement, CMS proposes to:

- Establish requirements for all D-SNPs, relative to the role they play in assisting FBDE individuals, to assist with Medicaid-related coverage issues and grievances.

- Establish new requirements to create integrated grievance and appeals systems for a limited subset of D-SNPs ("applicable integrated plans").
- Make a number of technical and conforming changes to existing provisions in parts 422 and 438.

The processes would apply to D-SNPs with fully aligned enrollment and the affiliated Medicaid managed care organization, where one organization is responsible for managing Medicare and Medicaid benefits for all enrollees. In such D-SNPs, enrollees would have simpler, more straightforward grievance and appeals processes. While the 2018 BBA requires these new procedures be in place by April 2020, CMS interprets the law as allowing states to adopt these provisions as soon as these regulations are final.

As part of this alignment, CMS proposes new language requiring all D-SNPs to assist enrollees with resolving Medicaid coverage problems regardless of whether such coverage is in a Medicaid FFS or a Medicaid managed care plan, including assistance obtaining authorizations for coverage, filing grievances and appeals, requesting coverage and appeals, and obtaining documentation in support of a request for authorization or appeal.

Recommendation #5:

BCBSA supports CMS' goals and overall approach to aligning Medicare and Medicaid grievance processes. With respect to assisting with Medicaid coverage, we recommend CMS modify its proposal so that plans would only be responsible to assist members with appeals and grievances and other matters for services available within the D-SNP plan.

Rationale #5:

In general, these proposals are consistent with the BBA's intent to unify, to the extent possible, Medicare and Medicaid grievance processes. Plans should not be responsible for resolving Medicaid coverage issues outside of the services provided under the plan.

Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts

Issue #1: <u>Background</u>

This section of the proposed rule sets forth CMS' proposals to implement section 50354 of the BBA of 2018, which provides that the Secretary shall establish a process under which the sponsor of a Prescription Drug Plan (PDP) may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format standardized extracts of Medicare claims data about its plan enrollees. Such extracts would contain a subset of Medicare Parts A and B claims data as determined by the Secretary.

Recommendation #1:

BCBSA appreciates CMS' implementation of this statutory change and supports the ability of PDP sponsors to be able to request this information to assist in the care management of their members.

Rationale #1:

If provided in a timely and efficient manner, this information will assist PDP sponsors in providing the best quality care for beneficiaries in the Part D program.

Issue #2: Purposes and Limitations on Use of the Data

Consistent with the statute, CMS proposes that PDP sponsors would be permitted to use Medicare claims data to optimize therapeutic outcomes through improved medication use, and to improve care coordination so as to prevent adverse health outcomes. In addition, CMS proposes to permit PDP sponsors to use Medicare claims data for the purposes described in the first or second paragraph of "health care operations" under 45 CFR 164.501, or that qualify as "fraud and abuse detection or compliance activities" under 45 CFR 165.504(C)(4). CMS also proposes to permit disclosures that qualify as a "required by law" disclosure as defined at 45 CFR 164.103. They request comments on whether there are any additional purposes for which PDP sponsors should be permitted to use Medicare claims data under this section.

Consistent with statutory limitations, CMS also proposes that PDP sponsors must not use Medicare claims data provided by CMS under this subsection for any of the following purposes: (1) to inform coverage determinations under Part D; (2) to conduct retroactive reviews of medically accepted indications determinations; (3) to facilitate enrollment changes to a different prescription drug plan or an MA-PD plan offered by the same parent organization; and/or (4) to inform marketing of benefits.

Recommendation #2:

BCSBA disagrees with the limitations on using these data for coverage determinations and to conduct retroactive reviews of medically accepted indications determinations. While we understand that some of these are statutory limitations placed on the use of these data, we believe that these data can assist PDP sponsors in identifying possible adverse outcomes and in conducting other care coordination services.

Rationale #2:

Because plan sponsors that offer standalone Part D benefits (PDP sponsors) have no contracts with prescribing providers, they currently have no mechanism for ensuring that medications are appropriate.

Access to claims data would allow PDPs to validate whether prescriptions are medically supported as well as to identify other interventions related to opioid overutilization, medication adherence, risk adjustment and other functions related to requirements of a Part D sponsors.

Issue #2: Data Request

CMS proposes to accept data requests on an ongoing basis beginning January 1, 2020. CMS would require that the data requests be submitted in a form and manner specified by CMS, and proposes not to allow PDP sponsors to request data for subsets of their enrolled beneficiary populations. CMS proposes to allow requests to be submitted without an end date, such that the request, once reviewed for completeness and approved, will remain in effect until the PDP notifies CMS it no longer wants to receive claims, CMS cancels access because the sponsor leaves the Part D program, or CMS concludes or has reasonable belief that the sponsor has misused the data.

Recommendation #2:

BCBSA has concerns about the timeliness of data and urges CMS to consider options that would allow PDP sponsors access to more recent data.

Rationale #2:

CMS anticipates that Medicare claims data would be provided at least quarterly with approximately a three-month lag from the last day of the month to the prior quarter. CMS anticipates it could take up to two months to process and ship the data extracts from the date the quarterly data are available. Therefore it proposes that the first standardized data extract would be available to PDP sponsors no earlier than August 15, 2020, which would include, at a minimum, data for the period beginning January 1, 2020 and ending March 1, 2020. Under this schedule, PDP sponsors would be receiving data that is nearly 6 months old, preventing timely coordination of care.

Issue #3: Data Extract Content

CMS proposes to initially include the following Medicare Parts A and B claims data elements in the standardized extract: an enrollee identifier, diagnosis and procedure codes, dates of service, place of service, provider numbers, and claims processing and linking identifiers/codes. CMS will continue to evaluate the data elements provided to PDP sponsors to determine if data elements should be added or removed based on the information needed to carry out the permitted uses of the data.

Recommendation #3:

BCBSA supports CMS' proposal regarding the data elements.

Rationale #3:

Access to the provider number, diagnosis and procedure codes, and place of service will allow PDPs to maximize the value of these data for care coordination.

Section B: Improving Program Quality and Accessibility

Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

Overall BCBSA was pleased to see the increased transparency as to the Star Rating system and the ability to comment on several aspects of this program, including cut points, affected areas modifications, and measure updates.

Issue #1: Cut Point Methodology for non-CAHPs Measures

CMS proposes an enhanced cut point methodology for data collected during the 2020 measurement year and associated 2022 Star Ratings intended to improve stability and predictability and reduce the influence of outliers by implementing a guardrail so that cut points do not increase or decrease more than the cap from one year to the next. Specifically, CMS proposes two enhancements to the current hierarchical clustering methodology that is used to set cut points for non-CAHPS measure stars, including mean resampling and guardrails.

Mean resampling would reduce the sensitivity of the clustering algorithm to outliers but would not restrict changes in the values of the cut-points. Guardrails, either those based on an absolute percentage or a restricted range, would restrict movement in the cut-points, either up or down, over the prior year's cut points. The proposed guardrail would be a bi-directional cap that would restrict movement both above and below the prior year's cut points. CMS proposes an absolute five percentage point cap for all measures scored on a 0-100 scale and five percent of the restricted range for all measures not on a 0-100 scale, but solicits comments on alternatives, such as a three percentage point/percent cap.

Recommendation #1:

Overall, BCBSA supports CMS' proposal to add additional stability and predictability to measure cut points. However, we disagree with the five percentage-point cap and instead support the alternative proposal of a three percentage point cap for all measures, not just those measures that have been in the Part C and D Ratings program for more than three years.

In addition, BCBSA supports bi-directional caps for all measures. We also encourage CMS to consider similar guardrails, of around 0.5 to 1.00 for all CAHPS measures, where cut points are not established by clustering algorithms.

BCBSA does not support implementing mean resampling as the sole method for solving changes in cut points from year to year, as it does not directly impact year-to-year changes. However, we believe that mean resampling may inform CMS of the impact of outliers on the clustering and thus may prove helpful in CMS' decisions around a measure's cut-points.

Rationale #1:

A three percentage point cap is preferable to five percentage point because the lower rate of change from one year to the next improves predictability for Star Ratings for MA and Part D plans. Additionally, although CAHPS cut points have been more stable than the cut points for non-CAHPS measures, plans believe a cap would improve the predictability of Star Ratings for CAHPS measures year over year.

Issue #2: Measure Updates

CMS is proposing to modify four existing measures for 2022 and 2023 STAR Ratings:

- *Controlling High Blood Pressure (Part C)* – to align with new clinical guidelines related to hypertension; CMS proposes for the 2022 Star Ratings with a weight of one for the first year and a weight of three thereafter
- *Measure Plan Finder Price Accuracy (Part D)* – to better measure the reliability of a contract's advertised price; CMS proposes as a display measure in 2020 and 2021 and with a weight of one in the 2022 Star Ratings
- *Plan All-Cause Readmissions (Part C)* – to include observation stays and remove individuals with high frequency hospitalizations; CMS proposes as a display measure for 2021 and 2022 and with a weight of one beginning in the 2023 Star Ratings and a weight of three thereafter
- *Improvement measures (Parts C and D*) – to exclude from the improvement calculation any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year

Recommendation #2:

BCBSA appreciates the opportunity to comment on these measure modifications and offers the following recommendations:

- *Controlling High Blood Pressure (Part C)* – We agree with the measure update to align with new clinical guidelines and recommend that CMS provide additional detail on these guidelines in the Final Rule.
- *Measure Plan Finder Price Accuracy (Part D)* – BCBSA agrees with this proposal.
- *Plan All-Cause Readmissions (Part C)* – BCBSA agrees with this proposal.
- *Improvement measures (Parts C and D*) – BCBSA is very supportive of this change and thanks the agency for this measure modification.

Rationale #2:

BCBSA believes that these changes will improve the accuracy, stability, and appropriateness of these measures.

Issue #3: Data Integrity

Currently, CMS rules required scaled reductions to the Star Ratings for a contract's Part C or Part D appeals measures because the relevant Independent Review Entity (IRE) data are not complete based on the Timeliness Monitoring Project (TMP) or audit information. CMS proposes adding an additional regulatory provision that would assign a one-star rating to the applicable appeals measure(s) if a contract fails to submit TMP data for CMS's review to ensure the completeness of their IRE data.

Recommendation #3:

BCBSA believes that a reduction should only occur when there is a complete failure to submit TMP data for CMS review**.**

Rationale #3:

The assignment of one star to measures where plans that are totally non-compliant with CMS regulations regarding TMP data submission assists in ensuring a more valid quality rating system for MA and Part D plans. We continue to believe that distinguishing between generally well-functioning plans that may have an occasional data error versus plans that have significant, material errors due to major systemic issues is critical when assessing and rating plans based on the integrity of their data.

Issue #4: Review of Sponsors' Data

CMS proposes to codify a policy regarding the deadlines for a plan sponsor to request CMS or the IRE to review a contract's appeals or CMS to review a contract's Complaints Tracking Module (CTM) data. To allow enough time for the IRE to make any necessary changes to ensure the accuracy of a contract's measure score, CMS proposes that requests for CMS or the IRE to review contract data must be received no later than June 30 of the following year in order to have time to use accurate information in the Star Ratings calculations. In addition, reopenings are not considered under this proposed deadline for corrections to the IRE data. When the decision is evaluated for purposes of the appeals measures, if a reopening occurs and is decided prior to May 1, the revised determination is used in place of the original reconsidered determination. If the revised determination occurs on or after May 1, the original reconsidered determination is used. CMS also proposes that any requests for adjustments following CMS's CTM Standard Operating Procedures for the complaints' measures be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data.

Recommendation #4:

BCBSA supports CMS' proposed changes in their timeline for reviewing data prior to finalizing MA and Part D Star Ratings. However, BCBSA requests that CMS clarify the application of the deadline related to CTM data. If CMS moves forward in finalizing these provisions, BCBSA requests that CMS provide plans with a minimum of two weeks to review each set of data, prior to implementing any deadlines.

Rationale #4:

CMS is proposing multiple constraints on the time periods for reviewing and requesting reconsideration of data used for Star Ratings. While limitations placed on the ability of plans to review data are reasonable, BCBSA is concerned that MA and Part D plans must have reasonable advanced notice in order to perform proper review of data.

Issue #5: Extreme and Uncontrollable Circumstances: General Proposal

CMS proposes to adjust the Star Ratings methodology for affected MA and Part D plans/contracts to take into account the effects of extreme and uncontrollable circumstances, such as hurricanes, that occur during the performance of the measurement period. The proposed policy is similar to the one implemented for the 2019 Star Ratings, with the exception of eliminating the difference-in-difference adjustment for survey data (which showed no consistent, negative impact from extreme and uncontrollable circumstances). In general, this policy compares a contract's previous year and current year (in which the extreme and uncontrollable circumstance occurred) Star Ratings and corresponding measure score and uses the higher of the two measure scores.

Recommendation #5:

BCBSA appreciates CMS' attention to the impact of natural disasters and uncontrollable circumstances, as well as efforts to work with plans, providers, and beneficiaries negatively impacted by extreme and uncontrollable circumstances.

In order to achieve its stated goal of holding contracts harmless in extreme and uncontrollable circumstances, we recommend that CMS continue its policy of ensuring that the higher of both Star Ratings and measure scores are used, as outlined in the methodology finalized in the 2019 Final Call Letter.[1]

While we support the proposed policies for 2020, we believe that in the long-run, CMS may need to consider alternative policies to address the impact of recurrent natural disasters that occur in specific geographic areas and contracts.

Rationale #5:

With extreme disaster becoming more frequent, the current policy may become unworkable, as the same areas could suffer significant disasters in consecutive years, thus making the "higher of" policy inappropriate, and the number of contracts excluded from cut point and reward calculations could become significant.

For contracts affected by recurring catastrophes, CMS could consider treating the affected contracts similar to the way that "new" contracts are treated or determining whether Star Ratings

[1] "Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter." April 2, 2018.

could be based on a very small set of measures. Alternatively, for events that impact only a small portion of a contract's geography, CMS could consider basing the ratings only on the remainder of the service area.

Because many BCBS Plans have contracts in areas that have suffered these extreme and uncontrollable circumstances, we would be happy to work with CMS to develop a long-term solution that ensures plans can continue to serve their communities amid devastation.

Issue #6: Extreme and Uncontrollable Circumstances: Identification of Affected Areas

CMS proposes to tailor the adjustments to the specific areas experiencing the extreme and uncontrollable circumstances to avoid unnecessary over- or under-adjustments. Specifically, CMS proposes to identify contracts affected by extreme and uncontrollable circumstances during the performance or measurement period that may have affected their Star Ratings performance or their ability to collect necessary measure-level data. For a plan to be considered an affected contract, it would need to meet all of the following criteria:

- The service area is within an "emergency area" during an "emergency period."
- The service area is within a county, Parrish, territory or tribal area designated in a major disaster declaration and the Secretary exercised authority under SSA sec. 1135(g).
- A minimum percentage (25 percent for measure Star adjustments or 60 percent for exclusion from cut point and Reward Factor calculation) of the enrollees under the contract must resident in a FEMA-designated Individual Assistance area at the time of the circumstance. Contracts that do not meet these criteria would not be eligible for any adjustments based on the occurrence of the extreme and uncontrollable circumstances

Recommendation #6:

BCBSA supports CMS' proposed criteria for an affected contract. In order to improve transparency, BCBSA recommends that CMS announce these areas/contracts that have been designated as experiencing extreme and uncontrollable circumstances on a quarterly basis so that plans will understand where they stand prior to finalizing Star Ratings.

Rationale #6:

For the 2019 Star Ratings, some Plans were not aware of which areas/contracts had been designated as a disaster area for purposes of Star Ratings until close to the time when Star Ratings were finalized. Because of this late announcement, Plans were unaware of how these adjustments affected their ratings. Identifying areas/contracts designated as disasters for the purposes of Star Ratings on a quarterly basis would improve transparency.

Issue #7: Extreme and Uncontrollable Circumstances: Measure Adjustments:

For CAHPs, CMS proposes the ability to request an exemption from having to administer the CAHPS survey if the contract demonstrates to CMS that the required sample cannot be

contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster in the prior calendar year.

For most other measures, CMS proposes that affected contracts with at least 25 percent of enrollees residing in Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score).

CMS is also proposing to exclude a contract from the cut point and reward calculations if more than 60 percent of a contract's enrollees are affected by such circumstances.

Recommendation #7:

BCBSA supports CMS' proposal and requests clarification that CMS intends to use the higher of the previous or current year's measure scores to ensure that plans are truly held harmless.

Rationale #7:

BCBSA believes CMS' proposal represents a fair and appropriate policy for contracts affected by extreme and uncontrollable circumstances. However, one BCBS Plan experienced a situation recently where CMS did not use the higher of two measure scores between 2017 and 2018 because the Star Ratings were consistent despite a lower measure score in 2018. The measure was therefore subject to use in the improvement calculation and the Plan was not truly held harmless.

Improving Clarity of the Exceptions Timeframes for Part D Drugs

Issue #1: <u>Part D Adjudication Timeframes for Exception Requests</u>

CMS proposes a change in the Part D adjudication timeframes related to exception requests in cases where a prescribing physicians or other prescriber's supporting statement has not been received by the plan sponsor. Specifically, CMS proposes to limit the amount of time an exception request can be held open in a pending status and would require that plans notify enrollees of its decision no later than 72 hours (24 hours for expedited decisions) or receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever comes first.

Recommendation #1:

BCBSA supports this proposed change and recommends that CMS finalize the proposal.

Rationale #1:

Plans appreciate CMS' clarity and guidance that would limit the amount of time an exception request can be held in a pending status and believe that the proposed timeframes are reasonable.

Section C: Clarifying Program Integrity Policies

Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans and PACE

Issue #1: Multiple Issuances of Guidance in Last Year

CMS has produced multiple documents over more than six months describing different elements of the implementation of preclusion. These documents include the final 2018 regulation published in April 2018 (CMS-4182-F), an HPMS memorandum entitled "Preclusion List Requirements" on Nov. 2, the NPRM on which this set of comments is based, and an HPMS memo, entitled "Preclusion List Frequently Asked Questions (FAQs), released on Dec. 14. These multiple issuances have resulted in overlapping and conflicting requirements.

Recommendation #1:

BCBSA recommends that CMS delay the implementation of preclusion for a minimum of one year pending consolidation of issues covered in multiple documents from CMS to ensure consistency and an integrated process for MA and Part D plans and the resolution of a number of policy issues.

In addition, we recommend that CMS address the following outstanding issues and questions either in the Final Rule or additional guidance:

- There are timing issues between the release of the OIG exclusion list (which is mid-month) and the preclusion list (which is released around the beginning of the month).
- If the lists are supposed to be treated the same, why are there two lists?
- Will there be a link to the preclusion list, or do we have to wait for CMS to transmit it?
- While we understand that the member cannot appeal the provider's status of preclusion, can they appeal the plan's denial of a claim? While we understand that a member who received the notice that the provider was excluded but continued to use that provider could not appeal the denial of that claim, what about the member who for some reason did NOT receive the notice?

Rationale #1:

BCBSA recently submitted to CMS a lengthy list of unresolved questions that reflect issues stemming from the final 2018 regulation and from the recently published HPMS memo. Although many were answered in the recent FAQs, the remaining issues reflect overlapping and conflicting requirements that CMS must address prior to implementation. Because of these unresolved issues, BCBSA recommends a delay in the implementation of preclusion by at least one year.

Issue #2: Consolidation of Appeals Processes for Revocation and Preclusion List

Under the final April 2018 rule, there could be up to a 9-month delay between revocation and placement of the provider's name on the preclusion list. By consolidating the appeals processes for revocation and preclusion, the delay would be reduced to 5 months.

Recommendation #2:

BCBSA supports the consolidation of the revocation and preclusion list appeals processes.

Rationale #2:

The changes in this Proposed Rule to consolidate the appeals processes for revocation and preclusion would reduce the delay in placing the provider's name on the preclusion list and allow MA and Part D plans to appropriately deny claims payment in a more timely manner.

Issue #3: Placing Provider's Name on Preclusion List after 60 Days

CMS is proposing to place the provider's name on the preclusion list after 60 days has expired if the provider has failed to request a reconsideration or CMS has denied the provider's request for a reconsideration.

Recommendation #3:

BCBSA agrees with this recommendation.

Rationale #3:

This proposed change is consistent with the prior issue (consolidating the appeals processes for revocation and preclusion) and will ensure timelier implementation of claims denial by plans.

Issue #4: Effective Dates

CMS proposes that these changes would effective Jan. 1, 2020 but also solicits comments on an alternative effective date of 60 days after the regulation is finalized.

Recommendation #4:

BCBSA recommends that these changes should be effective Jan. 1, 2020 and further reiterates our recommendation to delay implementation of the entire preclusion list policy by at least one year.

Rationale #4:

There are numerous operational issues that have not been addressed by CMS that must be resolved prior to implementation of these changes. Implementing these changes within 60 days would impose a substantial hardship on plans.

Issue #5: Extension of Initial Timing for Claim Denials and Beneficiary Notification

In the 2018 Final Rule, CMS finalized a 90-day process before a claim could be denied by a plan, including a 30-day period for the plan to notify the member and a subsequent 60-day period for the member to obtain services from a provider who was not on the preclusion list. This schedule was intended only for the initial implementation of the preclusion list. In this proposed rule, CMS is extending this approach for all issuances of the preclusion list.

Recommendation #5:

BCBSA agrees with this schedule.

Rationale #5:

The original schedule offered by CMS in the final 2018 rule allowed plans time to contact the beneficiary and afforded the beneficiary time to arrange for an alternative provider. Continuing this timeline for all issuances of the preclusion list provides plans and beneficiaries with sufficient notice.

Issue #6: New Regulatory Text Regarding Appeals and Timing

CMS is proposing regulatory text to confirm two policies discussed in the preamble to the 2018 Final Rule but not included in the regulatory text. Specifically, CMS proposes that beneficiaries may not appeal payment denials based on a provider's name being found on the preclusion list, and that unenrolled prescribers and providers should stay on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed had that prescriber or provider been enrolled and then revoked.

Recommendation #6:

BCBSA agrees with these changes

Rational #6:

These changes are consistent with the intent of the final 2018 regulation and ensures that MA plans can effectively implement claims denials for precluded providers and do so for the full period allowable.

Issue #7: Beneficiary Financial Liability

CMS is proposing to clarify that the beneficiary should be held harmless for financial liability if their provider is included on the preclusion list. This applies only to contracted providers, but CMS believes that it would assist those members who use non-contracted providers who have been placed on the preclusion list.

Recommendation #7:

BCBSA agrees with this change. However, we acknowledge that members who use non-contracted providers who are included on the preclusion list are vulnerable to inappropriate demands for payments sent directly to them by these unscrupulous providers.

Rationale #7:

MA members are generally not financially liable for payments to contracted providers. This proposal is consistent with that policy. However, BCBSA believes that additional communication and transparency around all providers who are on the preclusion list would help to minimize inappropriate billing.

Section C: Clarifying Program Integrity Policies

Medicare Advantage Risk Adjustment Data Validation Provisions

We will submit detailed comments before the extended April 30, 2019 comment submission deadline.

TAB 11

HealthPartners Comments

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4185-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: File Code CMS–4185–P

Filed Electronically: www.regulations.gov

Dear Sir/Madam:

Thank you for this opportunity to offer our comments on the *Medicare Program; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021* proposed rule. HealthPartners is a not-for-profit plan sponsor and has participated in the Medicare Program since 1984. We hold five contracts with the Centers for Medicare & Medicaid Services (CMS): H2422 (MA FIDE SNP), H2462 (1876 Cost), H3416 (MA-PD PPO), H4882 (MA-PD PPO), and S1822 (Employer Group only PDP).

HealthPartners is an integrated organization offering both care and coverage and is driving change that helps our members live healthier lives at lower costs. Through our unique wellness programs, innovative provider payment approaches which incent and reward quality, and convenient member tools and services, we are able to provide better value for our members. By partnering with providers, members, purchasers, and the community, we are leveraging our capabilities to develop initiatives which improve health, member experience, and affordability.

We welcome this opportunity to offer our perspective on provisions in the proposed rule. The overall direction CMS is taking provides plans needed relief of outdated requirements as well as flexibility to improve access to quality care.

COMMENTS

Section II. A. Implementing the Bipartisan Budget Act (BBA) of 2018 Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (Section II.A.1, page 54987). We appreciate and support CMS' proposed flexibility in defining types and uses of electronic exchanges as part of the implementation of the BBA of 2018 provision of additional telehealth benefits. HealthPartners has a long history of covering telehealth benefits in the form of remote access technologies. For plan year 2012 HealthPartners was one of the first organizations to offer supplemental coverage of online care, initially focusing on our own online clinic virtuwell. We worked very closely with CMS to address safety and care protocols concerns, and preserved the beneficiary's access to in-person

care. Since 2012 we have expanded coverage to include e-visits, telephone visits and real-time interactive audio and video technologies. Based on our experience, we offer the following recommendations on the proposed provisions.

Recommendations:

a. CMS not place any limitations on what types of Part B items and services can be additional telehealth benefits. Plans and providers are best positioned to determine if clinically appropriate.

b. CMS provide plans flexibility with how the notice of coverage of additional telehealth benefits is provided for in the EOC and provider directory.

   EOC: CMS require in the EOC a general description of covered telehealth benefits. Plans would then detail in a medical coverage policy the information on clinically appropriate services covered by the plan via an electronic exchange. Based on our experience clinical appropriateness of telehealth services for a beneficiary should happen with the provider, and too much information in the EOC would be misleading for some beneficiaries and care givers.

   Provider directory: CMS allow plans to include a general notice/statement that some providers offer telehealth services and to contact the provider or plan for more information. In addition, provide plans the option to list providers offering telehealth services exclusively. Alternatively, CMS allow plans the option to identify providers offering telehealth services, both those offering exclusively and those offering both telehealth and in-person visits. This approach allows plans needing to focus on existing provider directory accuracy requirements the option to continue to do so.

c. CMS include telehealth providers in the network adequacy assessment, especially when there is a lack of eligible providers with whom to contract or when a provider is unwilling to contract with a plan and a contracted provider is just outside the time and distance standard. Time and distance standards are outdated and more meaningful standards should include access to providers via real-time interactive video or other similar telehealth visits.

d. CMS allow coverage of additional telehealth benefits by non-contracted providers as long as the provider is eligible for Medicare payment. Today plans do not have oversight of non-contracted providers for in-person visits and those providers are responsible for following any medical ethics and treatment guidelines outlined by their respective professional organizations as well as any state requirements. There should not be any difference for visits furnished via an electronic exchange or in-person. In addition, this recommendation would align with the CMS requirement that PPO plans furnish all plan-covered services both in-network and out-of-network.

e. CMS allow diagnoses obtained through telehealth encounters to be included for risk adjustment purposes. CMS acknowledges that the telehealth industry has made significant advances in technology and that it has become an appropriate care delivery option for MA enrollees. As such, we strongly believe that any diagnosis obtained during an additional telehealth encounter be allowed under risk adjustment. This approach is further supported by the fact that the services will be included in the MA basic benefit package.

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2. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (Sec. II.A.2.b, page 54999). We appreciate and support CMS' focus on distinct policies that support an integrated approach to denials, appeals and grievances for HIDE and FIDESNPs. Current guidance requires denial and appeal notices be sent whenever a Medicare service is denied, even if it is covered by Medicaid and the FIDESNP holds both. This is very confusing to members because ultimately the service is covered by the FIDESNP, just not by the Medicare part of the benefit. Requiring FIDESNPs to send out a denial notice in this case causes confusion and worry to members and unnecessary administrative work to plans.

Recommendation: CMS only require the denial notice and appeal rights be sent when there is a denial by all coverage sources managed by the FIDESNP. In addition, we request that CMS ensure the continued utilization of the Integrated Denial Notice (CMS-10003) to meet the notice of adverse determination requirements in the proposed provision of the rule.

3. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (Sec. II.A.3, page 55015). HealthPartners supports CMS' proposal to permit PDP sponsors to use Medicare Part A and B claims data to optimize therapeutic outcomes through improved medication use, to improve care coordination, and for healthcare operations or compliance activities as defined by regulation. However, we have concerns with the timing of the availability of the data extracts. Receiving 1st quarter data in mid-August makes it challenging for sponsors to use the data in a meaningful way.

Recommendation: CMS establish a process to provide the claims data more frequently and timely than proposed. We suggest data be provided on a monthly basis that contains all new claims data received since the last data pull. For example, the first data extract would be made available in March for claims paid 1/1-1/31, then in April for claims paid 2/1-2/28, etc.

Section II. B. Improving Program Quality and Accessibility

4. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (Sec. II.B.1, page 55018).

a. Measure-Level Star Ratings and Cut Points

We support CMS' desire to enhance the cut point methodology. Without more data and simulation from CMS it is difficult to evaluate how a cap or guardrail would impact the program and what is the most effective percentage level (3% vs 5%).

HealthPartners continues to support the use of established cut points to provide stability over time and put improvement in ratings under the control of the plan. We also believe that cut points need to reflect meaningful differences in plan performance.

Recommendation:

CMS implement the following changes:

- Set caps to the range of cut point changes to limit volatility.
- Set predetermined cut points so plans and providers have targets to strive for.
- Retire measures when there are 1 percentage point differences in the same direction between cut points year over year (e.g., 3 years).

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b. Extreme and Uncontrollable Circumstances

Our organization supports the codifying of rules for calculating star ratings in extreme and uncontrollable circumstances but would like to see more transparency regarding who/how many contracts have received adjustments due to these circumstances.

Recommendation: CMS add information to the industry star rating results noting which contracts received adjustments.

c. Other – Patient Reported Outcome Measures

HealthPartners would also like to note that there are important star ratings issues that are not addressed in this proposed rule. One of those is the use of Health Outcomes Survey (HOS) measures in in the star ratings. While HealthPartners supports the HOS to collect self-reported experience information from beneficiaries, its use in star ratings needs to reflect this specific value rather than a broader implication. HealthPartners continues to strongly believe that survey measures such as the HOS measures that are self-reported are not objectively reflective of health outcomes. Furthermore, it is inappropriate to assign self-reported measures the weight of 3x. The HOS questions related to these measures are based on members' experiences and thus should be categorized as experience measures. Members may be receiving appropriate health care services; however, their responses regarding their physical health and mental status are based on experience and personal benchmark rather than on medical measures of functionality. We do not believe measures such as these help people with Medicare accurately compare the quality of health and drug plans being offered in their area.

Recommendation: CMS work with industry on the development, testing and refinement of patient-reported outcomes measures, recognizing the difficulty in constructing reliable measures, and in the meantime lower the weighting of HOS measures to 2X.

5. Improving Clarity of the Exceptions Timeframes for Part D Drugs (Sec. II.B.3, page 55028). HealthPartners supports the proposed changes to the Part D exceptions timeframes and appreciates CMS' clarification in guidance.

Section II. C. Clarifying Program Integrity Policies

6. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (Sec. II.C.1, page 55029). HealthPartners appreciates CMS' efforts to combat fraud, waste, and abuse in the Medicare program; however we are not supportive of the proposed process for the preclusion list requirements. Administering the preclusion list differently that the OIG exclusion list increases administrative burden for plans while adding little value and potential confusion for beneficiaries.

Our organization supports terminating providers and denying claims in a time frame consistent with the OIG exclusion process, rather than waiting for at least 60 days upon release of the preclusion list. This would align with the current OIG exclusions process as well as our organization's contractual language with providers. There should not be a 60 day period before claim denials- a provider would know they are precluded and should not be seeing Medicare beneficiaries or prescribing drugs. Separate beneficiary

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notices and claims denial timeframes like CMS is proposing have the potential for beneficiary confusion. Due to our position, we also do not support the application of the new provisions 60 days after publication of the proposed rule.

Recommendation: CMS use one list that combines the exclusions and preclusions. Alternatively, CMS revise the preclusion list requirements to apply in the same manner as the OIG list, allowing plans to deny claims upon release of the list.

Thank you for the consideration of our comments. If you have any questions regarding our comments, please feel free to contact me at 952-967-5117 or Amy.L.Schultz@HealthPartners.com.

Sincerely,

Amy L. Schultz
Sr. Medicare Programs Manager
HealthPartners

TAB 12

AmeriHealth Caritas Comments

AmeriHealth Caritas

200 Stevens Drive
Philadelphia, PA 19113-1570
215-937-8000

December 31, 2018

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-4185-P, P.O. Box 8013,
Baltimore, MD 21244-8013
Submitted Electronically to http://www.regulations.gov

RE: Comments on CMS-4185-P

Dear Secretary Azar,

On behalf of the AmeriHealth Caritas Family of Companies (AmeriHealth Caritas), I am writing to provide comments on the proposed rule published by your Office on November 1, 2018, titled "Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021." In general, we support the efforts of the Centers for Medicare & Medicaid Services (CMS) toward further alignment of the Medicare and Medicaid programs. We believe that the changes to the programs that are proposed in this Notice of Proposed Rulemaking (NPRM) continue the important conversation of integration spurred by the new requirements included in the Bipartisan Budget Act of 2018 and the "Request for Stakeholder Input: Implementing the Dual Eligible Special Needs Plans (D-SNPs) Provisions of the Bipartisan Budget Act of 2018" issued by the Medicare Medicaid Coordination Office (MMCO) in March 2018, subsequently referred to in this letter as the "RSI." In our response to the RSI, we applauded CMS' commitment to the advancement of fully integrated plans for dually eligible individuals; we appreciate the opportunity to further delineate on our perspective through these comments to the NPRM.

In addition to commenting on the proposed changes to D-SNPs, we also address the proposed changes to the Star ratings methodology and the Risk Adjustment Data Validation (RADV) portions of the NPRM. These proposed changes may have significant consequential impact on the stability of the Medicare Advantage market; we therefore encourage CMS to provide further data and, if possible, simulations of the outcomes of these changes.

Background on AmeriHealth Caritas:

With more than 35 years of experience, AmeriHealth Caritas is one of the nation's leaders in health care solutions for those most in need. Operating in 15 states and the District of Columbia, AmeriHealth Caritas serves more than 5 million Medicaid, Medicare and CHIP members through its integrated managed care products, pharmaceutical benefit management and specialty pharmacy services, and behavioral health services. Our lines of business include a D-SNP plan in Pennsylvania and Medicare Medicaid Plans (MMP) in Michigan and South Carolina. We are committed to furthering the cause of greater integration between Medicare and Medicaid and we welcome the opportunity to engage with CMS on this important topic.

Comments:

AmeriHealth Caritas has experienced firsthand the benefits that accrue to beneficiaries, to our partnering states, and to CMS through greater integration in managed care. The holistic approach to care management offered by D-SNPs provides beneficiaries a streamlined approach to accessing Medicare and Medicaid services as well as greater coordination between traditionally disparate sets of providers. This type of integrated care can lead to positive health outcomes as well as decreases in overall service utilization. As a result, states and CMS benefit from more comprehensive and predictable population-level expense information, which allows for more accurate rate setting and increased stability in program funding.

D-SNPs can best achieve these benefits through consistent stakeholder engagement, meaningful data sharing partnerships, targeted program design, and predictable and sufficient enrollment mechanisms. Currently, D-SNPs suffer from the instability caused by unpredictable beneficiary enrollment and disenrollment. This type of rapid enrollment "churn" prevents beneficiaries, plans, and government partners from realizing the potential benefits of the model because it precludes the necessary investment of time needed to properly manage beneficiary care. In our response to the RSI, we stressed that without reliable expectations as to the source, consistency, and size of enrollment, it is difficult for a managed care organization to achieve the integration goals to which the D-SNP program aspires. We further emphasized that greater stability in the D-SNP market depends on greater utilization of policy levers to address these enrollment issues. These levers include lock-in provisions, default enrollment, and deeming of eligibility. We take this opportunity to reinforce these points and urge CMS to continue working toward greater stability in D-SNP enrollment.

Below you will find our comments on some of the key elements of the proposed rule.

Requirements for Integration

The proposed rule clearly evinces CMS' sincerity in acting on the goal of achieving greater integration between Medicare and Medicaid for dual eligible individuals in a practical and incremental fashion. In particular, we appreciate that CMS recognizes the impact that the diversity of relevant state policies has on the D-SNPs. Clearly, health plan partners that sponsor D–SNPs will need to respond in kind with the continued proliferation of integrated approaches, resulting in creative and innovative solutions to the integration conundrum.

At the same time, we also believe that CMS should continue to seek the authority to better align many of the operational and administrative components that stand in the way of streamlined integration. Without incentives or pathways to develop the infrastructure necessary for state agencies and health plans to better coordinate, communicate, and share relevant information, it will continue to be extremely difficult to meet the lofty goals of integration set by the proposed definitions along the spectrum of integration.

Below we outline our thoughts in greater detail.

(1) Definitions of a "Dual Eligible Special Needs Plan", "Fully Integrated Dual Eligible Special Needs Plan", "Highly Integrated Dual Eligible Special Needs Plan", and "Aligned Enrollment" (§ 422.2)

CMS proposes to combine existing statutory and regulatory sources in an effort to create unified definitions of key terms.

AmeriHealth Caritas applauds CMS in its efforts to bring more clarity to the definitions of the various types of D-SNP plans. We believe that the terms better encompass the various forms that D-SNP contracts can take in different states. Furthermore, we appreciate the effort to create a spectrum of integration represented by D-SNPs on the least integrated end, HIDE SNPs as moderately integrated plans, and FIDE SNPs as fully integrated plans. This structure provides states and plans clear starting points from which to better define their goals and objectives. However, we do have a few concerns about some of the components of the definitions.

First, CMS proposes in its definition of D-SNPs that such plans "provide[], as applicable, and coordinate[] the delivery of Medicare and Medicaid services, including long-term services and supports and behavioral health services" for eligible beneficiaries.[1] We are concerned that the use of the conjunctive "and" to connect "provide, as applicable," and "coordinate the delivery of" could be misinterpreted as requiring that all D-SNPs must actually "provide" *as well as* "coordinate the delivery of" long-term services and supports and behavioral health services. We appreciate that such an interpretation ignores the qualifier "as applicable." We also recognize that the definition is meant to encapsulate the entirety of D-SNP plans, which includes those plans that *are* required to provide such services. However, we are concerned that the relationship between the word "and" and the qualifier "as applicable" is not clear enough to eliminate the possibility of a misinterpretation of the definition as requiring that all D-SNPs must provide. While the risk of such a misinterpretation is small, the consequences of it could be significant, especially if the party interpreting the definition is a state partner.

With respect to the qualifying term "coordinates the delivery of," CMS states that it is purposefully leaving the term broadly defined.[2] The proposed rule does provide some illustrative examples of the types of activities that would qualify as "coordinating the delivery of." It also states the term means, in part, that all D-SNPs must "facilitate a beneficiary's meaningful access to such [Medicaid] benefits."[3] Overall, we agree with the decision to leave this term broadly defined. The definition remains flexible to adapt to the particular realities of diverse state policies. However, we ask CMS to consider whether further guidance on the term could serve as a means of persuading states to standardize their approaches to the alignment of their Medicaid programs with the MA program. For example, CMS could issue further guidance on how states can work to establish viable health information exchanges as a means of facilitating communication and data exchange between plans and state Medicaid agencies. Such actions could qualify as "coordinating the delivery of" these services.

We also suggest that CMS provide further clarification of how the term "consistent with state policy," which appears in the definition of HIDE SNP and FIDE SNP, relates to the actual services that D-SNPs must cover. In the proposed rule, CMS requires HIDE SNPs to have capitated contracts with the state Medicaid agency that cover "LTSS, behavioral health services, or both, *consistent with state policy*" (emphasis added).[4] Similarly, FIDE SNPs must have contracts that cover LTSS *and* behavioral health services consistent with state policy. In the rule, CMS mentions that the term "consistent with state policy" is meant to account for the variety of state Medicaid coverage carve-outs that states currently adopt.[5] As a result, HIDE SNPs must only cover LTSS and/or behavioral health services to the extent permitted under state policy. FIDE SNPs must cover both, but again only to the extent permitted under state policy.

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[1] 83 FR, 54993.
[2] Id.
[3] Id.
[4] Id.
[5] Id.

We appreciate the need for flexibility in the D-SNP model, especially in the context of adapting it to meet state policies. However, we believe CMS should consider further clarifying how the term "consistent with state policy" affects the ability of D-SNP plans and states to meet the definition of HIDE SNP and FIDE SNP. For example, if a state carves out LTSS services from its Medicaid managed care program, does that mean that no D-SNP in that state can qualify as a FIDE SNP, since FIDE SNPs must cover some element of LTSS? We would appreciate a clearer explanation of the types of flexibilities that the term "consistent with state policy" actually provides to both plans and their state partners.

Finally, when comparing the definition of a HIDE SNP to a FIDE SNP, CMS notes that "any FIDE SNP would … be a HIDE SNP, but not all HIDE SNPs would qualify to be FIDE SNPs."[6] Logically, this statement allows for the possibility that some HIDE SNPs *may* be FIDE SNPs. We ask that CMS further clarify the distinction between these two terms. Based on their proposed definitions, the key differentiating factors between the two appear to be: (1) whether the plan in question is part of a parent organization or another entity owned and controlled by its parent organization (HIDE SNPs) or whether it is a single entity covering both Medicaid and Medicare (FIDE SNP); and (2) the degree to which the plan covers LTSS and behavioral health services. With respect to the first element, we seek clarification on how the structure of the entity relates to the classification of a plan on the three-part integration spectrum. Will states have a degree of latitude to interpret and apply what "parent organization" and "another entity" mean? If plans wish to meet the seemingly more stringent FIDE SNP classification, what considerations should they take into account as they establish their administrative, operational, and financial structures? With respect to the second element, we request that CMS clarify the extent to which a FIDE SNP and HIDE SNP are required to cover LTSS and behavioral health services. We view such a clarification as a natural extension of the conversation around the term "consistent with state policy" discussed above.

(2) Dual Eligible Special Needs Plans and Contracts with States (§ 422.107)

CMS proposes to require any non-HIDE SNP or non-FIDE SNP to notify the state Medicaid agency, or individuals or entities designated by the state Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full benefit dual eligible individuals, as determined by the state Medicaid agency.[7]

Generally, we support CMS in its decision to introduce incremental integration requirements onto D-SNPs as a means of moving toward greater integration. As a result, we do not disagree with this new requirement outright. However, we do have some concerns about the administrative and operational issues that it raises.

CMS states that in implementing this proposal, it will give wide latitude to state Medicaid agencies in establishing the types of notification procedures, protocols, and timeframes required. As we have stated previously, we appreciate and support the need for state flexibility. However, it is our experience that some state Medicaid agencies may, in turn, entirely shift these types of coordination responsibilities onto the plans. We would therefore request that CMS consider obligating state agencies to assist D-SNPs with the development of the relevant administrative components, which could be included as a required element in a MIPPA contract. Alternatively, CMS could consider developing incentives for states to assist in the development of administrative technologies.

CMS also suggests that states and plans can use existing health information exchanges (HIE) to satisfy this new requirement. We strongly support the use of HIEs in this context and encourage CMS to explore ways to proliferate their use. In our comments to the RSI, we noted the success that we have had with the Michigan

[6] Id.
[7] Id. at 54996

HIE, where we operate an MMP. We are pleased to see that CMS recognizes the value that this infrastructure provides.

Unified Grievance and Appeal Process

Grievance and Appeals processes represent one of the largest hurdles of integration between Medicare and Medicaid. As we discussed in our response to the RSI, through our experience in operating both D-SNPs and MMPs, we find that the MMP program offers the opportunity for greater alignment and allows our grievance and appeals teams to operate more smoothly and efficiently. As an example, our Michigan and South Carolina MMPs have written communications that combine the appeals language of both Medicare and Medicaid. This educates members about all relevant options at the time they are notified of an adverse coverage determination, as opposed to requiring the member to seek that information on their own. We encourage CMS to consider the differences between the models and adopt the advantageous components of the MMP model.

Below you will find responses to some of the specific questions related to Grievances and Appeals procedures posed in the NPRM:

(1) Assisting With Medicaid Coverage Issues and Grievances (§ 422.562(a)(5))

CMS proposes that all D-SNPs must provide assistance to all enrollees in the actual filing of grievances and appeals. This proposal is intended to result in a more seamless process for enrollees in accessing Medicaid benefits and pursuing grievance and appeals for D-SNP enrollees.

We are generally supportive of CMS' efforts to further integrate D-SNPs and better assist beneficiaries with appeals and grievances. However, we believe that CMS should provide further clarification on a number of terms and concepts that remain unclear. Overall, our position is that CMS should explore the lessons learned from the MMP model and provide guidance accordingly.

CMS proposes that all D-SNPs must affirmatively "offer to assist" beneficiaries whenever the plan "becomes aware of an enrollee's need for a Medicaid covered service."[8] CMS does not clarify when a plan "becomes aware of an enrollee's need" beyond saying that they expect that D-SNPs, as plans responsible for coordinating both Medicaid and Medicare services, should be able to identify a potential Medicaid coverage issue.[9] This explanation is not entirely clear, and potentially creates serious conflicts of interest. For example, if a FIDE SNP subject to these provisions makes what it deems to be a medically justifiable reduction in a beneficiary's Medicaid services, does that plan simultaneously "become aware" of an enrollee's need for Medicaid-covered services? If so, is the plan then obligated to affirmatively undertake an appeal of its own decision without being requested by the beneficiary? This type of interpretation could lead to significant unnecessary stresses and burdens on plans and beneficiaries alike.

Furthermore, in its proposed regulatory language, CMS provides examples of the type of assistance that plans are expected to offer.[10] This includes providing an enrollee "reasonable assistance" in completing forms and aiding in the procedural steps of filing. We recognize the term "reasonable assistance" as currently existing in the MMP context and believe this is a clear opportunity to apply lessons learned from the alignment demonstration projects. We encourage CMS to directly consult with MMP plans on their

[8] Id. at 55078
[9] Id. at 55002
[10] Id. at 55078

implementation of this requirement. As MMPs represent the highest level of integration, they are the ideal reference point for alignment opportunities.

CMS proposes to require that D-SNPs and states maintain data sharing that allows D–SNPs to determine the type and source of Medicaid coverage of their enrollees. This proposal is intended to facilitate compliance with the requirement to provide assistance to enrollees by giving care coordinators the tools they need to navigate the enrollee's coverage.

We are supportive of data sharing agreements between Medicaid agencies and D-SNPs to facilitate integration. However, we ask for clarification on specifically what information should be shared between Medicaid agencies and D-SNPs and how this information should be accessed. State approaches to data sharing vary widely and we believe that CMS should encourage greater standardization in this area.

(3) Definitions of "Applicable Integrated Plan", "Integrated Appeal", "Integrated Grievance", "Integrated Organization Determination", and "Integrated Reconsideration," and General Requirements for Applicable Integrated Plans (§§ 422.561 and 422.629)

CMS proposes to define a new term – "Applicable Integrated Plan" – that effectively applies the proposed unified grievance and appeals process only to the subset of D-SNPs that have "exclusively aligned enrollment."

We would like to take this opportunity to comment on CMS's proposed definitions of the terms "aligned enrollment" and "applicable integrated plan." Although the term "aligned enrollment" appears in the integration standards portion of the rule, we address it here because CMS proposes to apply it only in the context of grievances and appeals. CMS defines the term "aligned enrollment" as enrollment by full benefit dual-eligibles into a plan whose Medicaid benefits are also covered by that plan or another entity associated with that plan (e.g. parent organization structure).[11] CMS further states that "exclusively aligned enrollment" occurs when a state's policy limits D-SNP enrollment only to plans with aligned enrollment. CMS states that the newly proposed unified grievance and appeals process would impact only an "applicable integrated plan," which it defines as FIDE SNPs and HIDE SNPs with exclusively aligned enrollment.[12]

In the integration standards section of the rule, CMS speaks extensively on the need to be sensitive to the diversity of state D-SNP policies. However, CMS' approach in the context of D-SNP appeals and grievances appears to be different. There, CMS states that "it is most feasible to unify grievance and appeals systems under exclusively aligned enrollment because an organization is responsible for both Medicare and Medicaid coverage," which is why they propose to limit the unified process to "applicable integrated plans."[13] Of course, as CMS is aware, plans that operate in states *without* exclusively aligned enrollment, meaning plans that exist in states with more permissive D-SNP policies, may nevertheless have aligned enrollment, and thus still be "responsible for both Medicare and Medicaid coverage." This suggests that CMS believes there is something unique about the policies of exclusively aligned states that allows plans operating in those states to better unify appeals and grievances than similarly integrated plans in non-exclusively aligned states.

We believe that all stakeholders would benefit from further clarity on the relationship between the terms "aligned enrollment," "exclusively aligned enrollment," and "applicable integrated plan." Specifically, we ask that CMS elucidate the relationship between the plan-specific nature of "aligned enrollment," the state policy-specific nature of "exclusively aligned enrollment," and whether it is actually CMS' intent that the

[11] Id. at 54995
[12] Id. at 55003.
[13] Id. at 55003

term "applicable integrated plans" be a function of state policy and not of individual plan structure. Is it CMS' intent to use this concept of "exclusively aligned enrollment" as a policy benchmark for states to meet? If so, does CMS intend to somehow influence states toward that goal? Furthermore, does CMS believe that a HIDE SNP or FIDE SNP operating in a state without exclusively aligned enrollment cannot or should not unify their appeals and grievances in the fashion outlined in this section?

CMS proposes to require that applicable integrated plans provide reasonable assistance to enrollees with completing and submitting integrated appeals and grievances. This provision would impose a similar standard as applies to Medicaid managed care plans on applicable integrated plans.

We appreciate the importance of ensuring that enrollees of applicable integrated plans that are seeking assistance receive the help that they require. However, as in our earlier comments, we ask for clarification on what constitutes "reasonable assistance." We note that ambiguity in this provision could increase the administrative burden on plans that may err on the side of caution and provide assistance when it is unnecessary. As discussed above, we recommend that CMS consider issuing further guidance on the term using existing MMP contract language as a model.

CMS proposes to require applicable integrated plans to send the enrollee an acknowledgement of receipt in writing for all integrated grievances and integrated reconsiderations. This provision would impose a similar standard as applies to Medicaid under § 438.406(b) on applicable integrated plans.

We note that the requirement to provide written acknowledgment of receipt for all integrated grievances and integrated reconsiderations is very likely to increase the administrative burden on plans. This requirement could also lead to confusion for enrollees. For instance, when a grievance is resolved and an additional letter is mailed, an enrollee might receive two letters (one for the initial filing of the grievance and a second for the resolution), which could lead to uncertainty. We recommend that CMS not require written acknowledgment of receipt in following the initiation of a grievance.

(5) Integrated Grievances (§ 422.630)

CMS proposes to adopt a combination of MA and MMC requirements for how an applicable integrated plan must notify an enrollee of an extension on an integrated grievance determination—such that applicable integrated plan must notify enrollees immediately, but no later than within two calendar days.

We applaud CMS' efforts to ensure that enrollees are notified of extensions in a timely manner. However, we ask for clarification on when this notification should occur. Without additional clarification, we can think of a few scenarios that may potentially trigger the two calendar day period. For example, should notification occur within two calendar days of the plan discovering that an extension is needed? Should it occur within two calendar days of receipt of the grievance? Or should it occur two calendar days before the original due date?

(7) Continuation of Benefits Pending Appeal (§ 422.632)

CMS proposes that the existing standards for continuation of benefits at § 438.420 apply to applicable integrated plans for Medicare benefits under Parts A and B and Medicaid benefits. Under the proposal, as is applicable to Medicaid managed care plans currently, if an applicable integrated plan decides to stop or reduce a benefit that the enrollee is currently authorized to receive, the enrollee could request that the benefit continue to be provided at the currently authorized level while the enrollee's appeal is pending through the integrated reconsideration.

We support CMS' efforts to ensure that enrollees continue to receive benefits pending the adjudication of

their appeal. However, we note that the appeals process for Medicare in particular can take months in some instances, particularly with regards to state and court level appeals. We seek additional clarification on how long through the appeals process plans will be required to continue providing benefits. We recommend that those steps be limited to the integrated organization determination, the integrated reconsideration and the review by the Independent Review Entity (IRE). This will avoid imposing an unnecessary burden on plans of having to provide benefits through the entire course of an appeal, including, potentially, through relevant court actions. Furthermore, it would mitigate the possibility of enrollees facing significant financial burdens caused by the accrual of cost associated with services provided during the pendency of a lengthy and ultimately unsuccessful appeal.

(8) Integrated Reconsiderations (§ 422.633)

CMS is proposing a 30-calendar day period for resolving post-service appeals (standard reconsiderations) and on permitting expedited post-service integrated reconsideration. Medicaid regulations impose a 30-calendar day period for resolving post-service appeals, while MA regulations allow 60 days to resolve post-service denials of payment. CMS proposes to adopt the 30 day standard so that integrated reconsiderations can be resolved more rapidly, given the significant financial needs of the D-SNP population.

We appreciate CMS' efforts to ensure an efficient and streamlined appeals process for enrollees. We are supportive of aligning the timeframe for the resolution of appeals for member reimbursements; but we seek clarity on the extent to which this change could impact non-participating provider appeals. We ask for clarification on specifically what appeals this timeframe applies to.

(9) Unifying Medicare and Medicaid Appeals Subsequent to Integrated Reconsideration

CMS proposes that a state entity with expertise in both Medicare and Medicaid coverage rules would review all adverse integrated reconsiderations issued by the plan. This entity would conduct its review in the form of an automatic state fair hearing consistent with Medicaid hearing procedures. The automatic fair hearing would also constitute the independent external review required by section 1852(g)(4) of the Act. CMS suggests that this proposal aims to ensure dually eligible beneficiaries' timely access to a fair hearing.

We applaud CMS' efforts to reduce costs and to improve the efficiency of the appeals process. However, we are concerned that the removal of IREs from the appeals process could lead to an increased number of state fair hearings. An increase in state fair hearings could be burdensome for plans and for the Medicaid agency. States would likely have to hire more hearing officers and appropriate administrative supports to avoid significant backlogs. Similarly, plans would have to account for the increased administrative costs associated with fair hearings. We encourage CMS to retain IREs in order to reduce the potential number of state fair hearings and to reduce the burden on plans and State Medicaid agencies.

Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

c. Measure-Level Star Ratings (§ 422.166(a), 423.186(a))

CMS proposes an enhanced cut point methodology for data collected during the 2020 measurement year, with the intention of improving stability and predictability and reducing the influence of outliers. Specifically, they propose to implement a 5% guardrail so that cut points do not increase or decrease beyond that guardrail from one year to the next. CMS would also like to add mean resampling to the current clustering algorithm in order to reduce the sensitivity of the clustering algorithm to outliers and to reduce the random variation that contributes to fluctuations in cut points.

We support CMS' efforts to improve stability and predictability in cut points for Star ratings. In order to better understand the impact that these changes are likely to have on plans, we request that CMS publish a

simulation of what Star ratings would have been using 2019 data and this proposed methodology. It is difficult for us to thoughtfully comment without better understanding the potential impact. We are interested to see whether this methodology will have unintended consequences for MA D-SNPs.

d. Updating Measures

(5) Data Integrity

CMS proposes to add a regulatory provision that would assign a 1-star rating to the applicable appeals measure(s) if a contract fails to submit TMP data for CMS's review to ensure the completeness of their IRE data. CMS believes that it is appropriate to assume that there is an issue related to the performance when the MA organization or Part D plan sponsor has refused to provide information for the purposes of CMS oversight of the compliance with the appeals requirements.

We appreciate CMS' efforts to promote program integrity and promote quality in D-SNPs. However, we ask for clarification on this provision, particularly in regard to submitting data late. Our understanding is that currently, because there is no late submission deadline for submitting TMP data, the penalty is a reduction to one star. We seek to understand the impact of submitting data late under this new provision, and how this provision differs from the existing one.

e. Extreme and Uncontrollable Circumstances

CMS proposes to adjust the Star ratings methodology for affected MA and Part D plans to take into account the effects of extreme and uncontrollable circumstances, such as hurricanes, that occur during the performance of the measurement period.

We applaud CMS' efforts to avoid penalizing the ratings of plans that operate in areas with natural disasters. However, we are concerned that this provision may have unintended consequences. As cut points for Star ratings are distributed on a bell curve, we are concerned that this adjustment may adversely impact plans that were performing at a high level but were not impacted by natural disasters in a given year. Although affected plans with at least 60% of enrollees impacted by natural disasters will be omitted from the clustering algorithm for cut points, other affected plans with 25-59% of enrollees impacted will receive adjustments to their ratings, and will be factored into the clustering algorithm. Plans that are not in disaster zones may make efforts to improve overall and in multiple measures, but because of the nature of the clustering algorithm, may not reap the benefits of their efforts, as cut points will change. There is also a possibility that a plan that scored well in the previous year and was subjected to a natural disaster in the current year will make less of an effort to improve on measures, knowing that the previous year's scores will be used. A lack of accountability for these plans could be especially problematic given the needs of enrollees after a natural disaster.

We ask that CMS consider the potential unintended consequences of this provision. We also request that CMS provide a simulation of what Star ratings would be using this methodology and 2019 data. This simulation would provide plans with clarity on the potential impacts of this methodology before it is implemented.

Medicare Advantage Risk Adjustment Data Validation provisions

CMS proposes to recover overpayments from MA plans based on extrapolated RADV audit findings. CMS is concerned that MA plans may be incentivized to over-report diagnoses so that they can increase their payment, and these audits are intended to ensure that reporting is supported by medical record

documentation. CMS proposes to use this methodology to recover overpayments for every year to present starting in 2011.

We applaud CMS' efforts to improve program integrity and recover overpayments. We ask for clarification on whether CMS intends to continue using the methodology they have been using to determine recovery, or if they intend to implement a new methodology. Specifically, we seek confirmation whether the extrapolated audit methodology based on sub-cohort will replace or augment currently defined contract level methodology. Further, if the methodology is intended as a replacement, we ask for clarification on how the HCC groups utilized to identify sub-cohorts will be determined. We are concerned that there could be unintended negative consequences for plans, if the sub-cohort selection is limited to HCC groups using diagnoses known to be at higher risk of over-coding. Overall, we are supportive of stratification for the sub-cohort methodology.

Plans are likely to have undertaken projects to obtain medical records supporting HCCs reports for dates of service going back to 2010. If this updated methodology results in a selection of different or additional members, we are concerned that it may not be feasible to obtain supporting medical record documentation for this new selection of members.

We also ask that CMS publish a simulation of an RADV audit using this methodology, so that it can be clear to plans how CMS intends to proceed.

CMS proposes to expand MA organizations' RADV appeal rights, particularly in light of the upcoming auditing and recoveries in the MA program.

We are generally supportive of increased appeal rights for MA organizations, especially so in the context of something as important as the RADV calculation process. It is crucial that plans be provided appropriate opportunities to highlight potential flaws and misapplications of CMS's methodologies.

Thank you for the opportunity to engage with you on these important topics. We hope that our comments will be helpful in your efforts. If you have any questions concerning this letter, please contact me at (215) 937-7271 or by email at sowens2@amerihealthcaritas.com.

Sincerely,



Sarah M. Owens
President, Medicare

TAB 13

AHIP Comments

America's Health Insurance Plans
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Washington, DC 20004

Matthew Eyles
President and CEO

December 28, 2018

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4185–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Policy and Technical Changes to Medicare Advantage and Medicare Prescription Drug Plans for Years 2020 and 2021 ("Proposed Rule")

Dear Administrator Verma:

America's Health Insurance Plans (AHIP) appreciates the opportunity to comment on the Proposed Rule, which would make policy and technical changes to Medicare Advantage (MA) and Medicare Prescription Drug Plans for plan years 2020 and 2021.

AHIP is the national association whose members provide coverage for health care and related services for millions of Americans. Through these offerings, including MA and Part D plans covering tens of millions of Medicare beneficiaries, we improve and protect the health and financial security for consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers. The MA and Part D programs are critical to achieving national policy goals for improved health care, and we share your strong commitment to delivering better health outcomes, value, and satisfaction to enrollees through MA and Part D.

We strongly support steps CMS has taken to strengthen the MA program, including adding additional benefit flexibilities and reducing certain unnecessary administrative burdens. We commend CMS for following a similar approach in the Proposed Rule for implementing important legislative changes that expand access to telehealth services and enhance integration of Medicare and Medicaid benefits for individuals in dual-eligible Special Needs Plans (D-SNPs). Below we summarize our comments on these and several other provisions in the Proposed Rule. We have also attached detailed comments that discuss these and other issues.

On December 20, 2018, CMS issued new guidance that the agency will delay the original December 31 comment deadline on proposed changes related to the Risk Adjustment Data Validation (RADV) program until April 30, 2019. At the same time, CMS also indicated that the agency intends to release data underlying its study relating to the fee-for-service (FFS) adjuster. We understand that stakeholders have had pending requests for data, assumptions, and methodology disclosures. Particularly in light of this, we encourage CMS to release this information as soon as possible. A later release could endanger the public's ability to adequately analyze the data on a timely basis. We will review the information and submit extensive and detailed comments on the proposal by the new deadline.

However, based on our review of the information and data already released by CMS, we have very serious legal and policy objections to the extrapolation and FFS adjuster proposals and strongly believe the agency should withdraw the RADV provisions in their entirety.

If finalized as proposed by CMS, the RADV provisions would, among other things, reverse course on the need for an FFS adjuster to meet statutory and actuarial requirements and implement unprecedented regulatory changes to the MA program on a retroactive basis. These changes would inject significant uncertainty and risk into the system, undermine the partnership between Medicare and the private sector, and weaken the MA program for both seniors and taxpayers.

Extending the comment deadline and providing underlying data on the FFS adjuster study will not cure the proposed fatally-flawed approach. We recommend and urge CMS to: (1) withdraw these RADV provisions entirely; and (2) engage in direct and meaningful dialogue with MA plans and other stakeholders to develop a fair, consistent, and appropriate oversight process.

Policy Proposals
As noted above, the Proposed Rule contains a number of other important changes to the MA and Part D programs, including:

Expanded Telehealth Benefits. CMS proposes to expand the use of telehealth in MA basic benefits, in accordance with provisions in the Bipartisan Budget Act of 2018 (BBA). We support CMS' proposed approach, which would provide plans with flexibility to design telehealth benefits to best meet the needs of Medicare enrollees and improve access to quality care. However, we recommend that CMS also provide flexibility for plan assessment of capital and infrastructure costs and investments relating to these benefits.

D-SNP Integration and Integrated Appeals and Grievances. CMS proposes to require certain levels of integration for D-SNPs and for D-SNPs to have aligned Medicare and Medicaid appeals and grievances processes where possible. We commend CMS for adhering closely to its statutory mandate and proposing a thoughtful approach to expand integration while limiting potential for disruption to beneficiaries and states.

Star Ratings Changes. We appreciate the intent of CMS' proposal to establish guardrails and use mean resampling to increase predictability and stability of the cut points for non-CAHPS measures from year to year. However, sponsors need more data to evaluate the impacts and comment on these proposed changes. We also reiterate our prior calls for the agency to reinstate predetermined cut points in advance of measurement periods. This is the best means to ensure transparency, predictability, stability, and quality improvement.

Preclusion List Policy. We again commend CMS for withdrawing provider and prescriber enrollment rules for MA and Part D that would have taken effect in 2019 and that would have created significant disruption and confusion for enrollees. While we generally support CMS' decision to create a new preclusion list for certain providers and prescribers, we are concerned that requirements in the Proposed Rule for 2020 would create unnecessary administrative burdens by adding new notice requirements and claims denial deadlines that deviate from the well-established approach used for the OIG exclusion list.

Prescription Drug Plan (PDP) Access to Claims Data. CMS proposes to establish a process for PDP sponsor access to Medicare claims data in accordance with the BBA. While we strongly support PDP access to data, the lag times proposed for the data (three-months from the last day of the prior quarter) are much too long for the data to be useful to plans. CMS can do better (e.g., it provides final claims data monthly in a bundled payment demonstration), and we believe PDPs (which do not need final claims data) should have even faster access.

The Value of Medicare Advantage

MA plans provide coverage and offer meaningful value to over 20 million seniors and those with disabilities. Since 2010, Medicare beneficiaries have increasingly chosen to enroll in a MA plan rather than remain in traditional Medicare. As a result, the MA program has grown by more than 70 percent since 2010, and CMS projects that MA enrollment will represent nearly 37 percent of all beneficiaries next year. MA plans deliver better care and better value through innovative, patient-centered programs that improve quality and reduce beneficiary costs:

- **Greater care coordination and more comprehensive benefits.** MA plans work with their members to prevent, detect, and manage chronic conditions through programs that integrate and coordinate care. In addition, plans provide more comprehensive benefits than the traditional Medicare program – such as dental, hearing, and vision coverage. MA plans also can offer more extensive telehealth services and new types of supplemental benefits (e.g., home safety modifications, in-home health aides, and expanded transportation for physician visits and other medical services) recognizing the social and environmental factors that can have a profound impact on beneficiary health and outcomes.
- **More financial security.** All MA plans include a cap on beneficiary annual out-of-pocket costs, and 90 percent of beneficiaries can enroll in a MA plan that offers drug coverage for no additional premium.
- **Better health outcomes.** Recent peer-reviewed research studies have found that MA plans have outperformed the traditional Medicare program on clinical quality measures[1], employed value-based payment arrangements to improve survival rates while lowering costs[2], reduced hospital readmissions as well as beneficiary days spent in rehabilitation facilities and nursing homes[3,4], and lowered hospital use in the last days of life.[5]
- **Cost efficiency for beneficiaries and taxpayers.** On average, payments to MA plans are equivalent to traditional Medicare costs.[6] In areas where MA is popular, additional

[1] Timbie, Justin W., Bogart, Andy, Damberg, Cheryl et al. Medicare Advantage and fee-for-service performance on clinical quality and patient experience measures: Comparisons from three large states. *Health Services Research* 52(6), Part I: 2038-2060. December 2017.
[2] Mandal, Aloke K., Tagomori, Gene K., Felix, Randell V. et al. Value-based contracting innovated Medicare Advantage healthcare delivery and improved survival. *American Journal of Managed Care* 23(2): e41-e49. February 2017.
[3] Kumar, Amit, Rahman, Momotazur, Trivedi, Amal N. et al. Comparing post-acute rehabilitation use, length of stay, and outcomes experienced by Medicare fee-for-service and Medicare Advantage beneficiaries with hip fracture in the United States: A secondary analysis of administrative data. *PLoSMed* 15(6): e1002592.
[4] Huckfeldt, Peter J., Escarce, Jose J., Rabideau, Brendan, et al. Less intense post-acute care, better outcomes for enrollees in Medicare Advantage than those in fee-for-service. *Health Affairs* 36(1): 91-100. January 2017.
[5] Teno, Joan M., Gozalo, Pedro, Trivedi, Amal N. et al. Site of death, place of care, and health care transitions among US Medicare beneficiaries, 2000-2015. *JAMA* Published online June 25, 2018.
[6] Medicare Payment Advisory Commission. Medicare Advantage program: Status report [presentation]. December 7, 2018.

enrollment leads to slower traditional Medicare spending growth as providers use MA practice patterns and care guidelines for their remaining traditional Medicare patients.[7]

In addition, a recent survey finds continued high beneficiary satisfaction with the MA program, with 90 percent of MA members reporting satisfaction with their health care coverage and preventive services, and 84 percent satisfied with their prescription drug coverage.[8]

Conclusion

We reiterate the industry's appreciation for CMS' approach in recent years of expanding flexibility and reducing administrative burdens for MA plans and commend CMS for continuing that approach in several parts of the Proposed Rule. However, we have very serious concerns with the RADV provisions and urge CMS to withdraw the proposal and begin a meaningful dialogue with industry to develop a fair and appropriate oversight process. We look forward to providing any additional information you may need and to continuing to work together to improve the health of the beneficiaries our members serve.

Sincerely,

Matthew Eyles

Matthew Eyles
President and CEO

[7] Johnson, Garret, Figuero, Jose F., Zhou, Xiner, et al. Recent growth in Medicare Advantage enrollment associated with decreased fee-for-service spending in certain US counties. *Health Affairs* 35(9): 1707-1715. September 2016.
[8] Morning Consult National Poll. November 28-29, 2018.

Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

AHIP Detailed Comments

I. Implementing the Bipartisan Budget Act of 2018 Provisions

A. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§422.100, 422.135, 422.252, 422.254, and 422.264, Preamble pp. 54987-54992)

CMS proposes rules that implement section 1852(m) of the Social Security Act (SSA), as added by the Bipartisan Budget Act of 2018 (BBA). Section 1852(m) allows MA plans to provide "additional telehealth benefits" starting in plan year 2020 and to treat such benefits as basic benefits for purposes of bid submission and payment by CMS. This provision applies to services that would be covered under Medicare Part B but for the fact they are provided through electronic information and telecommunications technology (referred to as "electronic exchange") rather than in-person.

In general, CMS proposes significant flexibility in defining the types and uses of electronic exchanges that will qualify as additional telehealth benefits. For example, MA plans could determine the circumstances under which it is clinically appropriate for a Part B item or service to be furnished through electronic exchange. CMS also proposes to permit different cost-sharing for Part B services furnished through electronic exchange compared to in-person visits.

AHIP strongly supports CMS' approach. It would accommodate a wide variety of telehealth benefits and services and future technological advancements, consistent with legislative intent. However, we have the following recommendations to further support the flexibility needed by MA plans to design telehealth benefits to best meet the needs of Medicare enrollees and improve access to quality care.

i. Capital and infrastructure costs and investments

Consistent with the statutory language, the Proposed Rule excludes capital and infrastructure costs and investments relating to such benefits from amounts treated as additional telehealth benefits for bid purposes. In the preamble, CMS states that it is not providing specific definitions for capital and infrastructure costs or investments given the potential variations among MA plans. However, CMS also states in its regulatory impact analysis that the agency assumes "15 percent of the additional telehealth benefits would be considered capital and infrastructure expenses." CMS indicates it used the administrative costs permitted under Medical Loss Ratio (MLR) rules as a proxy for the portion of telehealth benefits it assumes would be treated as capital and infrastructure costs and investments. We urge CMS to better explain the basis for this assumption. The types of additional telehealth services that will be offered and used will be wide ranging. We are concerned this 15 percent level could be viewed by CMS as a de-facto standard that will not provide individual plans the ability to demonstrate that a different level is appropriate. We recommend that the final rule specify that plans will have the flexibility to assess their own individual costs of capital and infrastructure expenses

based on the types of telehealth service benefits being provided and exclude those costs from their bids.

ii. Telehealth and network adequacy

CMS requests comments on whether additional telehealth benefit providers should be considered in the assessment of network adequacy. We strongly support such an approach. Current MA network adequacy criteria, which rely on time and distance criteria, fail to consider how telemedicine, mobile medical applications, and other electronic information and telecommunications technologies can ensure beneficiaries receive the high-quality care they need, when they need it.

We recommend that CMS provide MA plans with more flexibility in meeting network adequacy requirements through the use of telehealth providers and other high value care and delivery system innovations and approaches. In addition, CMS' 2019 MA Network Adequacy Guidance allows plans to request an exception to use telehealth providers for network adequacy but only in very limited cases such as in rural counties or areas with extreme access issues. CMS should also consider allowing more flexibility in the exceptions process. Further, where there is a shortage of providers or suppliers offering traditional Medicare benefits (e.g., under the Medicare Diabetes Prevention Program), CMS could permit use of telehealth services to better ensure access to care.

iii. Qualifications for contracted providers of additional telehealth benefits

CMS proposes to require MA plans offering additional telehealth benefits to comply with existing MA provider selection and credentialing requirements. In addition, plans would have to ensure that telehealth network providers comply with state licensing requirements and other applicable state laws where the enrollee is located and receiving the telehealth service.

CMS solicits comments on whether to impose additional qualification requirements for MA providers of additional telehealth benefits beyond those in the Proposed Rule. We strongly recommend against such an approach. We believe the proposed requirements are sufficiently protective. Given the diversity of MA plan and provider network arrangements and telehealth services, CMS should instead provide plans with the flexibility to apply their own additional network rules and conditions as they determine necessary to ensure enrollees receive high quality care.

iv. Appeals

CMS indicates in the preamble on p. 54989 that an MA enrollee has the right to request additional telehealth benefits through the organization determination and appeal processes. CMS further states that "these rights help ensure access to medically necessary services, including additional telehealth benefits offered by an MA plan as proposed in this rule."

For clarity purposes, we recommend that CMS specify in the final rule that such organization determination and appeals processes apply only to requests for telehealth services included in the MA plan's benefit package.

Finally, while not specifically addressed in the Proposed Rule, we encourage CMS to provide future guidance on issues related to additional telehealth services, including encounter data submissions. We also strongly urge CMS to establish rules under which diagnoses obtained through telehealth encounters can be considered for risk adjustment purposes, since these services will be incorporated in the MA basic benefit package starting in 2020.

B. Dual Eligible Special Needs Plans

i. Integration Requirements for Dual Eligible Special Needs Plans (§§422.2, 422.60, 422.102, 422.107, 422.111, and 422.752, Preamble pp. 54992-54999)

CMS proposes several regulatory changes to implement the BBA's integration requirements for D-SNPs effective 2021. CMS delineates the three types of D-SNPs permitted by the statute and their respective responsibilities to coordinate or cover Medicare and Medicaid benefits. Furthermore, CMS proposes additional performance requirements on all D-SNPs to coordinate the delivery of benefits. States continue to retain authority for determining their Medicare-Medicaid integration environments and D-SNP options available to their dual eligible residents.

We commend CMS for the approach it has taken in the Proposed Rule, which closely adheres to the intent of the BBA. We believe the proposals will enhance Medicare-Medicaid integration with minimal disruption to states and beneficiaries by providing different pathways for states in which higher levels of integration would be challenging (such as states that exclude dually eligible individuals from Medicaid managed care).

We also support structural changes in the regulatory language, which include consolidating statutory and regulatory references and the minimum requirements for each type of D-SNP. We believe these changes should assist stakeholders, including state Medicaid agencies, in better understanding the updated SNP definitions, their respective characteristics, and implications for Medicaid program operations.

However, we believe states, D-SNPs, and other stakeholders would benefit from the following additional clarifications and examples in the requirements.

a. Arranging for benefits

Section 1859(f)(3)(D) of the SSA, which pre-dated the BBA, requires D-SNPs to provide benefits, or arrange for benefits to be provided, to which a person is entitled under Medicaid. CMS notes that it has not previously issued guidance on this requirement. CMS now proposes to interpret "arrange for benefits" as requiring that a D-SNP, at a minimum, coordinate the delivery of Medicare and Medicaid benefits. CMS proposes to include this interpretation in the proposed D-SNP definition.

While the regulatory language itself does not include specifics, the preamble notes that a D-SNP's responsibility to coordinate under this provision would encompass a wide range of activities. For example, CMS indicates that coordination for an individual with functional limitations would include verification of eligibility for specific Medicaid services like long term services and supports (LTSS), determination of how they receive services (e.g., through Medicaid FFS or Medicaid managed care),

and arrangement for receipt of services from the appropriate payer and/or provider. CMS observes that under this coordination requirement, it would not be enough for a D-SNP to simply tell an enrollee to contact a Medicaid managed care plan or the state agency without: providing specific contact information; coaching the member on the respective roles of the state Medicaid agency, the Medicaid managed care plan, and the D-SNP; and offering additional support if needed. CMS solicits comment on whether the proposed definition should be more prescriptive in identifying plan activities required for coordination or remain broadly defined.

We support the Proposed Rule's approach of broadly requiring coordination without more specific standards. This would allow states and their contracting D-SNPs a degree of flexibility in collaborating to identify specific plan activities that might differ by program or type of service. At the same time, however, prior to operationalizing this requirement, we believe states and D-SNPs would find it helpful if CMS provided clearer parameters for demonstrating sufficient coordination (e.g., through a combination of guiding principles and additional examples).

b. Notification of admissions for high risk members

CMS proposes in §422.107(d) to require that a D-SNP that is not a FIDE SNP or HIDE SNP notify the state Medicaid agency or its designee(s) of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, as identified by the state Medicaid agency. The state Medicaid agency would also establish the timeframe(s) and method(s) by which notice would be provided.

To ensure an efficient implementation of this requirement and minimize potential uncertainty and confusion among stakeholders, we recommend that CMS provide states with technical assistance and additional guidance regarding appropriate methods, content, and timeframes for notifications. The guidance could also address specific items such as formats for data exchanges (including data feeds and portal access), plan uses of data (e.g., for determining Medicaid eligibility, identifying available waiver services, or receiving payer/payment information), and processes for designating contacts who will receive admission information. The guidance would be particularly helpful for state Medicaid programs with little experience in managed care.

In addition, the preamble to the Proposed Rule gives several examples of how high-risk full-benefit dual eligible individuals might be identified. CMS indicates processes could include, e.g., targeting groups based on eligibility for particular waiver services, or through predictive analytics of claims history. We recommend that CMS encourage states to collaborate closely with their contracted D-SNPs and Medicaid MCOs in developing criteria and processes for identifying such high-risk members.

c. Enrollment of partial dual eligibles

CMS notes that it considered proposing limits on enrollment of partial duals in D-SNPs. The agency questioned whether their continued eligibility for D-SNPs was consistent with the new statutory integration requirements, given that partial duals are eligible only for Medicaid coverage of Medicare premiums and/or cost sharing, and that there are no Medicaid services for a D-SNP to integrate or

coordinate. CMS decided against proposing such limits but continues to consider this issue and invites comments.

We support the approach in the Proposed Rule and strongly recommend that CMS continue to permit state Medicaid agencies to determine D-SNP enrollment policies for beneficiaries, including enrollment of partial dual eligibles. To the extent that a state determines it is in the interests of its partial dual eligible residents to enroll in D-SNPs, we believe that such individuals can benefit from an enhanced degree of care coordination, even if the extent of their Medicaid benefits is limited.

ii. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§422.560 – 562, 422.566, 422.629 – 634, 438.210, 438.400, and 438.402, Preamble pp. 54999-55015)

CMS proposes to implement unified grievance and appeals procedures for D-SNP enrollees pursuant to SSA section 1859(f)(8)(C), as added by the BBA. The Agency proposals are in two major categories: (1) assistance that all D-SNPs must provide their members with Medicaid-related coverage issues and grievances; and (2) integrated appeals and grievances systems for exclusively aligned HIDE and FIDE SNPs.

We support CMS' overall approach in the Proposed Rule to implement the new requirements in a way that will achieve the goals of the statute while minimizing administrative complexity and burden where possible. We believe the proposals appropriately recognize that the Medicare and Medicaid statutes and benefit structures conflict too much in some cases to allow a fully unified appeals process, including post-plan appeals. Furthermore, we agree that targeted application of the rules is appropriate given the difficulty of implementing these types of procedures for plans that are not exclusively aligned.

While we support the overall approach, we believe CMS should provide the following additional clarifications and other guidance to assist stakeholders in implementing these provisions.

a. Enrollee assistance with appeals and grievances

CMS proposes to require that all D-SNPs assist their enrollees with Medicaid coverage appeals and grievances. As with the integration requirements discussed above, we believe additional CMS guidance on several matters would help state Medicaid agencies and MA D-SNPs more efficiently interpret and apply this requirement. We recommend that CMS consider providing states and D-SNPs with technical assistance in several forms.

+ CMS should consider establishing a technical expert panel that would convene participants with backgrounds in Medicaid and Medicare appeals and grievance processes. The panel would make recommendations to CMS on appropriate practices around enrollee assistance, including guidelines for coaching enrollees on self-advocacy.
+ Based on input from the technical expert panel, CMS should develop guidance that establishes guiding principles for enrollee assistance, provides examples, and identifies related issues for states and Medicaid plans to consider. CMS should also consider

providing incentives to states to further integration. These could prove especially helpful to state Medicaid programs that have little experience with managed care.

b. Integrated notice of adverse determination

Per proposed §422.631(d)(1), CMS would require that an applicable integrated plan send an integrated notice to an enrollee when the plan issues an adverse organization determination. The proposed notice would include information about the determination, as well as information about the enrollee's appeal rights for both Medicare and Medicaid covered benefits. We request that CMS clarify whether the CMS-10003 Integrated Denial Notice meets the proposed notice requirements.

c. Interaction with appeals and grievance requirements for MMPs

In the final rule or subsequent sub-regulatory guidance, we request that CMS discuss how regulatory changes affecting appeals and grievance processes may impact or be implemented in the ongoing Medicare-Medicaid Plan (MMP) demonstrations.

C. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§423.153, Preamble pp. 55015-55017)

CMS proposes rules to implement section 1860D-4(c)(6) of the SSA, as added by the BBA. This provision requires the agency to establish a process for a Prescription Drug Plan (PDP) sponsor to request to receive, beginning in plan year 2020, on a periodic basis and in an electronic format, standardized extracts of Medicare Part A and B claims data for its enrollees. Section 1860D-4(c)(6) also instructs the agency to include data "as current as practicable."

In its proposal, CMS would provide PDPs with Medicare claims data no sooner than on a quarterly basis with a 3-month lag from the last day of the last month of the prior quarter. We are concerned that the proposed timeframe would significantly delay access to and impact the utility of the data and is not consistent with congressional intent for providing actionable information.

We believe it is "practicable" for CMS to provide the information more frequently and promptly. For example, in the Bundled Payments for Care Improvement (BPCI) Initiative, CMS provides all participants with FFS claims files across all sites of service (i.e., inpatient and outpatient hospital, physician office, inpatient rehab, skilled nursing, home health, and durable medical equipment) on a monthly basis for each beneficiary who qualifies for a bundle under the demonstration. These files represent adjudicated (i.e., final action) claims, have at most a 1-month lag, and reflect a 14-month look back period. Participants can download these files from CMS through a unique electronic file transfer (EFT) site. In fact, we recommend that CMS should provide the data to PDPs even faster than under the BPCI demonstration, since PDPs do not require final action claims in order to use the information for care coordination and other clinical purposes.

In addition, CMS proposes to require PDPs to contractually bind contractors and any other data recipients to the terms and conditions imposed on the PDP sponsor, and to submit an attestation to the agency regarding permitted and prohibited data uses. We look forward to reviewing and

commenting on the related data request and attestation materials for PDP sponsors that CMS released through the Paperwork Reduction Act comment opportunity collection process.

II. Improving Program Quality and Accessibility

A. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§422.162(a) and 423.182(a), §§422.166(a) and 423.186(a), §§422.164 and 423.184, and §§422.166(i)(1) and 423.186(i)(1), Preamble pp. 55018-55028)

CMS proposes changes to the MA and Part D Star Ratings program affecting the cut point methodology for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures, the specifications for several existing measures, and the data integrity policy related to appeals measures. The Proposed Rule also codifies requirements for calculating Star Ratings in cases of extreme and uncontrollable circumstances. Our comments and related recommendations regarding the agency's proposals are discussed below.

i. Changes to the cut point methodology for non-CAHPS measures

Starting with 2022 Star Ratings, CMS proposes to add mean resampling to reduce the sensitivity of the clustering algorithm to outliers and reduce the random variation that contributes to fluctuation in cut points. In addition, CMS proposes to implement a 5 percent bi-directional cap that restricts movement both above and below the prior year's cut points. The bi-directional cap would be used for measures that have been in the Part C and D Star Ratings program for more than 3 years.

We appreciate CMS' willingness to consider changes to increase predictability and stability of the cut points from year to year. However, without access to simulation data and detail regarding the methodology, it is very challenging to assess and comment on the impact of CMS' proposed changes. We urge CMS to provide plans with this information as quickly as possible to permit them to conduct the needed evaluation and analysis and provide the agency with meaningful comments.

Further, AHIP continues to urge CMS to reinstate the policy that will best ensure such predictability and stability: predetermined cut points in advance of the measurement period. We believe the elimination of pre-determined thresholds has impeded CMS' goal of promoting continued quality improvement. It has undermined the ability of plans and their providers to set markers for performance activities that are consistent with CMS' expectations. Moreover, as plans have transitioned to value-based arrangements with providers, setting goals is essential to help both parties assess the effectiveness of their efforts to improve quality of care and reduce costs while maintaining high performance and rating levels. Pre-determined thresholds also provide transparency in the Star Ratings system, enabling plans and providers to understand the standards and work towards them in a deliberative process. Moreover, set cut points in advance of the measurement period would help to simplify the Star Ratings program and reduce burdens on providers contracting with multiple plans, who otherwise may face varying and conflicting quality performance metrics on the same quality measures. Predetermined cut points would thus promote a key Administration goal of reducing unnecessary regulatory burdens.

We understand CMS' concerns that the Star Rating program establish goals using more recent performance data, including large performance improvements that can be seen in newer measures, and provide continued incentives for improvement. As noted above, we believe pre-determined thresholds are the best approach to provide those incentives, and that the other positive elements (including greater transparency and simplicity and reduced burdens) far outweigh other potential concerns. Therefore, we urge CMS to issue for public comments the use of pre-determined thresholds and related methodology as soon as possible.

ii. Medicare Plan Finder (MPF) Price Accuracy measure

CMS is proposing changes to the existing MPF Price Accuracy measure for the 2022 Star Ratings. As we have indicated in previous comments, due to the frequent fluctuations in drug prices common to the pharmaceutical marketplace (which may result in changes on a weekly or even daily basis), it remains challenging for plan sponsors to ensure the MPF is updated immediately to reflect the market price of a drug. We are concerned that the proposed changes could penalize Part D plans that are continuing to make substantial investments in the accuracy of their cost reporting.

We continue to recommend that the MPF price accuracy measure be aligned with pricing practices inherent in the pharmaceutical marketplace. Further, before proposing any additional changes, CMS should clearly assess the additional value to beneficiaries of the MPF measure based on usage patterns for price data, etc., and weigh that against the costs to the program (through higher plan bids) that will arise from additional investments that may be required for Part D plans to comply with the revised methodology for this measure.

iii. Modification to data integrity policy for appeals measures

CMS proposes to assign a 1-star rating to applicable appeals measure(s) if a contract fails to submit Appeals Timeliness Monitoring Project (TMP) data for CMS' review. As we have noted in prior comments on this subject, AHIP strongly objects to Star Ratings adjustments based on compliance audit findings. This approach is highly problematic for both policy and methodological reasons. We support CMS' use of program audits to monitor plan compliance with regulatory requirements. However, the purpose and intent of the MA and Part D program audits differ significantly from those in the Star Ratings system. These audits are qualitative assessments of MA plan and Part D sponsor processes and protocols. Conversely, the Star Ratings system uses representative statistical samples from a variety of data sources to measure and compare clinical quality and beneficiary outcomes in one contract's beneficiary population with the beneficiary populations of other contracts.

We do not support CMS' proposal to modify its data integrity policy for appeals measures. CMS should ensure that the Star Ratings system is focused on improving quality of care received by beneficiaries instead of incorporating penalties on plans for compliance purposes.

iv. Codification of requirements for calculating Star Ratings in the case of extreme and uncontrollable circumstances

CMS proposes to codify rules (reflected in the 2019 Call Letter) for calculation of Star Ratings of certain contracts in certain extreme and uncontrollable circumstances (e.g., natural disasters).

AHIP supports CMS' proposal to codify such rules. At the same time, we recommend that CMS promote transparency by providing more information about the impacts of such adjustments. This can include making information publicly available on the identity of affected contracts and assessing/reporting on the impacts for the Star Ratings program both as a whole and at more granular levels, including in cases where an adjustment might span more than one measurement period.

We also note that there are important Star Ratings issues that are not addressed in the Proposed Rule that will be in the 2020 draft Call Letter, such as proposed enhancements to the Categorical Adjustment Index (CAI) methodology. AHIP supports the continued use of the CAI in the Star Ratings system while CMS develops a long-term solution to address disparities in MA plan performance associated with socio-economic status (SES) and other social risk factors. We look forward to addressing these and other important Star Ratings issues raised in the upcoming Call Letter.

B. Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§423.568, 423.570, and 423.572, Preamble pp. 55028-55029)

CMS proposes to change the Part D adjudication timeframes for exception requests when a prescribing physician's or other prescriber's supporting statement has not been received by the plan sponsor. The current guidance lacks certainty about the timeframe applicable to the exception request process pending receipt of the prescriber's supporting statement. In the proposal, CMS would require the plan to notify the enrollee (and prescribing physician or other prescriber) of its decision no later than 72 hours (or 24 hours for an expedited decision) after receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever happens first.

We support CMS' proposal. It provides plans with needed clarity on the exceptions timeframes.

III. Clarifying Program Integrity Policies

A. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§422.222 and 423.120, Preamble pp. 55029-55037)

CMS proposes revisions to the preclusion list policy finalized in the CY 2019 MA & Part D final rule. CMS' proposal encompasses both substantive changes to the policy and codification of provisions that were detailed in the preamble of the 2019 final rule. The substantive changes include CMS' proposal to require plans, on an ongoing monthly basis, to send a notice to potentially impacted beneficiaries within 30 days of the date a provider or prescriber is added to the preclusion list. In addition, plans would be required to deny claims for Part D drugs and MA items or services that are prescribed or furnished by prescribers and providers on the preclusion list beginning 60 days after sending the notice to the impacted beneficiary.

We appreciate CMS' efforts to reduce fraud and abuse in the Medicare program while also reducing unnecessary administrative burdens. To that end, we reiterate our strong support for CMS' decision in the 2019 final rule to remove the prescriber and provider enrollment requirements that raised serious beneficiary access issues and administrative costs. We also support CMS' general approach to implementing the preclusion list, including the agency's decision to not finalize a proposal that

would have required provisional fills for prescriptions written by prescribers on the preclusion list. However, we are concerned that CMS is now proposing changes to its preclusion list policy that would create additional complexity while providing limited value to beneficiaries.

As CMS noted in the 2019 final rule, CMS chose to not implement the provisional fill requirement for several reasons, including: the potential beneficiary confusion in taking an approach different from the exclusion list; the fact it would enable payments to be made for problematic prescribers for a long period of time, including those prescribing opioids or other potentially dangerous drugs; and the complexity and administrative burdens it would add.[1] To address these concerns, CMS indicated its goal is that "the preclusion list will be operationalized in the same manner as the OIG exclusion list …."

We are concerned that the Proposed Rule, particularly separate required beneficiary notices and claims denial deadlines triggered by the notice, is inconsistent with this goal. We believe the proposal has the potential for causing beneficiary confusion, could enable a longer period for coverage related to problematic prescribers and providers, will present operational challenges for plans, and will increase administrative burdens.

We urge CMS not to implement this proposal. Instead, consistent with CMS' stated intent, the preclusion list should be operationalized the same way as the OIG exclusion list. Under the exclusion list process, CMS makes the exclusion list public, updates the list on a monthly basis, generally posts it 15 days prior to the exclusion effective date, and expects plans to deny claims as of the effective date. We note that providers and prescribers are given a chance to appeal before being added to the agency's preclusion list; therefore, we believe it would be appropriate for CMS to make the preclusion list public and implement it in the same manner as the exclusion list.

[1] 83 Fed. Reg. 16660.

TAB 14

VIVA Health Comments

Comments to the 2020/2021 Proposed Rule

VIVA HEALTH, Inc. appreciates CMS efforts to update and improve the rules related to the Medicare Advantage program and improving the member experience. VIVA HEALTH also appreciates the opportunity to comment on the proposed rules. Our comments are below:

Integration Requirements for D-SNPs

Each state's Medicaid population, providers, Medicaid programs, and coordination needs and challenges are unique. As described in the proposed regulation and in the letter CMS sent to the State Medicaid Directors on December 19th, states already have the ability to require greater integration from D-SNPs. The states are best positioned to determine what integration activities will be meaningful so to the extent possible under current law, CMS should leave integration decisions to the states and focus on making them aware of their options and successful efforts in other states.

CMS provides no additional funding for the additional care coordination requirements D-SNPs undertake today. Adding significantly to these requirements as proposed may discourage D-SNP participation and/or result in benefit or service reductions for D-SNP members and create new compliance oversight burdens for the D-SNPs and CMS. The D-SNP program is already successful in helping dual eligibles achieve better quality of life and health outcomes. New requirements should be made in the smallest increments possible to avoid doing more harm than good remembering:

- Some states offer very few additional and/or overlapping benefits so the need for integration is much lower. Each State Medicaid Director should have the ability to opt its state's D-SNPs out of any integration requirements the state does not wish to pursue.

- D-SNPs already have every incentive to assist recipients in accessing care and are already doing excellent work in this regard. Successful integration ensures high marks on member satisfaction surveys, member retention, and because ensuring access to Medicaid benefits is helpful to D-SNPs in controlling their medical costs.

Integration standards

In regard to implementation dates and sanctions for failing to meet the integration standards, we recommend extending each. Given the complexity of the requirements, the variation in Medicaid programs and capabilities across states, the time needed to negotiate and execute new Medicaid agreements, and the need to develop new processes between the D-SNPs and Medicaid agencies, we recommend the effective date of the new requirements be 2022 instead of 2021. Medicaid agreements would have to be finalized in early 2020 to be taken into account for 2021 bids which does not provide enough time given that the requirements are not yet finalized.

We also recommend states have the flexibility to implement alternative integration methods rather than being limited to the three outlined in the proposed regulations to maintain maximum flexibility to pursue integration activities that will be meaningful in that state. Based on state and D-SNP negotiations, we ask any financial risk arrangement for LTSS or behavioral health

services qualify under option 2 versus the proposed requirement of only capitated contracts qualifying. The D-SNP and/or state might initially wish to contract on a shared-savings, shared–risk or performance bonus basis versus full capitation risk so it would read:

• "A D-SNP must either-- (1) meet the requirements of a fully integrated dual eligible special needs plan described in section 1853(a)(1)(B)(iv)(II) of the Act (other than the requirement that the plan have similar average levels of frailty as the PACE program); or (2) enter into a ~~capitated~~ contract with the state Medicaid agency ~~to provide~~ that places the D-SNP at financial risk for LTSS, behavioral health services, or both."

Finally, we recommend enrollment sanctions not be required for failure to fully comply as delays in compliance may result from a state's inability or unwillingness to prioritize integration. We also recommend the option to sanction be delayed until 2023 (so 2023-2028) in the event significant provider contracting, system or other modifications are necessary under the new Medicaid agreements and to allow time for deficiencies to be identified and corrective action formulated and implemented before sanctions are considered. We also recommend sanctions only be applied to D-SNPs in states where the state Medicaid Agency has successfully integrated with other D-SNPs in the integration methods the D-SNP being sanctioned has selected (if the state Medicaid Agency does not desire and cooperate in a particular integration option, the D-SNP should not be penalized).

Benefit coordination

We disagree with requiring D-SNPs to extensively coordinate Medicaid benefits. If barriers exist to accessing benefits that are too onerous for some recipients, CMS should address this directly with the states by working with them to reduce the barriers and/or provide hotlines or additional assistance certain recipients may need. We agree D-SNPs should be aware of the Medicaid benefits available, help members understand these benefits, and provide contacts, forms, and other helpful information to assist in accessing these benefits. Beyond that, D-SNPs may choose to, but should not be mandated to, complete paperwork or secure financial, medical, or other documentation needed to access Medicaid benefits or any other non-SNP benefits (housing, food stamps, utility assistance). Most D-SNPs already help members access Medicaid benefits and other social services and financial assistance available in their communities through our care management efforts because it is in our best interests to do so as described above (member satisfaction, retention, and cost reduction). No evidence was presented to support that current efforts are not successful in improving access. The determination of what level of effort is adequate is highly subjective and should be left to the D-SNP to decide. Each state should be allowed to work with its D-SNPs to develop reasonable, objective coordination expectations to include in their agreements. States should establish a line of communication D-SNPs can use to refer recipients who need extra assistance accessing Medicaid benefits.

While CMS' desire for a resource to facilitate access to Medicaid benefits is understandable, asking the D-SNPs to take on this significant role with no additional compensation and without clear and limited expectations is an unfair burden to place on the D-SNP and should be the role of the state Medicaid agencies.

Partial duals

We believe partial duals benefit significantly from the care coordination and additional benefits offered by D-SNPs. Because states have differing income requirements for who qualifies as a partial dual versus a full dual, the same recipient could fall into either bucket depending on in which state the recipient resides. A full dual recipient in one state may only qualify as a partial dual recipient in another stare, but that does not mean he/she is in any less need of the coordination and care management services the D-SNP provides. We see no reason CMS would deny partial duals access to D-SNP services since no additional monies are paid by CMS for them.

Unified grievance and appeals procedures

In states where there is almost no overlap between Medicare and Medicaid benefits, there is very little confusion among enrollees in terms of who to file grievances and appeals with and little need to integrate the two processes. The current Medicare Advantage process is already extremely complicated and compliance audit results indicate that even highly experienced MA plans struggle to meet CMS expectations. To require D-SNPs, who typically also offer MA-PD plans, to administer two separate grievance and appeal procedures is overly-burdensome. Further, requiring a D-SNP to continue to provide Medicare benefits while an appeal is pending creates a two-tiered system of Medicare benefits where low-income beneficiaries receive more benefits than non-low-income beneficiaries. This requirement will also have significant cost implications for D-SNPs resulting in potential benefit reductions in other areas to finance the services provided during the appeal.

Exception tolling limit

VIVA HEALTH agrees with establishing a 14 day time limit for tolling exception requests to receive a supporting statement for Part D exception requests. The 14 day standard would provide a consistent standard for all providers and plan sponsors for allowed tolling and it creates a consistent time limit to measure timeliness for all exception requests. We disagree with the recommendation to establish a hard completion deadline of 14 days from request receipt. We recommend keeping the existing standards of notifying the member within 24 hours (expedited) or 72 hours (standard) following receipt of the supporting statement to ensure plans have sufficient time to review the supporting statement and obtain any additional information needed to make an appropriate decision. Additionally, 14 day hard deadline would effectively reduce the tolling limit to below 14 days, because decisions would have to be made on days 12 and 13 to ensure plan decision and member notification standards are met.

MAPD Plan Quality Rating (Star Ratings) Topic

1. Improving Program Quality and Accessibility
   - VIVA HEALTH supports continued codifying of methodology for the Star Rating Program.
   - VIVA HEALTH supports CMS stance that all substantive measure changes be proposed through rulemaking. However, what is "substantive" is not clear and open to interpretation. VIVA HEALTH encourages CMS clearly codify what is defined as substantive. Example: New advanced illness and frailty HEDIS 2019 exclusions could be considered substantive; VIVA HEALTH's OMW measure denominator was reduced by 40% after exclusions were applied. However, these exclusions did not result in consideration for temporary removal for this, or any other, affected measure from Star Ratings.

2. Non-CAHPS Star Ratings Cut-points – Current Methodology
   - VIVA HEALTH supports consideration of cut-point methodology that improves stability, limits unpredictability, reduces the influence of outliers, and restricts movement of the cut-points from one year to the next. The current application of cut-point methodology does not provide significant utility for the majority of Contracts.
   - Major issues:
     - While the nation often maintains consistent annual performance, cut-point thresholds change with more volatility. For 2019 Stars, eight star measures that use a 1-100 scale had a 4 or 5 Star cut-point change over 5%.
     - Cut-point thresholds often move independently of industry performance. For 2019 Stars, eight stars measures had a 4 or 5 Star cut-point move in the opposite direction as the national average.
     - Low enrollment contracts too easily can establish high or low cut-points.
     - The current methodology results in frequent misclassification for Contracts, where performance increases but Star Rating falls, or vice-versa. 87% of Contracts had improvement on an adherence measure but received a lower Star Rating. 39% of Contracts had declines but received a higher Star Rating. This instability hampers a Contract's ability to establish improvement goals.

3. Non-CAHPS Star Ratings Cut-points – Pre-announced Cut-points
   - VIVA HEALTH supports CMS stance against pre-announced cut-points. Using old data to predict future performance is unreliable, especially for young measures. Additionally, pre-set cut-points could discourage improvement once threshold is met.
   - However, VIVA HEALTH acknowledges some benefits to greater cut-point predictability – easier to establish goals and performance targets, reduces unpredictability of Plan's overall Star Rating leading up to the September release.

4. Non-CAHPS Star Ratings Cut-points – Mean Resampling
   - VIVA HEALTH supports consideration of cut-point methodology that improves stability, limits unpredictability, reduces the influence of outliers, and restricts movement of the cut points from one year to the next.
   - VIVA HEALTH encourages CMS to share mean resampling simulations to better gauge impact to cut-point change sensitivity.
   - Our two greatest concerns with the proposed methodology are:
     - Random assignment of Contracts into each of the 10 groups lead to inherent randomness in results, impact of outliers may actually be larger since they are not explicitly excluded from the 10 groups and can influence cut-point formation within those groups.
     - The intent of the change to use mean resampling did not align with demonstrated impact in simulations.
   - VIVA HEALTH recommends CMS delay implementation of mean resampling until a more consistent reduction of impact of outlier performance is demonstrated.

5. Non-CAHPS Star Ratings Cut-points – Guardrails
   - VIVA HEALTH supports consideration of cut-point methodology that improves stability, limits unpredictability, reduces the influence of outliers, and restricts movement of the cut points from one year to the next.
   - VIVA HEALTH supports immediate implementation of Star Rating cut-point guardrails for 2020 Star Ratings in advance and independent of future additional cut-point methodology changes. Guardrails would reduce impact of outliers, increase predictability, and reduce chance of misclassification.
   - VIVA HEALTH believes a 5% cap is not restrictive enough. VIVA HEALTH supports a more restrictive cap of 3% or a guardrail that matches the national average performance change. CMS states a 3% cap would not "meet our programmatic needs and goals of providing accurate pictures of the underlying performance of each contract and its comparison to other contracts." Viva Health believes this explanation does not offer a supportive argument without additional information. VIVA HEALTH encourages CMS to consider different guardrails for new/old measures.
   - VIVA HEALTH encourages CMS to consider the "base" cut-points that guardrails would be built upon. If guardrails are added for 2020 Stars, then the "base" cut-points would be from 2019 Stars, which themselves are based on the previous clustering methodology. A recalculation of "base" cut-points using other proposed new or improved methodology may be appropriate prior to application of guardrails.

6. Non-CAHPS Star Ratings Cut-points - HER Incentive and MU initiative
   - VIVA HEALTH does not support adoption of Star measures enabled through HER.

7. Non-CAHPS Star Ratings Cut-points – Summary
   - VIVA HEALTH supports a 3% guardrail cap or 1x industry average change cap.
   - VIVA HEALTH supports a cap as an absolute difference for measures on a 1-100 scale.
   - VIVA HEALTH supports a percent range cap without outliers for the subset of measures not on a 0 to 100 scale.
   - VIVA HEALTH supports a guardrail cap in both directions.
   - VIVA HEALTH supports alternative methods to account for outliers.

8. Proposed Measure Update – Controlling Blood Pressure
   - VIVA HEALTH supports retirement of the Controlling Blood Pressure measure to the Display Page for 2020 and 2021 Star Ratings. Changes to the measure are substantive and necessitate temporary retirement.
   - VIVA HEALTH supports continued improving risk-stratification and/or adjustment for Dual/LIS/Dis membership for this measure.

9. Proposed Measure Update – MPF Price Accuracy
   - VIVA HEALTH recommends CMS address the current timing difference between CMS updates to Plan Finder versus the natural fluctuation of market prices that occur outside of these updates at point of sale. The lag leads to inaccuracy in measurement that may harm Contracts' performance unfairly.

- VIVA HEALTH supports the proposal to round MPF drug costs to two decimal places but requests consideration of differences of at least $0.02 toward the accuracy score, up from $0.005 (and up from the $0.01 proposed).
- VIVA HEALTH will offer additional comments when 2020 Display Page results are published.

10. Proposed Measure Update – Plan All-Cause Readmissions
    - VIVA HEALTH does not support the proposed inclusion of observation stays in the Plan All-Cause Readmissions measure. An observation stay is considered an outpatient service and is an appropriate option when a member's condition does not warrant inpatient admission. If CMS considers observation stays following discharge should be tracked and evaluated, a distinct measure should be developed.
    - VIVA HEALTH is concerned over inclusion of age 18-64 membership into the measure. To be eligible for Medicare, this population is a higher percentage Dual/LIS/Disabled as compared to the 65 and older Medicare population, and Contracts with higher percentages of Dual/LIS/Disabled members could be disadvantaged. If adopted, VIVA HEALTH encourages CMS to consider appropriate risk-stratification for this measure

11. Improvement Measures
    - VIVA HEALTH supports the proposed changes to Improvement Measure calculation/processes.

12. Data Integrity
    - VIVA HEALTH supports the concept of scaled reduction for appeals related audit findings. The findings from the new audit timeliness protocols demonstrate the variety of good-faith interpretations of CMS rules that are possible given the complexity of appeals regulatory and sub-regulatory guidance.
    - VIVA HEALTH requests when new audits and monitoring efforts are implemented, CMS wait a minimum of two calendar years to use the findings in a punitive manner to allow for due process to run (which may take months) and for the plans to adapt their processes to the ultimate outcome.
    - VIVA HEALTH requests CMS examine any methods to simplify appeals administration language and address areas of subjectivity identified within the guidelines that result in differing interpretations.

13. Extreme and Uncontrollable Circumstances
    - VIVA HEALTH supports the concept to offer fair allowances for Contracts affected by extreme circumstances.
    - VIVA HEALTH has observed multiple scenarios certain MA plans may be "gaming" the current system. By deliberately combining contracts with membership from a non-disaster area with membership in a disaster area, the resulting contract can still maintain the 25% threshold needed for Star Ratings adjustments and have the entire member population reap the Stars benefit. VIVA HEALTH encourages CMS to implement safe-guards to prevent potential abuse of disaster allowances perhaps by not allowing contract consolidations into impacted contracts.

- VIVA HEALTH strongly encourages CMS to publish a list of all Contracts who met the 25% and 60% member thresholds for Star Ratings extreme circumstance adjustments each year when Star Ratings are released.

Preclusion List

The current Preclusion List guidance allows plans up to 30 days to review a new preclusion list file and then a required 60 days to notify members before denying claims which could allow claims to be denied between 61 – 90 days following list publication. To ensure consistency across the industry, we recommend a hard timeline of 90 days from file release to claim denial.

The recently released HPMS memos on the Preclusion List have contradictory statements on whether plans should notify providers of their inclusion on the Preclusion List. Since CMS has previously notified the providers and the providers had the opportunity to appeal their inclusion to the list, we do not see the value in plans being required to notify the providers again. We believe a notice from CMS would have more impact to providers and would cause less confusion to the provider than receiving multiple notices from MA plans.

TAB 15

MMM Holdings Comments

MMM Holdings

December 28, 2018

http://www.regulations.gov
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-4185-P,
P.O. Box 8013,
Baltimore, MD 21244-8013.

RE: ***CMS-4185-P:***
Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

-on Behalf of-
InnovaCare, Inc. / MMM Healthcare, LLC /MMM of Florida, Inc.
(Contracts H4003, H4004, H7522, H3293)

Dear Ladies and Gentlemen:

The undersigned, the Chief Compliance Officer of MMM Healthcare, LLC, is hereby submitting the comments below to CMS with respect to the proposed rule CMS- 4185- P "
Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021" ("Proposed Rule").

Medicare Advantage and Part D Prescription Drug Program Quality Rating System

We applaud recent efforts to generate significant transformation to the healthcare system in order to improve quality of care, and that this entails a monumental task that requires the development of complex and holistic strategies. The MA Quality Rating System has proven to be an important tool to support these efforts. We commend CMS for taking the steps to codify the existing Star Ratings System for the MA and Part D programs, while pursuing the objective of clarifying rules and providing plans with more predictability to encourage long-term initiatives. We have analyzed the Proposed Rule in this regard and would like to share with you our comments, concerns and recommendations. We have delineated a set of topics under which discussion will be expanded.

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ADJUSTMENT OF STAR RATINGS TO TAKE INTO ACCOUNT EXTREME AND UNCONTROLLABLE CIRCUMSATANCES (PP. 149-159) AND PUERTO RICO ISSUES GENERALLY

I. Star Rating Program Methodologies

a. Continue Prior Adjustments for Lack of Low-Income Subsidy

We acknowledge and are grateful for previous methodological and ratings adjustments to recognize unique factors that distinguish Puerto Rico from other MA jurisdictions and service areas. CMS should continue its prior Star Ratings adjustments, which are as necessary to the Puerto Rico health care system as ever before. These include accounting for the lack of the Low-Income Subsidy (LIS) by continuing to reduce the weights for the adherence measures to zero for the summary and overall rating calculations and maintain the weight of 3 for the adherence measures for the improvement measure calculations for contracts that solely serve Puerto Rico.

b. Continue 2019 Adjustments Accounting for Ongoing Effects of Natural Disasters

CMS determined last year to adjust 2019 Star Ratings and 2018 surveys for all contracts serving only Puerto Rico to recognize the effects of extreme and uncontrollable circumstances from Hurricane Maria that occurred that occurred during the 2017 performance period. We ask that CMS continue these special disaster-related policies for the 2020 Star Ratings in order to assist plans and providers with the ongoing impact of Hurricane Maria during the 2018 performance period and beyond.

The impacts of Hurricane Maria did not end in 2017. The Public Health Emergency Declaration for the hurricane was not lifted until June 13, 2018 and Puerto Rico is still in a transitional recovery period as beneficiary population slowly return to Puerto Rico from the mainland. We ask that CMS continue the following disaster-related adjustments for plans operating in Puerto Rico only:

- CAHPS - Continue disaster policy and make the 2020 CAHPS survey optional and allow plans to use survey results from 2018 or 2019. If a plan chooses to administer the survey, it would receive the higher of its scores from 2018-2020 Star Ratings for each CAHPS survey measure.

- HOS - Continue disaster policy and make the 2019 HOS survey optional, given substantial ongoing issues contacting enrollees in Puerto Rico, the continuing

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loss of electricity, and damage to infrastructure in several areas. If a plan chooses not to administer the 2019 HOS Cohort 21 Baseline and Cohort 19 Follow-up surveys, it would receive the previous year's Star Ratings for HOS and HEDIS-HOS measures in the 2021 Star Ratings. If a plan chooses to administer the 2019 HOS surveys, it would receive the higher of the current or previous year's Star Rating for each HOS and HEDIS-HOS measure in the 2021 Star Ratings.

- HEDIS – Continue the option for HEDIS reporting in 2020 that covers the 2019 measurement year that plans would have the option to report "NA" for all HEDIS measures. Where a plan reports an "NA" for any of the Star Ratings measures, the contract would receive the 2018 or 2019 Star Ratings for that measure. If a plan chooses to report any of the HEDIS measures, the plan would receive the higher of the 2018, 2019 or 2020 Star Rating for each HEDIS measure reported.

c. Additional Adjustments to Account for Unique Puerto Rico Factors

i. Annual Flu Vaccine

Presently, "Annual Flu Vaccine" is the only CAHPS question without any adjustment, in spite of vaccination rates being highly impacted by cultural factors. The current survey question fails to recognize a patient's right to refuse the administration of the vaccine and therefore does not measure how effective a plan is on delivering annual flu vaccination to a willing patient population. Negative outcomes on this measure may penalize a plan for the cultural attitudes of its patient population regarding vaccine under which certain patients exercise their recognized rights to refuse the vaccine.

Based on available information from the Centers for Disease Control and Prevention (CDC) illustrated below, residents of Puerto Rico receive immunizations at a much lower rate than the US mainland. For flu vaccinations, the lowest vaccination rate in a jurisdiction in the mainland lies about halfway between the median and Puerto Rico over the last several years. Rates for other immunizations, such as pneumonia, tetanus, and shingles, are even more drastic. Although tetanus and shingles are not part of the CAHPS survey, and include individuals who are aged 18 years or older, both help illustrate a territory-wide ambivalence toward vaccines.

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IMMUNIZATION PREVALENCE

	Flu Shot[1]					Pneumonia Vaccination[1]					Tetanus Shot[2]	Shingles Vaccine[2]
	2016	2015	2014	2013	2012	2016	2015	2014	2013	2012	2013	2014
Min (of 50 States & DC)	49.5%	51.4%	51.6%	51.6%	50.0%	64.4%	63.4%	60.5%	61.9%	61.6%	47.8%	12.9%
Max (of 50 States & DC)	67.5%	70.6%	70.7%	73.9%	70.1%	79.8%	78.7%	76.2%	75.6%	76.2%	73.1%	30.5%
Median (of 50 States & DC)	58.6%	61.3%	60.8%	62.8%	60.1%	73.4%	72.7%	70.3%	69.5%	68.8%	58.7%	22.2%
Puerto Rico	**42.2%**	**42.6%**	**39.7%**	**31.1%**	**26.3%**	**30.3%**	**29.0%**	**26.7%**	**26.4%**	**22.2%**	**25.4%**	**4.1%**

[1] Aged 65+

[2] Aged 18+

Source: https://nccd.cdc.gov/BRFSSPrevalence/

We have supported local efforts to improve awareness and appreciation of the annual flu vaccine though organizations such as VOCES: Vaccination Coalition of Puerto Rico. VOCES and others could accomplish even more progress to reverse vaccine-ambivalent attitudes with additional support from CDC. CMS could assist through Spanish-language culturally appropriate educational material through MLN to assist providers in improving attitudes towards vaccines. We encourage HHS and the administration to consider the unique needs of Puerto Rico and the Territories when considering vaccine promotion activities and welcome any such promotional assistance targeted towards Puerto Rico.

While federal, local, and private vaccine awareness promotion continues, in order to prevent plans from being penalized for this cultural attitude, we request that CMS review the CAHPS survey methodology, and add a question to validate, in the cases the patient answers "No", the reason why he/she was not vaccinated. CMS could then make adjustments, as has been implemented for other CAHPS measures, so that the "No's" for reason of vaccine refusal are not counted against the plan's score. While these adjustments are refined and tested, CMS could move the Annual Flu Vaccine measure to display only status. CMS could also implement and adjustment similar to that used in other measures; namely, to bear a weight of 0.0 but to count against the Improvement measure.

ii. Getting Appointments and Care Quickly

Puerto Rico plans and providers show persistently low performance on this composite measure, mainly attributable to the question on whether the time waiting for an appointment exceeded a 15 minutes standard. 15 minutes is not a realistic standard within the realities of the Puerto Rico health care system. Recent studies have confirmed this persistent difference in Puerto Rico and attributed it to several variables: Provider attrition;

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Providers not exclusively serving the MA population; Arrival to appointments earlier than scheduled due to limited transportation options; others.

Provider supply alone is enough to demonstrate that Puerto Rico is at a clear disadvantage on this particular question compared to all other jurisdictions. Extrapolating from 7,569 total providers in Puerto Rico and approximately 779,000 eligible individuals,[1] there are approximately 9.7 providers for every 1,000 individuals on the island. The states and DC average approximately 24.0 providers for every 1,000 individuals. Even the lowest state, Nevada, has approximately 17.1 providers for every 1,000 individuals, which is nearly twice as many providers than Puerto Rico.

The Getting Appointments and Care Quickly measure can avoid penalizing the provider shortage and other structural differences in Puerto Rico by accounting only for the other two composite questions in the measure which better illustrate the capability of having access to care when needed. Those other questions indeed demonstrate that patients can and do access care in case of urgency or on regular appointments as necessary.

HIERARCHICAL CLUSTERING METHODOLOGY: MEAN RESAMPLING AND GUARRAILS FOR MEASURES IN PLACE FOR 3+ YEARS (PP. 136-138)

We appreciate the efforts to enhance the current hierarchical clustering methodology. With regard to the proposed mean resampling we recommend that actual results are modeled to enable plans to preview the impact of the proposed methodology on the measure scores for RY2019. In addition, with respect to CAHPS measures we recommend that cut point determinations be made using similar rules to Non-CAHPS measures to ensure predictability and stability, while still motivating improvement.

With regard to the proposed 5% guardrail for measures in place for more than three years, we appreciate the desire for predictability, but no empirical support has been provided for using 5% as the limit. An alternative approach would be to make the guiderail percentage equal to the historical change between years two and three for each such measure.

[1] July 2016 figures

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REVIEW OF SPONSOR'S DATA: ADJUSTMENTS DUE TO APPEALS OR CTM DATA (PP. 148-149)

The proposed rule establishes a deadline of May 1 of the year following the measurement year to consider appeals reopening determinations, even though the independent review entity (IRE) has up to 6 months to complete its review in the event a plan contests a determination made by the IRE. Due to the mismatch between the IRE timeline to respond on a reopened case and the due date to consider redeterminations on cases reopened, we recommend that the measurement period on appeals runs from November 1st of the year prior to the measurement year to October 31 of the measurement year. This provides the opportunity for cases determined by October 31 to be referred to the IRE and still have time enough for the case to be determined in time for the May 1 redetermination due date. This will also promote changes in the IREs turnaround time to make their redetermination, often six months, compared to the very short response time afforded plans, 24 hours at times. The shorter timeframe is important not only because of its impact on Stars ratings but also because of the impact in some cases on patient safety.

PRESCRIPTION DRUG PLAN SPONSORS'ACCESS TO MEDICARE PARTS A AND B CLAIMS DATA EXTRACTS (PP. 118-126)

Please provide clarification on how CMS would propose to limit PDP's use of the data to the allowable data uses. We also note that we do not recommend expanding the permitted uses beyond those already enumerated in the Proposed Rule.

* * *

We very much appreciate the opportunity to comment on these proposals and to present the recommendations we believe will help the beneficiaries enrolled in the MA program, in Puerto Rico and elsewhere. We trust that these comments will be taken into consideration and incorporated in the Final Call Letter and Guidance.

Very truly yours,

Myra Plumey
Chief Compliance Office

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TAB 16

MCS Advantage Comments

MCS Advantage

MCS Advantage, Inc.
P.O. Box 191720
San Juan, P.R. 00919-1720

December 28, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-4185-P
P.O. Box 8013 Baltimore, MD 21244-8013

Re: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS-4185-P)

Dear Administrator Verma:

MCS Advantage, Inc. appreciates the opportunity to comment on the Centers of Medicare and Medicaid Services regarding the *Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, and Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS-4185-P) specifically related to the section for Stars Ratings*

1. CMS should keep the current Controlling Blood Pressure Measure for Stars 2020 and implement the proposed changes for Stars 2021 and move it to the 2021 Display Measure Section.

We commend CMS proactivity to keep up with the new medical guidelines in order to guarantee that our beneficiaries receive the latest preventive care recommendations to improve their quality of life. We understand NCQA new revisions regarding the blood pressure target, and modification of the patient encounter data, instead of the medical record confirmation of hypertension. Allowing the use of telehealth, the inclusion of the administrative approach that utilizes CPT category II code and the use of monitoring devices can make a significant improvement in the effort to monitor the preventive care for our beneficiaries. However, changing the measure after the measuring period, in which efforts by Medicare Advantage sponsors have been invested, will not reflect CMS Stars Ratings core values of providing our beneficiaries quality of care. As a Medicare Advantage Healthcare Organization, we have been working under the conditions that were consistent with the standard quality that was recommend until November of this year. We recognize the positive impact that these changes will have on the preventive care, which has been and will continue to be the main purpose of our organization.

High blood pressure is recognized as one of the leading risk factors for the development of cardiovascular and cerebrovascular disease. Cardiovascular disease is the leading cause of death in Puerto Rico and the US. Both cardiovascular and cerebrovascular disease are among the leading causes of disability in the elderly population.

The importance of this measure is underscored by the emphasis given to the control of high blood pressure in important national initiatives such as Healthy People 2020 and the CDC's Million Hearts campaign. This is an extremely important target for the prevention of mortality and morbidity in this population. Having said this, we formally request that the Controlling Blood Pressure Stars Rating Measure remain for the 2020 Stars Rating. and move it to the Display section for 2021 Stars Rating, as was done for the High Risk Medication Measure for the 2017 Stars Rating cycle. We understand that by doing this CMS will continue the objective evaluation that has been consistent through the entire Stars Ratings evaluation system.

2. CMS should apply the guardrails of 5 percent bi-directionally to reduce the sensibility of the clustering algorithm to outliers and reduce the movement of the cut points in order to increase the predictability

We appreciate CMS effort to address and revise the concerns regarding the cut points in order to serve its purpose of capturing the meaningful differences in quality across the Evaluation System (Stars Rating) scale and minimize the risk of classification. As a healthcare organization, our main focus is to help our beneficiaries to have a healthier lifestyle. We understand that the true purpose of the Stars Rating is to make sure that the contracts are aligned with CMS core goals. As the Stars Ratings have evolved so have the measures, and the methodology that guides the system. In order to keep with the evolution of the program without compromising its ultimate goal, it is fair to make sure that misclassification of the contracts does not occur, since it could translate into rewarding contracts that are not necessary providing the best health care available to its beneficiaries. Therefore, it is important that the cut points are stable, predictable, and free of undue influence of outliers.

The proposed methodology to enhance the current Hierarchical Clustering Methodology consists of two combined methods in order to add more predictability to the cut points. The first proposal is to add the *"mean resampling, measure-specific scores for the current year's Stars Ratings are randomly separated into 10 equal groups"*.[1] However, CMS also recognizes that this enhancement can't fully capture the predictability that they want to have on its own. Therefore, CMS decided to proposed a second enhancement to the clustering algorithm. In order to comply with the desired probability, they will also implement a *"A guardrail for measures that have been in the Part C and D Star Ratings program for more than 3 years. The proposed guardrail of 5 percent would be a bi-directional cap that restricts movement both above and below the prior year's cut points. A 5 percent cap restricts the*

[1] Proposed Rules for Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021. Federal Register.Vol.83, No.212, Thursday, November 1st 2018. Pg. 55020

movement of a cut point by imposing a rule for the maximum allowable movement per measure threshold; thus, it allows a degree of predictability". [2] As stated before, we understand that CMS wants to keep up with the changes in the market without misclassifying a contract and sending the wrong message. The proposed method will still require for another adjustment to restrict the movement of the cut points. This disadvantage somehow is intended to be minimized by the guardrail of 5 percent bi-directionally. Therefore, it implies that means resampling does not reduce the sensitivity of the clustering algorithm. The mean resampling method, produces inferences that do not require assuming a parametric form for a population distribution or/and not treat the original sample as a population. Instead, it assumes that sampling with replacement from the original sample will behave in the same way when is taking a sample from a larger population. Taking a sample from a larger population require of stringent assumption that mean resampling does not require. The mean resampling replication method could not be exact, contrary to what hierarchical clustering can offer. This proposed regulation establishes "*The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values. Mean resampling reduces the sensitivity of the clustering algorithm to outliers and reduces the random variation that contributes to fluctuations in cut points*".[3] One of the advantages that the current hierarchical Clustering Methodology that CMS has been used for the Stars Ratings is that it can accurately be replicated. This aligns with CMS transparency regarding Stars Ratings.

The Federal Register is proposing a Mean Resampling, but there is no further description clarifying which specific method will be used. The Mean Resampling can be done applying 4 different methodologies, each one of them with positive or negative aspects regarding the Stars Rating application. Since there is no further description, it is almost impossible for us to thoroughly analyze each one of them.

However, several researches that have been published in different journals suggest that even though Mean Resampling if often used for data analysis, some opponents questions the accuracy of Resampling estimates.[4] Some critics are skeptics of this method because they think that *"You use the same numbers over and over again until you get an answer that you can't get any other way. In order to do that you have to assume something, and you may live to regret that that hidden assumption later on".*[5] Another article published by Rutgers University stated that "*...For large samples, one is bound to end up with an inaccurate*

[2] Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021. Pg. 55020

[3] Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021. Pg. 55020

[4] Chong, H. Practical Assessment Research & Evaluation. Resampling Methods: Concepts, Applications and Justifications. Volume 8, Number 19. September 2003

[5] Peterson I. Science News. Pick A Sample. July 1991.

statistical inference".[6] Also it has been stated that there are some counterexamples that shows the bootstrap produces wrong solutions, providing some inconsistent estimations.[7,8,9,10,11]

After a careful analysis of the proposed change to the hierarchical Clustering Methodology it's our understanding that this methodology will not improve CMS desirable accuracy and predictability. Regarding the 5 percent bi-directional cap, we concur this will attend somehow the undue influence of outliers, providing restrictions to upward, downward or both movements of the cut points, as stated in this Federal Register. This will " *balances the desire to continue to create incentives for contracts to focus on the quality of care of their enrollees and strive to improve performance*".[12] Which we commend CMS for addressing.

3. CMS should apply the "affected contract HEDIS adjustments" for the Osteoporosis Management in Women who had a Fracture Measure for contracts that operate solely Puerto Rico

HEDIS is one of the most important sources of information for the Stars Rating System. Not only it focuses on the overall health of the members, but it is also serves as an effective way to measure both the health plan and the provider's performance. The Osteoporosis Management in Women who had a Fracture (OMW), identifies the percentage of woman MA enrollees age 67-85 who suffered a fracture and had either a bone mineral density test or prescription for a drug that treats osteoporosis in the six months after the fracture. As Figure 1 shows this measure is further described on the NCQA HEDIS 2018 Technical Specifications Volume 2, page 165. In this section it is stated that the cycle of data used to calculate this measure is from "…*July 1st of the year prior to the measurement year and ends on June 30th of the measurement year…*".[13]

Figure 1: **Medicare 2019 Part C & D Star Ratings Technical Notes, page 36**

[6] Kesar S. Minge X.; Rutgers University. Bootstraps: A statistical Method.
[7]K. B. Athreya, Bootstrap of the mean in the infinite variance case, Ann. Statist. 15 (1987), 724-731.
[8] G. J. Babu, Bootstrapping statistics with linear combinations of chi-squares as weak limit, Sankhyä Ser. A 46 (1984), 85-93.
[9]P. J. Bickel and D. A. Freedman, Some asymptotic theory for the bootstrap, Ann. Statist. 9 (1981), 1196-1217.
[10] J. S. Huang, P. K. Sen, and J. Shao, Sample quantités in some nonregular cases and the vulnerable bootstrap, preprint, 1992.
[11]W.-Y. Loh, Estimating an endpoint of a distribution with resampling methods, Ann. Statist. 12(1984), 1543-1550.
[12] Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021. Pg. 55021
[13] NCQA HEDIS 2018 Technical Specifications Volume 2, page 165

Measure: C12 - Osteoporosis Management in Women who had a Fracture	
Title	**Description**
Label for Stars:	Osteoporosis Management
Label for Data:	Osteoporosis Management
Description:	Percent of female plan members who broke a bone and got screening or treatment for osteoporosis within 6 months.
HEDIS Label:	Osteoporosis Management in Women Who Had a Fracture (OMW)
Measure Reference:	NCQA HEDIS 2018 Technical Specifications Volume 2, page 165
Metric:	The percentage of woman MA enrollees 67 - 85 who suffered a fracture (denominator) and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture (numerator).

On September 5th 2017, the Secretary of Health and Human Services issued a Public Health Emergency Declaration for the Commonwealth of Puerto Rico as a consequence of the impact that Hurricane Irma had on the island. Later on September 10th the Federal Emergency Management Agency (FEMA) declared the Commonwealth of Puerto Rico a Major Disaster Zone. This declaration was modified by President Donald J. Trump on September 21, 2017, effective from September 17, 2017 to include the effects of Hurricane María on Puerto Rico. FEMA Major Disaster zones included all seventy-six (76) municipalities on the main island as well as the two (2) island municipalities.

As part of the emergency efforts, the Administrator of CMS issued and authorized on September 19th a Social Security Act, Section 1135 waiver for those persons who were evacuated, transferred or dislocated as a result of the effect of Hurricane María in 2017. The waiver intended to prevent gaps in access to care for beneficiaries impacted by the emergency. This waiver was extended two additional times, first until March 15, 2018 and then extended again on March 16,2018 to June 2018. Both waivers for Puerto Rico expired on June 13, 2018.

As mentioned above, the Federal Government and CMS recognized through many actions the dire state of Puerto Rico during the period of late September 2017 through June 2018. Considering that the OMW has a span of six months to be compliant since the event of a fracture, eligible women who were enrolled in a contract solely operated in Puerto Rico and had a fracture on the second half of 2017, might have faced barriers to get proper treatment and be compliant with his measure. Taking into account this information, we request CMS to apply the affected contract HEDIS adjustments *"…contract solely operated in Puerto Rico will have the option to report "NA" for all HEDIS measures… If a Puerto Rico contract reports an "NA" for any of the Star Ratings measures, the contract will receive the 2018 Star Ratings for that measure. If a Puerto Rico contract chooses to report any of the HEDIS measures, the contract will receive the higher of the 2018 or 2019 Star Rating (and corresponding measure score) for each HEDIS measure reported"*[14] for the Osteoporosis Management in Women who had a Fracture Measure for contracts that operate solely Puerto Rico for Star Ratings 2020.

[14] CMS. Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 8, 2017. Page 154

Applying this provision will neutralize the unintended consequences that created a disadvantage for al Healthcare Organization in Puerto Rico as a result both Hurricanes Irma & Maria.

4. CAI Calculation for Puerto Rico: CMS should establish a formalized rule with regards to the calculation of the LIS proxy for the final CAI Score.

The CAI is a value added to or subtracted from a contract's Overall, Part C and/or Part D Star Ratings to adjust for the average within-contract disparity in performance associated with a contract's percentages of beneficiaries with Low Income Subsidy/Dual Eligible (LIS/DE) and disability status.

We commend CMS for addressing the LIS/DE and disability effect with the implementation of the CAI. As a Medicare Advantage Organization from Puerto Rico with a large percentage of Low Income members, this adjustment represented a fairer assessment that took into consideration some of the unique challenges that only impact the Puerto Rico market. Nevertheless, we are concerned that the formula for the CAI calculation does not completely address Puerto Rico's unique situation.

The Attachment O of the Technical Notes for Stars Ratings 2019 explains how the LIS/DE percentage is calculated in order for it to be combined with the Disable percentage to apply the final CAI Adjustment. It is our understanding that the CAI score that was awarded to our contract H5577 is inconsistent with the information that was stated on the Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Call Letter), page 146, Section Additional Adjustment to Address Lack of an LIS Indicator for Enrollees in Puerto Rico.

"For the 2017 Star Ratings an additional adjustment for Puerto Rico-only contracts was applied to make the application of the CAI equitable for contracts operating solely in Puerto Rico in light of the lack of LIS. The additional adjustment resulted in a modified value for the percentage of LIS/DE for contracts operating solely in Puerto Rico. The adjustment resulted in a modified percentage of LIS/DE beneficiaries that was subsequently used to categorize contracts into the final adjustment category for the CAI."

"For the 2019 Star Ratings, CMS will continue to employ the additional adjustment for contracts operating solely in Puerto Rico (using the most recent data available at the time of development of the model for the 2019 Star Ratings). CMS will use the data sources identified in the draft Call Letter for this purpose."

This statement was consistent with our Stars Ratings 2018 final CAI adjustment were our LIS/DE% was adjusted to 100% and combined with our Disabled Percentage which resulted in the highest Adjustment Category and CAI value for our Overall, Part C and Part D CAI scores. However, in Stars Ratings 2019 this logic was not applied resulting in a lower CAI score for Stars Ratings 2019.

As CMS has recognized through several statements, the percentage of population living below poverty levels is higher than any state in the USA. Having said this, our Platino Population covers only beneficiaries between 0 through 87% Federal Poverty Level (FPL). However, when we used the 150 FPL that CMS utilizes for the CAI calculation, PR almost doubles the state of Mississippi which is the state with the highest percentage of population living below the 150 FPL among the United States. The same scenario repeats with the Income Per Capita, where PR individual income is approximately 45% less than Mississippi.

Having said this, we request that CMS apply the CAI adjustment rules that were announced in the 2019 Call letter. This adjustment not only will be consistent with the CAI application of Stars Ratings 2018, where PR contracts with the deepest levels of poverty and with the lowest Medicare and Medicaid funding were awarded a 100 %LIS/DE in combination with the DE% that resulted in the highest LIS/DE decile. This adjustment will also help to address PR unique situation in order to correctly address the disparity that results as an non intended consequence of the lack of LIS in Puerto Rico plans.

5. Annual Flu Vaccine: CMS should include a third option in the question were the beneficiary can state if the consciously decided to not get vaccinated.

The Consumer Assessment of Healthcare Provider and Systems (CAHPS) surveys ask consumers patients to report and evaluate their experiences with health care. These surveys cover topics that are important to consumers and focus on aspects of quality that consumers are best qualified to assess, such as the communication skills of providers and ease of access to health care services[15]. The survey response per question is the adjusted Case-Mix of the beneficiaries taking in consideration the respond of the specific survey questions.[16] However, the Annual Flu Vaccine Measure is the only measure that the case mix adjustment does not apply. As stated in the Technical Notes (Figure 2) this measure is composed of only one question

Figure 2: **Medicare 2019 Part C & D Star Ratings Technical Notes, page 27**

	• Have you had a flu shot since July 1, 2017?
Data Source Category:	Survey of Enrollees
General Notes:	This measure is not case-mix adjusted.

If we take in consideration the lack of case mix adjustment and add Puerto Rico cultural predispositions against the vaccine it creates a clear disadvantage when compared to their counterparts in mainland. As stated in the ASPE Issue Brief published by the Department of Health and Human Services (HHS) in January 2017[17] in the Access and Service section HHS recognized that the influenza vaccinations rates were low when compared to the US mainland. On this brief, HHS quote a study that concluded that one of the common reasons for non-vaccination, not wanting or needing the vaccine, safety concerns and other reasons. This study also indicated that when stratified by age groups the ≥65 years group stated that safety concerns were the most common rea-sons for non-vaccination.[18] These findings are also

[15] Retrieved on December 2018, US Department of Health and Human Services, Agency for Healthcare Research and Quality. https://www.ahrq.gov /cahps/about-cahps/index.html

[16] Medicare 2019 Part C & D Stars Ratings Technical notes. Attachment A: CAHPS and HOS Case-Mix Adjustment

[17] Retrieved on December 2018, Health and Human Department, Office of the Assistant Secretary for planning and Evaluation. ASPE Brief : Evidence Indicates a Range of Challenges for Puerto Rico Healthcare System. January 2017. http:aspe.hhs.gov

[18] Arriola, C. S., Mercado-Crespo, M. C., Rivera, B., Serrano-Rodríguez, R., Macklin, N., Rivera, A., … Kennedy, E. D. 2015. Reasons for low influenza vaccination coverage among adults in Puerto Rico, influenza season 2013-2014. *Vaccine*, *33*, 3829–

shared in a research performed by the Urban Institute on January 2017,[19] and concur with what was first presented by Lemon el all[20], regarding Flu Vaccination "*Several explanations are possible, including that non-Hispanic Blacks and Hispanics are less likely to use the healthcare system… differences in knowledge and beliefs about the procedure and possible side effects, mistrust in vaccination contents and language barriers…*" . On 2011 the BioMed Central with the sponsor of the World Health organization on a systematic review, also concluded that the people 65 years old or more presented "*concerns about the vaccine safety, effectiveness, side effects. Fear of pain, injections and getting the disease with the vaccine"*[21] these findings are consistent with another study published in the Expert Review Journal[22]

Having said this, we can conclude, that low Flu Vaccinations rates are a cultural factor that not only affects Puerto Rico. Studies performed in the USA have concluded that this cultural barrier is not exclusive to beneficiaries on the island and it is consistent among the Hispanic Population across the states. Contracts with a high percentage of Hispanic beneficiaries are penalized for cultural factors that are not easy to modify and does not directly depends on us. As a healthcare organization we understand the importance of the vaccine, and that is why we have done educational strategies that have gone form sending our beneficiaries letters, postcards, incentive programs, commercials on the major local TV channels, radio, newspaper ads on the most read newspapers across the island and educational presentations that provide facts that can help them understand why they should get the vaccine. But also, as a healthcare organization we have to respect our beneficiaries' decisions when it comes to getting vaccinated or not.

Therefore, we respectfully ask CMS to add another option on the Annual Flu Vaccine were the beneficiary can state if they decided to not get the vaccine by any reasons. The inclusion of this option would help contracts with a high percentage of Hispanic beneficiaries and mitigate the disadvantage that the exclusion of the measure for the case-mix adjustment that is used for all others CAHPS questions.

6. Getting Needed Care and Care and Getting Appointments and Care Quickly: CMS should take in consideration the Medically Underserved Area

The Getting Needed Care and Getting Appointments and Care Quickly measures are collected through CAHPS, as presented in page 49 and 51 of the Medicare 2019 Part C & D Star Rating Technical Notes (Figure 3 and 4). Even after the adjustments done by CMS, the questions of Getting Needed Care and one question in the Getting Appointments and Care Quickly that creates disadvantage within the final calculation for the Puerto Rico healthcare market. The two questions on the Getting Needed Care measure ask the beneficiaries how often did they got an appointment with a specialist when they needed and how easy it was for them to get care, tests or treatment when they need needed. The third question in the Getting Appointment

[19] Urban Institute, Environmental Scan of Puerto Rico's Health Care Infrastructure; January 2017

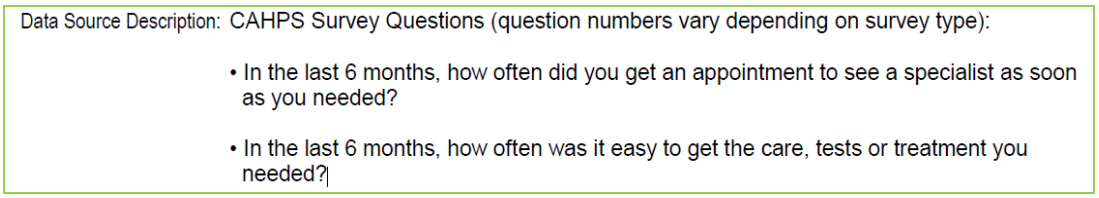
[20] Lemon, Stephenie C; Rakowski, William; Melissa A; Roy, Jason; Friedman, Peter D. American Journal of Health Behavior; Jul/Aug 2004;28;ProQuest Central pg 352

[21] Nagata et al. BMC Public Health 2011, 13:388 http:www.biomedicalcentral.com/1471-2458/13/388

[22] Ward J; Raude J; Understanding influenza vaccination behaviors: a comprehensive sociocultural framework. Expert Review Journal. Vaccines 13(1), 17-29, 2014

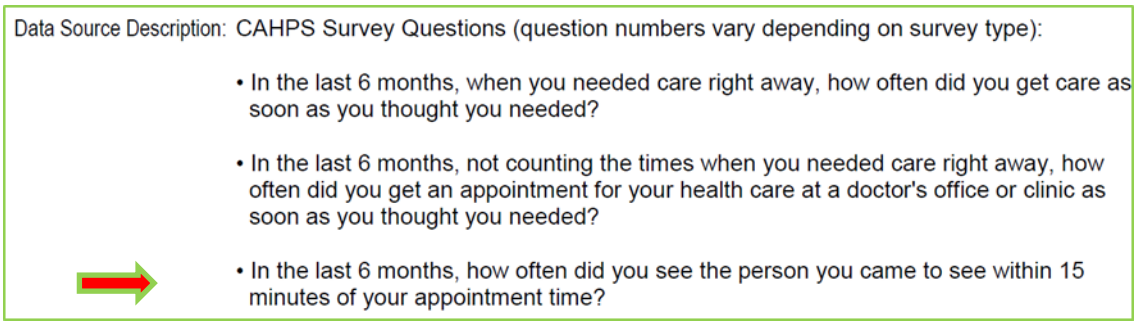
and Care Quickly asks the beneficiaries whether they saw the person they came to visit within 15 minutes of the appointment time.

Figure 3: **Medicare 2019 Part C & D Star Ratings Technical Notes, page 49**


Data Source Description: CAHPS Survey Questions (question numbers vary depending on survey type):

- In the last 6 months, how often did you get an appointment to see a specialist as soon as you needed?
- In the last 6 months, how often was it easy to get the care, tests or treatment you needed?

Figure 4: **Medicare 2019 Part C & D Star Ratings Technical Notes, page 51**


Data Source Description: CAHPS Survey Questions (question numbers vary depending on survey type):

- In the last 6 months, when you needed care right away, how often did you get care as soon as you thought you needed?
- In the last 6 months, not counting the times when you needed care right away, how often did you get an appointment for your health care at a doctor's office or clinic as soon as you thought you needed?
- In the last 6 months, how often did you see the person you came to see within 15 minutes of your appointment time?

In Puerto Rico, given our current situation, getting an appointment with a specialist or getting several treatments as well as a 15 minutes waiting standard is not realistic. As stated in the White House Task Force on Puerto Rico End of Administration Report, the U.S. Department of Health and Human Services includes in the future goals and sections the importance of working with Puerto Rico to address health care provider shortage[23]. Also the Office of the Assistant Secretary for Planning and Evaluation has recognized that "Puerto Rico has less than half the rates of emergency physicians; neurosurgeons; orthopedists and hand surgeons; plastic surgeons; and ear, nose, and throat specialists, compared to the availability of these providers on the U.S. mainland. Available evidence clearly indicates a shortage of specialists, and anecdotal evidence suggests a significant emigration of health care professionals to the U.S. mainland."[24] Urban Institute also analyzed this situation and concluded that: "Our environmental scan and site visit also provided some evidence of long wait times to see specialists. One government official has stated that specialized services have exceptionally

[23] Department of Health and Human Services, White House Task Force on Puerto Rico End of Administration Report; November 18, 2016.

[24] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, ASPE Issue Brief: Evidence Indicates a Range of Challenges for Puerto Rico Health Care System; January 12, 2017

longer waiting times, as many as nine months for some specialties. Separately, several site visit respondents also stated that long waiting times are a problem for adults and children, especially when making appointments with specialists."[25]

This situation is also reflected through the Health Resources and Services Administration (HRSA) within the US Department of Health and Human Services, Health Professional Shortage Areas (HPSAs) Designation. The Shortage Designation Branch in the HRSA, Bureau of Health Professions National Center for Health Workforce Analysis, develops shortage designation criteria and uses them to decide whether or not a geographic area or population group is a Medically Underserved Area.

According to the HRSA Data Warehouse in December 2018**[26]**, 72 out of 78 counties in Puerto Rico were identified as medically underserved areas. Based on CMS November Enrollment Data[27], 541,470 beneficiaries, or 93.67% of the entire population that was served by local MA organizations lived on those medical underserved counties. Additionally, Puerto Rico currently has 107 HPSAs that are also identified as medically underserved areas.

As a direct result of this situation Puerto Rico have assimilated and adapted to slightly longer waiting times. Given our current challenges, higher waiting times of – 30 to 60 minutes and above are to be expected. The same rationale has translate to the expectation of receiving an appointment to see a specialist, which could in some cases cause beneficiaries to wait more than a year for a medical appointment, given the shortage of physicians and the ongoing drain of specialists[28,29].

After analyzing Puerto Rico contracts historical data (2011 – 2018) for the questions included in the calculation of the overall measure score of each contract a pattern is observed. Therefore, for the Getting Needed Care measure, we suggest CMS to apply the same concession that they enforced with the Care Coordination measure for Stars 2018 to Puerto Rico operating contracts, in which they applied an adjustment that took in consideration the case mix of the eligible contracts

Regarding the Getting Appointments and Care Quickly, contracts in Puerto Rico had a significantly higher score vs. the national average in the first two questions, but a significantly lower score in the third one. As a result, we propose a change in methodology for Puerto Rico contracts, by weighting the third question at zero (0). The calculation would therefore only consider the first two questions. This subtle methodological change would provide remedy for the healthcare logistical challenges we have always faced, but which have now been utterly exacerbated.

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[25] Urban Institute, Environmental Scan of Puerto Rico's Health Care Infrastructure; January 2017

[26] Health Resources and Services Administration (HRSA) Data Warehouse, Health Professional Shortage Area (HPSA); January 2018, Retrieved February 20 2018 at https://datawarehouse.hrsa.gov/topics/shortageAreas.aspx

[27] Center for Medicare and Medicaid Services (2018). MA Enrollment by State/County/Contract-November 2018 [Data File] Available from cms.gov site: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-MA-Enrollment-by-State-County-Contract-Items/MA-Enrollment-by-SCC-2018-11.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending

[28] Respaut, R. (2016, October 11). Why people wait more than a year to see a doctor in Puerto Rico. *Reuters*, Retrieved December 13, 2018 at https://www.reuters.com/investigates/special-report/usa-puertorico-healthcare/

[29] Allen, G. (2016, March 12). SOS Puerto Rico is Losing Doctors, Leaving Patients Stranded. *NPR*, Retrieved December 13, 2018 at https://www.npr.org/sections/health-shots/2016/03/12/469974138/sos-puerto-rico-is-losing-doctors-leaving-patients-stranded

Sincerely,

Ixel Rivera Cabán
EVP Medical Operations

TAB 17

WellCare Comments

Sohini Gupta
Vice President, Federal Government Affairs & Advocacy

December 28, 2018

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4185-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-4185-P - Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

To Whom It May Concern:

WellCare Health Plans (WellCare) is pleased to submit the enclosed comments in response to the comment opportunity "Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021," published in the Federal Register on November 1, 2018 by the Centers for Medicare & Medicaid Services (CMS). The page numbers referenced in the below comments correspond to the Public Inspection Desk release.

For more than 30 years, WellCare has served families, children, seniors and individuals with complex medical needs. We partner with state and federal governments to coordinate managed care services for those eligible for Medicaid, Medicare Advantage (MA), Medicare Prescription Drug Plans (PDP) and Medicare ACO beneficiaries.

Founded in 1985 by a group of physicians in Tampa, Florida, today, WellCare serves more than 5.5 million members through Medicare Advantage, Medicaid Managed Care and Prescription Drug Plans as well as 160,000 Medicare ACO beneficiaries and partners with more than 636,000 healthcare providers, 68,000 pharmacies and more than 350,000 social support resources across the country.

Medicare Advantage

As of September 30 2018, WellCare's MA footprint spans 21 states and covers 544,000 members. In addition, we will operate 44 Dual Eligible Special Need Plans (DSNPs) in 2019 to provide care for the nearly 30 percent of our MA plan members that are eligible for both Medicare and Medicaid. We serve a predominantly complex and vulnerable population who can be hard to serve through traditional managed care outreach methods. Our members are elderly, retired and often live on fixed incomes. Some live below the federal poverty limits, and many face life threatening illnesses. To effectively support our members in all aspects of daily life, we employ an integrated care model

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including medical, behavioral, social, and pharmacy operations. In addition, we fully immerse ourselves in the communities we serve by fostering strong partnerships with providers, establishing trusted relationships with our state and federal partners, and addressing social barriers to care in our local communities.

Prescription Drug Plan

As of September 30, 2018, WellCare's PDP footprint spans all 50 states and the District of Columbia and covers 1.1 million members. Nearly 70 percent of our PDP members are low-income subsidy recipients and we continue to deploy innovative clinical programs to drive their outcomes. We are continuing to make meaningful strides with our PDP offering and are poised for significant membership growth in the near future.

Our comments to this proposed rule are based on the perspectives and learnings we have gained through our experiences serving vulnerable and complex members. Overall, we believe our health care system can be improved to better care for Medicare and Medicaid beneficiaries by reforming how we reimburse and provide care for and evaluate outcomes and quality for these complex populations. As CMS continues to align quality with outcomes, meet the evolving needs of expanding Medicare Advantage and Part D participation, and assist plans and providers as they grapple with escalating costs and medically complex, diverse populations, we believe there should be incentives, supports and guardrails to ensure that the most medically and socially fragile populations are addressed in a manner that ensures improvement in their health outcomes and quality of life. Further, WellCare appreciates the additional time to respond to the Medicare Advantage Risk Adjustment Data Validation Provisions contained in the proposed rule and we will submit our comments by the new April 30, 2019 deadline.

Overall, WellCare's comments below focus on the following areas:

- Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits
- Dual Eligible Special Needs Plans
- Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts
- Medicare Advantage and Part D Prescription Drug Plan Quality Rating System
- Improving Clarity of the Exceptions Timeframes for Part D Drugs
- Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE



A. Implementing the Bipartisan Budget Act of 2018 Provisions

1. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (page 14)

Overview

CMS's proposal intends to implement provisions of the Bipartisan Budget Act of 2018 that allow plans to provide "additional telehealth benefits" to enrollees in plan year 2020 and treat them as basic benefits for bid submission and payment by CMS.CMS acknowledges that telehealth may improve access to and timeliness of needed care, increase convenience for patients, increase communication between providers and patients, enhance care coordination, improve quality, and reduce costs related to in-person care.

In 2019, WellCare will offer telehealth as a supplemental benefit in 77 of our MA plans. We agree with CMS and view telehealth as a potential solution for improving access to care, especially in rural and underserved areas. For example, telehealth can be used to close coverage gaps and increase member access points so as to reduce urgent care and emergency room utilization. Recognizing the value and rising utilization of telehealth in the industry, WellCare support's CMS's proposal to allow MA plans to treat telehealth as a basic benefit for bid submission and payment.

Supplemental Benefits

As CMS thinks about other areas that should be supported, we encourage CMS to consider other benefits that health plans have invested in successfully. WellCare provides members with the social supports necessary to enable them to receive the care they need in the right setting at the right time. Such social supports include, but are not limited to, transportation, food, and housing. Given the fraud and abuse laws that health plans are subject to, CMS should consider giving plans greater flexibility in determining how such items and services should be included in their bids and offered in their plans to address the unique preferences and capabilities of their members. We look forward to continuing to partner with CMS to design other benefits and supports that enhance the quality of care and outcomes of our membership in all aspects of life and would welcome the opportunity to discuss our ideas with you further.



Proposal

"Additional Telehealth Benefits"

Overall, WellCare is supportive of CMS's proposal and believes it will be instrumental in expanding health plan offerings for members. WellCare supports the flexibility that CMS is providing to MA plans in defining what items and services they can offer as "additional telehealth benefits". WellCare agrees with CMS's proposal to define "additional telehealth benefits" as services that are furnished by a MA plan for which benefits are available under Part B but which are not payable under section 1834(m) of the Social Security Act and that have been identified by the MA plan for the applicable year as "clinically appropriate" to furnish through "electronic exchange". WellCare appreciates the flexibility that CMS is granting and does not believe that limitations should be placed on what types of Part B items and services can be considered "additional telehealth benefits". Relatedly, we appreciate CMS's proposal that services not covered under Part B, such as video-conferenced dental benefits, can still be offered as supplemental benefits. However, we request that CMS consider including remote devices, such as cell phones and tablets, as items that qualify as "additional telehealth benefits" given their ability to facilitate telehealth utilization.

Capital & Infrastructure Costs or Investments

WellCare disagrees with the exclusion of capital and infrastructure costs from "additional telehealth benefits" because they are vital to the provision of telehealth benefits. CMS proposes that "additional telehealth benefits" should not include any related capital and infrastructures costs and/or investments. WellCare has concerns about this aspect of the proposal and addresses this in further detail below.

CMS does not propose specific definitions for capital and infrastructure costs or investments, but notes they could include high-speed internet installation and service, communication platforms and software, and videoconferencing equipment. WellCare disagrees with this proposal because capital and infrastructure investments are vital to the provision of telehealth benefits, and as such, should be reflected in the basic bid. Flexibility for health plans to offer "additional telehealth benefits" or innovate in this space for members will be limited if they are not compensated for the implementation of the structure. Health plans are limited under fraud and abuse laws and can only incentivize and support infrastructure for practice groups providing the telehealth services to a certain extent. Including capital and infrastructure costs and investments in "additional telehealth benefits" will give health plans the flexibility needed to grant providers the incentives critical to providing telehealth services.

"Clinically Appropriate"

WellCare agrees with CMS's decision to let plans determine which "additional telehealth benefits" are clinically appropriate. CMS does not propose specific regulation text defining "clinically appropriate". Instead, CMS proposes allowing MA plans to independently determine which services each year are clinically appropriate to furnish. As such, CMS's proposed definition of "additional telehealth benefits" provides that the MA plan (not CMS) will identify the appropriate services for the applicable year. WellCare agrees with CMS's proposal. As professionally recognized standards of health care change over time and differ from practice area to practice area, we believe CMS's proposal is flexible enough to take these changes into account so that health plans can continue to provide the most appropriate services to members.

Network Adequacy

WellCare requests that CMS incorporate telehealth into network adequacy assessments. Given that CMS's proposal supports the expansion of telehealth offerings, we ask that CMS include telehealth in the assessment of health plan network adequacy. In the proposed Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care (CMS-2408-P) rule, CMS acknowledges that time and distance might not always accurately reflect provider availability and proposes new quantitative minimum access standards for determining network adequacy. Included in CMS's example of quantitative minimum access standards are minimum provider-to-enrollee ratios, maximum travel time or distance to providers, minimum percentage of providers that are accepting new patients, maximum appointment wait times, and hours of operation requirements. WellCare would urge CMS to consider similar approaches that acknowledge telehealth's potential to improve access in MA. We believe that telehealth could have meaningful impacts especially as it relates to network adequacy in rural or underserved areas. Additionally, telehealth can be used to satisfy requirements to provide services to members after hours and on weekends. However, we would also request that CMS provide guidance on how network adequacy standards adjusted for telehealth would interplay with state network laws that sometimes require in-person visits for select services.

In addition to network adequacy, telehealth is also beneficial in improving consumer choice. For example, telehealth expands the range of options from which members can choose when deciding how and when to receive their care. By offering access to telehealth, members in rural or underserved communities can access health care at a time and place that is convenient for their schedule.

Enrollee Choice

WellCare supports CMS's proposal. CMS proposes that if a MA plan covers a Part B service as an "additional telehealth benefit", then the MA plan must also provide access to the service through in-person visits. WellCare agrees with CMS's proposal and believes providing enrollees with choice is a critical component of the member's health care experience.

Provider Directory

WellCare requests additional clarity on CMS's proposal. CMS proposes that MA plans use their provider directory to identify providers offering services for "additional telehealth benefits" and in-person visits, or offering services exclusively for "additional telehealth benefits." WellCare requests clarity on whether such updates would need to be made for all providers within our networks or only a specific subset.

Provider Contracting Requirements

WellCare appreciates CMS's proposal that MA plans use contracted providers for "additional telehealth benefits", but has concerns with barriers posed by state licensing requirements. CMS proposes that MA plans must use contracted providers to furnish "additional telehealth benefits". They reason that limiting "additional telehealth benefits" to contracted providers should result in enrollees receiving services that are consistent with the proposal's intent since health plans would have more control over how and when such services are furnished. WellCare agrees that using contracted and credentialed providers is critical to providing high quality services.

However, we anticipate that state restrictions on cross-state licensing could create a barrier to building networks that provide "additional telehealth benefits". The majority of state medical boards require a doctor practicing medicine to have a license in each state in which he or she has appointments with patients. The same requirement applies for telehealth visits. In the rural areas that have limited access and stand to materially benefit from telehealth, doctors in bordering states cannot provide telehealth services due to state licensing issues. Currently, there is no federal standard of clinical guidelines for telehealth; medical boards and state regulatory boards across the country are each responsible for setting the standards for the appropriate practice of medicine via telehealth in their state. This has resulted in a patchwork of state laws that inhibit the proliferation of telehealth solutions in both the public and private sectors. It represents a significant barrier for health plans as they build their telehealth networks. As such, WellCare requests that CMS consider approaches for encouraging states to ease reciprocity for physician licensure as it relates to telehealth.

Preferred Provider Organization Plans

WellCare supports mandating that Preferred Provider Organization (PPO) plans use contracted providers for "additional telehealth benefits". CMS notes that Preferred Provider Organization (PPO) plans must reimburse all plan-covered medically necessary services from non-contracted providers without prior authorization. Since these health plans do not have the opportunity to review the qualifications of non-contracted providers or enact how "clinically appropriate" services are provided as "additional telehealth benefits", CMS does not believe that PPO plans are able to meet the proposal's requirements. CMS requests comment on whether to limit the contracted provider requirement to only PPOs, instead of all MA plan types. WellCare agrees that PPO plans should use contracted providers to ensure consistency of the benefits received by members.

2. Dual Eligible Special Needs Plans (page 30)

Overview

CMS's proposal intends to implement provisions of the Bipartisan Budget Act of 2018 that establish new requirements for DSNPs for the integration of Medicare and Medicaid benefits. As part of this, CMS provides new guidance on how it intends to define DSNPs and descriptions of three proposed integration requirements. Overall, WellCare appreciates that CMS is granting states flexibility and discretion in deciding which level of integration best suits their populations. More specifically, we appreciate that CMS is proposing integration standards that are compatible with states that do not currently participate in managed Medicaid or carve long-term supports and services (LTSS) and behavioral health (BH) into their Medicaid contracts.

CMS proposes to define DSNPs as a specialized MA plan for individuals who are eligible for Medicaid that provides and coordinates the delivery of Medicare and Medicaid services, including LTSS and BH; has a contract with the state Medicaid agency documenting each entity's roles and responsibilities with regard to dual eligibles; satisfies at least one of three integration requirements, including meeting additional state Medicaid agency contracting requirements, being a highly integrated dual eligible SNP, or being a fully integrated dual eligible SNP; and assists enrollees in filing grievances or appeals for Medicaid services.

WellCare continues to believe that even without full integration, DSNPs offer significant value to members beyond that of a traditional MA plan or fee-for-service plan. WellCare will offer 44 DSNPs in 2019. Our DSNPs plans offer expertise in care coordination, including specialized care management programs and tools, such as care managers, interdisciplinary teams, and specialized provider networks, to provide differentiated care for dual eligible beneficiaries. We also offer benefits above and beyond those offered by a traditional MA plan, tailored to this complex population with intensive health care needs. These additional benefits, including a model of care, drive improvement in both health outcomes and beneficiary experience. Relatedly, we offer social services and supplement benefits that effectively address social determinants of health, both within and outside

of the benefit structure, to improve health outcomes and quality of life. Lastly, through contracting strategies, including those mentioned in CMS's proposal, our DSNPs work with states to meet their unique program goals and better serve their populations, regardless of the level of integration offered by that particular state.

Proposal

DSNPs and Arranging for Benefits / Coordinating Benefits (page 35)

WellCare requests that CMS provide further clarity and guidance on arranging for and coordinating Medicaid benefits and infrastructure that can be leveraged. In proposing this definition, CMS does not provide a finite description of which health plan activities would constitute arranging and/or coordinating Medicaid benefits for an enrollee. Although WellCare appreciates CMS's proposed flexibility, we believe that CMS is being too broad and ask CMS to consider describing coordination of benefits activity more specifically. WellCare anticipates that plans could face barriers in arranging Medicaid benefits for enrollees, especially if such benefits are managed by other health plans. As such, we request that CMS provide more clarity on the activities that constitute arranging and/or coordinating Medicaid benefits to create consistency across stakeholders. We also request that CMS provide guidance on related procedures and infrastructure that can be leveraged to make the coordination process seamless. For example, the state of Tennessee currently requires DSNPs to use the TennCare Online System to coordinate benefits for enrollees that are eligible for Medicaid. CMS could consider the merits which may encourage other states to employ a similar approach.

Dual Eligible Special Needs Plans and Contracts with States (page 44)

WellCare supports granting states flexibility in choosing how to structure their DSNPs. CMS proposes codifying that an MA organization seeking to offer a DSNP must satisfy one (or more) of the three integration requirements. They also note that the statutory language requires plans to meet the requirements to the extent permitted under state law. Therefore, CMS proposes to interpret the statutory provision as providing multiple avenues for a MA plan to qualify as a DSNP. WellCare agrees with CMS's interpretation and believes that providing this flexibility is in the best interest of states.

WellCare offers CMS suggestions for streamlining the implementation of CMS's proposed state contracting requirements. CMS proposes that DSNPs that do not have a capitated Medicaid contract with the state must meet additional state contracting requirements beginning in 2021. CMS proposes that this new requirement could be met by having such MA-only DSNPs notify the state

Medicaid agency, or individuals or entities designated by the state, of hospital and SNF admissions for at least one group of high-risk full-benefit dual eligibles, as determined by the state Medicaid agency. CMS would also permit DSNPs to authorize other entities, such as network providers, to notify the state Medicaid agency on its behalf, with the understanding that the DSNP is ultimately responsible for compliance. Additionally, CMS proposes giving state Medicaid agencies broad latitude to establish notification procedures and protocols, including the recipients of the admission notifications, timeframes by which a DSNP must furnish this information directly or indirectly, and how such notification would occur (e.g. automated or manual process).

WellCare agrees that sharing this information with states could promote integration by establishing a requirement that increases DSNP's care coordination activity around care transitions. However, without knowing each individual state's capabilities to implement this contracting requirement, it is unclear if this incentive will be enough for plans and states to further integrate. WellCare requests that CMS provide states with clearly defined parameters for implementing the state contracting requirements so as to support implementation feasibility and mitigate operational burden for health plans. More specifically, we request that CMS provide states with parameters on how to implement technology infrastructure and standardized templates to facilitate data sharing and set timeliness requirements for their receipt of data. For instance, we would request that CMS provide guidance that timeliness standards must be structured to begin after the health plan is in receipt of the relevant data. We also ask that CMS consider setting a minimum size of populations for which states are able to request admissions data. Lastly, we request that CMS partner with states to undertake a fulsome educational rollout of plan requirements to both members and providers once the proposal is finalized to facilitate integration within minimal abrasion. In recognition of the efforts necessary to satisfy CMS's proposed integration standards and to reward performance, we ask that CMS expand opportunities for passive enrollment.

WellCare proposes additional state contracting requirements for CMS to consider. CMS notes that in developing its proposed state contracting requirements, it considered a variety of alternate strategies. WellCare appreciates CMS's initial proposal of sharing hospital and SNF admissions data and agrees that this data is relevant to effective care coordination. Further, we also incorporate additional care management activities through our model of care that we believe are equally imperative to driving care coordination and improving outcomes. Additional data sharing opportunities where technology permits that we would suggest to CMS include observation notifications, getting state input on model of care and health risk assessments, training plan staff and network providers on availability of LTSS services covered by Medicaid, identifying and notifying state of enrollees in need of LTSS and/or BH, and sharing data with state Medicaid agencies or other designated entities that would benefit from coordination of Medicare and Medicaid. We respectfully ask that CMS consider the merits of expanding its proposal to include the aforementioned suggestions.

Eligibility of Partial-Benefit Dual Eligible Individuals for Dual Eligible Special Needs Plans (page 56)

Beneficiaries in the Qualified Medicare Beneficiary (QMB) program should be eligible for DSNPs. QMBs have their Medicare Part A and Part B premiums and a portion of related Medicare coverage costs paid for by the Medicaid program. These beneficiaries also qualify for the low-income subsidy in Part D. Although these members do not qualify for full Medicaid benefits, QMBs are complex members and MA-only DSNPs would provide an opportunity for them to receive targeted care to drive their outcomes and improve quality of life. As such, WellCare requests that CMS consider granting eligibility for QMBs to enroll in MA-only DSNPs. In addition, we request that reimbursement rates for such enrollees be structured to accurately reflect the resources needed to adequately provide care to such complex populations.

Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (page 58)

WellCare supports unifying grievance and appeals procedures for plans that provide both Medicaid and Medicare coverage to their DSNPS. The Bipartisan Budget Act of 2018 directs CMS to establish a unified grievance and appeals procedure for DSNPs to the extent feasible. Under the act, CMS must establish new procedures that unify Medicare and Medicaid grievance and appeals procedures for DSNPs by no later than April 2020. Additionally, such requirements must be included in DSNP contracts for 2021 and onwards. CMS is using this opportunity to propose new procedures for DSNPs, including specific requirements for both DSNPs that have exclusively aligned enrollment and those that do not. WellCare supports unifying grievance and appeals procedures for plans that provide both Medicaid and Medicare coverage to their DSNPS. Our feedback and suggestions on specific aspects of the proposal are included below.

Assisting with Medicaid Coverage Issues and Grievances (page 64)

WellCare has concerns with the viability of CMS's proposal for all DSNPs to assist beneficiaries with Medicaid grievances and appeals. Consistent with the statutory requirement that DSNPs arrange for enrollee Medicaid benefits, CMS proposes that all DSNPs must assist enrollees with Medicaid coverage issues. More specifically, CMS proposes that when a DSNP receives an enrollee's request for services, appeals, or grievances related to Medicaid-covered services, the DSNP must provide assistance to the enrollee. CMS proposes that DSNPs must fulfill this requirement, even if they do not contract with the state to provide Medicaid services.

Although CMS clarifies that DSNPs would not be required to represent enrollees in appeals, is not overly prescriptive in outlining activities that would satisfy the requirement of assisting with Medicaid grievances and appeals. WellCare appreciates that CMS is granting flexibility in terms of how DSNPs can comply with the proposed requirement. We also appreciate that a DSNP's only obligation would

be to offer assistance and then provide assistance if the offer is accepted or a request for assistance is made by the enrollee.

However, we recognize that MA-only DSNPs that lack a Medicaid contract for the enrollee's Medicaid services might have limited access to critical enrollee information that is necessary to providing assistance. For example, to properly navigate and file an enrollee grievance or appeal, it would be helpful for the DSNP to know the enrollee's Medicaid MCO, but this information is not always readily available. Additionally, CMS also proposes that DSNPs assist enrollees in obtaining documentation to support their grievance or appeal. WellCare is concerned that this aspect of the proposal could expose health plans to potential liability in appeals denials.

WellCare offers suggestions to CMS for making this aspect of the proposal more feasible. To streamline the process and facilitate its implementation, WellCare requests that CMS consider implementing a baseline approach for assisting DSNPs with Medicaid grievances and appeals. One such approach would be for CMS to partner with states to develop standardized resource lists that can be shared with enrollees and DSNPs, containing critical information on key Medicaid contacts, streamline the navigation process and mitigate operation burden. Additionally, WellCare requests that CMS provide clarity on the extent of responsibility that DSNPs will assume when obtaining documentation, including the specific types of documentation that DSNPs might be able to provide.

Statutory Basis and Scope for Unifying Grievances and Appeals (page 72)

Overall, WellCare agrees with aligning Medicaid and Medicare grievance and appeals requirements for exclusively aligned DSNPs, but requests that CMS consider our concerns before finalizing the proposal. WellCare appreciates and agrees with CMS's proposal to align Medicaid and Medicare grievance and appeals requirements for DSNPs with exclusively aligned enrollment. We agree that unifying such procedures streamlines the grievance and appeals process for enrollees and plans. Furthermore, we are supportive of unifying Medicaid and Medicare grievances and appeals requirements for all enrollees, in addition to DSNPs. However, we ask CMS to consider the following concerns and related impacts as they finalize the approach.

Unifying procedures could result in increased volume of grievances and appeals and impact quality. Although WellCare is supportive of integrated grievances and appeals, we anticipate that unifying these procedures could result in an increase in the volume of grievances and appeals that a health plan receives. This could have a disproportionate effect on Stars performance as it relates to health plans that are increasing their DSNP membership or trying to integrate and comply with the new proposal. WellCare requests that CMS consider implementing a grace period for plans that

would mitigate any potential risks to quality performance as they operationalize and refine their unified procedures.

WellCare requests additional clarity on how the unified procedures will interact with prescription drug appeals. In the proposed rule, CMS also notes that that unifying grievances and appeals for Medicare Part D is outside the scope of their authority. Nonetheless, WellCare believes that a potential grey area exists in instances where a DSNP enrollee's prescription drug might be covered by either Medicaid or Medicare, but not both. In these instances, WellCare would request guidance from CMS on how to navigate such appeals under the proposed unified grievances and appeals procedures. For example, in instances where a prescription drug is only covered by the enrollee's Medicaid benefits, should the DSNP refer to the Medicaid-specific grievances and appeals process, or follow the proposed unified process. WellCare appreciates any additional guidance that CMS is able to provide.

3. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (Page 118)

WellCare appreciates CMS's proposal but requests a shorter timeframe for the receipt of claims data and application to the Part D enhanced Medication Therapy Management Model. WellCare appreciates CMS's proposal for providing PDP sponsors with access to Medicare Parts A and B claims data. We also request that CMS consider whether there is flexibility to further tighten the proposed timeframes for receipt of such data. On page 125, CMS proposes that "first standardized data extract would be available to PDP sponsors no earlier than August 15, 2020, which would include, at a minimum, data for the period beginning January 1, 2020, and ending on March 1, 2020." The ability to obtain the data within a shorter timeframe could prove valuable in administering timely care to enrollees. We would request that CMS enact a similar practice to that which was employed under the Bundled Payments of Care Initiative (BPCI), where participants received claims data on a monthly basis that included claims data from the 12 preceding months. For example, the claims data released in February 2015 would include data from January 2014 to January 2015. WellCare also requests that CMS consider applying similar approaches for data sharing, like those mentioned above for BPCI, to the CMS Innovation Center's Part D Enhanced Medication Therapy Management (MTM) Model. In this instance, providing participating plans access to timely data would be impactful in driving innovative MTM strategies that improve member outcomes and reduce the total cost of care.



B. Improving Program Quality and Accessibility

1. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (page 127)

Overview

WellCare appreciates the opportunity to provide comments to CMS on the proposed changes to the Medicare Advantage and Part D Quality Rating System. WellCare has made a significant investment in the Medicare Advantage program for our beneficiaries with a footprint that spans 21 states and we are committed to the long-term success of the program. WellCare values the unique offering of the MA program and supports CMS' goals of improving health outcomes for all MA beneficiaries and to maintain a Star Ratings program that recognizes high-quality care. WellCare submits this summary with recommendations and analysis in an effort to further refine the MA program.

CMS notes that comments from last year's Notice of Proposed Rulemaking indicated broad support for the hierarchical clustering methodology that determines the non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measure-specific cut points. However, many stakeholders also expressed a desire for cut points that are predictable, stable, and free from the influence of outliers. In addition, some commenters expressed interest in caps that would limit the amount of year to year movement in cut points. We appreciate CMS now proposing enhancements to the cut point methodology in response to the feedback received. We have outlined our suggestions in this section.

Along with the above changes, CMS is proposing substantive updates to the specifications for some of the measures. Two of the measures for 2022 Star Ratings (Controlling High Blood Pressure and Medicare Plan Finder Price Accuracy) and one measure for 2023 Star Ratings (Plan All-Cause Readmissions), a rule to exclude measures that received a reduction for data integrity from a plan's Parts C & D Improvement Measure scores, modifications to CMS's data integrity policy and procedure for requesting CME and/or Independent Review Entity (IRE) review of contract data, and rules for calculating Stars Ratings in the case of extreme and uncontrollable circumstances (for example, natural disasters) would be modified.

WellCare's feedback on CMS's proposal is not specific to any of our single plans, but rather based on experiences from our national MA footprint that currently spans 21 states and covers 544,000 members and our PDP footprint that spans all 50 states and the District of Columbia and covers 1.1 million members. WellCare maintains a strong commitment to quality and has improved in recent years due to our considerable focus on the Stars program. We serve a population that is predominately retired, elderly, living on a fixed income, and that are medically fragile and face numerous social barriers to receiving quality health care. Some live below the federal poverty limits, and many face life threatening illnesses. In 2019, we will operate 44 DSNPs that provide care to our MA plan members that are eligible for both Medicare and Medicaid. Of these dual eligible members, most have multiple chronic conditions and nearly half percent have one or more mental health conditions.

We believe in order to drive quality outcomes and not penalize plans for investing in these populations, the Star Ratings program needs to be reformed. Our specific reactions to the proposed changes and our guidance for the best path forward are captured below.

Proposal

Measure Level Star Ratings (page 130)

Overall, WellCare appreciates CMS's efforts to enhance the cut point methodology. As previously mentioned, CMS solicited feedback from stakeholders on the cut point methodology and many expressed that the following would be desirable: greater stability, predictability, attenuation of the influence of outliers, restricted movement of cut points from year to year, and pre-announced or pre-determined cut points. WellCare agrees with this stakeholder feedback.

The two proposed enhancements to the cut point methodology, mean resampling and guardrails for Stars measures that are more than three years old, could be overall beneficial, however additional data and transparency is required to fully assess the impact of the changes. We appreciate CMS's efforts and recognition for the need to provide greater stability and predictability in the cut points from year to year, while reducing the impact of outliers.

Data is needed to appropriately evaluate the mean resampling policy proposal. In general, we appreciate the proposal to introduce mean resampling into the clustering algorithm to attenuate the impact of outliers. WellCare believes that individual plan performance should not be adversely impacted by outliers that unduly skew industry results. Nonetheless, WellCare is cautious of supporting any adjustments that introduce additional complexity to the cut point methodology without having full transparency on the approach. WellCare is concerned about the limited insight provided on the mean resampling method that CMS endeavors to employ and would request that CMS provide simulation data on how the proposal would impact industry-wide Star Ratings prior to formalizing the approach. In addition, we request that CMS provide the associated SAS code so that stakeholders can replicate the approach and findings for purposes of transparency and validation of the approach's ability to mitigate the impact of outliers.

Proposed guardrails should vary within measures and have no larger than a 2 percentage point / percent cap, as opposed to a 5 percentage point / percent cap. WellCare is supportive of CMS's proposal to introduce guardrails for measures greater than three years old, but has concerns regarding the size of such guardrails and their potential impact on how performance is calculated. WellCare agrees with CMS's proposal to have guardrails be an absolute percentage cap for measures on a 0 to 100 scale. WellCare also agrees with CMS's proposal to have guardrails be

a restricted range cap for measures that are not on a 0 to 100 scale. However, WellCare disagrees with CMS's proposal of setting a 5 percentage point absolute cap for measures on a 0 to 100 scale and a 5 percent restricted range cap for measures that are not on a 0 to 100 scale. This figure is too large and allows for variance between year to year cut points that conflicts with the intent of the proposal to create predictability and stability.

It is our recommendation that CMS considers implementing no larger than a 2 percentage point absolute cap for measures on a 0 to 100 scale and a 2 percent restricted range cap for measures that are not on a 0 to 100 scale. For most measures, we believe that this figure is large enough to adequately capture changes in year to year industry performance while providing predictability and stability in cut points. However, we note that a 2 percentage point / percent cap might still be too large for measures where the distribution of Stars Ratings are clustered tightly together. In such instances, we ask CMS to calculate a percentage point / percent cap that is tied to the individual measure's distribution of clusters to adequately reflect performance.

WellCare believes that health plans should consistently be rewarded for forward progress. Although WellCare understands CMS's reasoning for structuring the proposed guardrails as bi-directional, we are critical of any changes to the cut point methodology that have potential to adversely impact how positive achievements in quality are measured and rewarded. The challenges associated with managing for MA's continued growth enrollment coupled with the dynamics of serving different geographies and communities highlights how important it is for health plans to receive consistent recognition for their forward progress in quality.

Health plans use their quality performance to demonstrate their ability to create positive experiences and drive outcomes for members. As such, it is critical that performance is accurately measured and rewarded so that plans may continue to make the long-term investments necessary to effectively service their membership. Moreover, accurately reporting positive performance supports member retention in that members will be more inclined to stay with their plans from year to year. This stability is critical in enabling plans to deploy personalized, integrated long-term solutions that stabilize costs and improve member outcomes and the overall patient experience.

WellCare believes that preset thresholds limit the impact of outliers and provide transparency into cut points. WellCare also encourages CMS to consider alternative approaches for limiting the impact of outliers. One such approach would be to reinstate the pre-determined 4 Star thresholds that CMS previously employed for HEDIS and Medication Adherence measures, but discontinued beginning with the 2016 Star Ratings. Alternatively, CMS might consider proposing that measure scores above 95 percentage points of 95 percent be scored as 5 Stars. We believe that preset thresholds such as these have the ability to limit the impact of outliers and reduce the additional steps required by the cut point methodology, while also providing transparency to plans that is meaningful in setting and realizing achievement goals.



WellCare finds that transparency on future methodologies is critical. Once the proposal is finalized and implemented, WellCare anticipates that CMS could consider additional adjustments to the calculation of measure-specific Star scores and cut points. WellCare continues to request that CMS proactively provide transparency into any additional methods that they might consider and provide public comment opportunity to stakeholders before implementation. We also request that CMS proposals be accompanied by measure impact analyses that provide transparency to stakeholders on the impact of proposed changes. WellCare remains apprehensive of any changes to the Stars methodology that do not provide adequate transparency on measurement to stakeholders.

Updating Measures (page 140)

Controlling High Blood Pressure (Part C)

WellCare is supportive of moving Controlling High Blood Pressure (Part C) measure to the display page for 2020 and 2021. The National Committee for Quality Assurance (NCQA) has implemented updates to the Controlling High Blood Pressure measure for HEDIS 2019 based on new hypertension treatment guidelines from the American College of Cardiology (ACC) and the American Heart Association (AHA). Based on these substantive changes, CMS proposes to move the measure to the display page for 2020 and 2021 Star Ratings and return the updated measure for 2022 Star Ratings using data from 2020 measurement year. CMS also proposes giving the measure a weight of 1 for its first year (2022) and a weight of 3 thereafter. WellCare agrees with CMS's proposal and appreciates CMS's inclusion of this measure to the display page since it allows health plans time to align their hypertension treatment programs with the new guidelines while also measuring the impact of the proposal during the display period. We continue to support the inclusion of outcomes measures such as this in the Stars program since it directly demonstrates the impact of quality initiatives on member patient's health.

Considering CMS' desire to move to more outcome based measures, WellCare believes that there needs to be additional reforms to support the transition and prepare for additional outcome based measures in the future. There needs to be a recognition that outcome based measures are more challenging to achieve for plans that are serving more complex populations.

As CMS continues to update Stars methodology and measures, there is opportunity to enhance the Categorical Adjustment Index. WellCare believes that there is opportunity to further refine the Categorical Adjustment Index in a manner than improves the program and accurately reflects performance. In 2016, CMS implemented the Categorical Adjustment Index (CAI) as an interim analytical adjustment to address the low income subsidy/dual eligible (LIS/DE) and disability

effect. The CAI provides an adjustment for the average within contract disparity in performance associated with a contract's percentages of beneficiaries with LIS/DE and disability status. WellCare appreciates CMS's work to more accurately measure plan performance as it relates to complex members, but believes that there is opportunity to improve the impact of the CAI by expanding the range of included measures and enhancing how the adjustment is applied to calculate the plan's performance.

WellCare requests inclusion of all three Medication Adherence measures in the CAI. CMS has previously noted that measures were chosen for inclusion in the CAI on the basis that there was a median absolute performance difference between LIS/DE and non-LIS/DE beneficiaries of 5 percent or more and/or the LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts. We respectfully disagree with the 5 percent threshold chosen by CMS on the basis that it is too large to recognize meaningful differences in performance between LIS/DE and non-LIS/DE members. We request that a smaller threshold of 2 percent is applied when considering which measures to include in the CAI. As a result, we would expect that other critical Medication Adherence measures, including Medication Adherence for Diabetes Medications and Medication Adherence for Cholesterol (Statins), would be included in the adjustment given the meaningful disparities in performance that we have observed.

There is a high correlation between Medication Adherence measures, with our experience indicating that members do not selectively choose which medications to which they will adhere. In addition, by including the outcome measure Diabetes Care – Blood Sugar Controlled in the CAI, but excluding the related Medicare Adherence for Diabetes Medication, the CAI misses out on the opportunity to get a more comprehensive view of disparities in performance for members with LIS/DE status. These observations further underscore the importance of capturing all three Medication Adherence measures to adequately adjust performance.

WellCare believes the comprehensiveness of CAI can be bolstered by including additional outcome measures. WellCare also believes the CAI could be improved by including additional measures to improve the comprehensiveness of the adjustment's scope. As previously mentioned, the 2018 measures used in the 2019 CAI adjustment calculations include Diabetes Care – Blood Sugar Controlled (Part C). However, there are four other Star measures that gauge quality for members with diabetes: Diabetes Care – Eye Exam, Diabetes Care – Kidney Disease Monitoring, Medication Adherence for Diabetes Medications, and Statin Use in Persons with Diabetes. Diabetes impacts over 40 percent of our DSNP membership. Given its prevalence, we believe that broadening the scope of the CAI to include all outcome measures with observed disparities between non-LIS/DE and LIS/DE members is necessary to having a multifaceted view of the disparities faced by these populations.



We suggest the following HOS measures be included in CAI and improving the representative nature of the survey. WellCare believes that the Health Outcomes Survey (HOS) is not structured to adequately capture and reflect performance with complex members. We request that the CAI incorporate HOS measures, including the mental and physical measures Improving or Maintaining Physical Health and Improving or Maintaining Mental Health. As is, the HOS measures the member's perception of their wellbeing. It is our opinion that HOS does not adequately capture how complex conditions and co-morbidities might influence one's perception of their own wellbeing, and as such, could contribute to lower HOS scores. In instances like these, there is potential for a lack of common understanding between member perception and what the health plan is actually accomplishing in terms of improving their overall wellbeing. This disconnect can lead to negatively skewed results. We appreciate that CMS is employing methods for evaluating how members are maintaining or improving their health, but believe there is opportunity to better incorporate objective year to year improvements in health. We believe that including HOS measures in the CAI presents an opportunity to counteract the aforementioned negative skew in results. Like CAHPS measures that are case-mix adjusted, a CAI adjustment to HOS would help to account for population demographics and complexities of our Medicare population.

WellCare is also concerned with CMS's requirement of a minimum survey response sample size of 30 or greater. For example, if a health plan with 10,000 members has 30 of their members complete the HOS, CMS would view this as an adequate sample to determine the health plan's performance on the HOS measure. We urge CMS to consider other approaches for determining sample sizes that are truly representative of a health plan's member population such as using a sample size that is proportionate to the contract population.

CAI should be applied at the measure-level as opposed to the contract's overall Star Ratings to more accurately reflect performance. As it stands, the CAI adjustment is added to or subtracted from a contract's overall and summary (Part C and Part D) Star Ratings. WellCare disagrees with this approach and believes the CAI would be more impactful in reflecting plan performance if the adjustment was applied to the nine measures included in the 2019 CAI adjustment calculations, as well as the additional measures that we proposed above. Applying the adjustment at the measure level should increase the measure's accuracy. Relatedly, this improvement in precision could ultimately result in a more accurate contract-level score.

CMS should consider other methods for measuring and rewarding quality for plans with complex members. Lastly, we request that CMS consider other methods for acknowledging and rewarding differences for plans that are making strides in managing care for complex members. As it currently stands, the CAI analyzes within contract variation between performance for members with and without LIS/DE and disability status. However, members without LIS/DE and disability status could still be impacted by social determinants of health that impact their outcomes. For instance,

such members could be lower income, and as a result, demonstrate similar outcomes to those with LIS/DE and disability status. As a result, analyzing within contract variation to decide a health plan's performance adjustment might obscure the true performance adjustment required to reward the effort commensurate with improving outcomes for complex members.

WellCare is supportive of the Pharmacy Quality Alliance's (PQA) interest in evaluating performance for dual eligible members and non-dual eligible members separately. We ask that CMS consider the merits of such an approach and its potential to more accurately measure plan performance. We also ask that CMS engage with both NCQA and PQA to drive the development of adjustments for socioeconomic factors for their respective measures and accelerate the inclusion of such adjusted measures in the Star Ratings program. We are also supportive of approaches that take into consideration the appropriateness of select measures for members with frailty and advanced illness. For instance, NCQA announced that for HEDIS 2019 they will exclude members with frailty and advanced illness from select measures where they are less likely to benefit.

Opportunity to incentivize providers to capture data that is critical to quality. WellCare is aligned with CMS in its acknowledgement that collecting member data is critical to driving quality. When documented, Current Procedural Terminology (CPT) II codes can be critical in capturing member outcome data. Nonetheless, CPT II codes do not have values assigned on the Medicare physician fee schedule, and as such, are not reimbursed. Since there is no reimbursement associated with the codes, they are often not captured or documented creating a lack of accuracy for Stars reporting and comprehensive medical record purposes. We urge CMS to consider new approaches that incentivize providers to collect data that drives member care for complex members. One such approach would be for CMS to directly reimburse providers for capturing CPTII codes. Another option would be for CMS to reward health plans that train and incentivize providers to document CPT II codes to facilitate the collection of outcome data.

MPF Price Accuracy (Part D)

WellCare is supportive of the existing MPF Price Accuracy measure and opposed to CMS's proposed changes. CMS proposes enhancements to measure the reliability of a contract's Medicare Plan Finder (MPF) advertised prices by measuring the magnitude of price differences between Point of Sale (POS) adjudication and the MPF, as well as the frequency of price differences. Additionally, CMS proposes to move the measure to the display page for 2020 and 2021 Star Ratings. This measure would be used in the 2022 Star Ratings in place of the existing MPF price accuracy measure, which will remain in the Star Ratings until replacement. The measure would have a weight of 1 for 2022 Star Ratings.

Although WellCare appreciates the value of the MPF and strives for its accuracy, WellCare is opposed to CMS's proposed changes. Market-based, real-time fluctuation in POS adjudication

prices can sometimes result in price differences from the MPF, which is updated on a less frequent basis by CMS. These less frequent updates to the MPF price can drive price differences that are outside of the health plan's control. The introduction of a frequency component to the calculation will further compound the impact of this issue. WellCare requests that CMS not make the proposed changes to MPF, but instead keep it as an active measure using the current methodology.

Plan All-Cause Readmissions (Part C)

WellCare is supportive of moving Plan All-Cause Readmissions to the display page for 2021 and 2022. NCQA is modifying the Plan All-Cause Readmissions measure for HEDIS 2020 (measurement year 2019) to add observation stays as hospital discharges and readmissions in the denominator and the numerator and remove individuals with high frequency hospitalizations. CMS also proposes to combine the 18-64 and 65+ age groups as the updated measure specifications are updated and to use NCQA's new recommendation of 150 as the minimum denominator. Based on these substantive changes, CMS proposes to move the measure to display page for 2021 and 2022 Star Ratings. CMS also proposes to return this measure to the 2023 Star Ratings using data from the 2021 measurement year with a weight of 1 in the first year and a weight of 3 thereafter. WellCare agrees with CMS' proposal to move this measure to the display page since it would allow health plans appropriate time to monitor changes to the hospital readmissions measure and bring forth any concerns prior to the inclusion of the proposed changes into the Star Ratings.

Improvement Measures (Parts C and D)

WellCare is supportive of excluding measures with data integrity concerns from the Improvement Measure. Currently, only measures that have a numeric score for each of the two years being examined are eligible to be included in the improvement measure calculation. CMS proposes adding an additional rule to exclude measures that received a Star rating reduction for data integrity concerns in either the current or prior year from the improvement measure. WellCare agrees with CMS's proposal since it could eliminate unnecessary fluctuation in the Improvement Measure calculation caused by data integrity issues.

Data Integrity

WellCare is supportive of the proposed penalty for plans that fail to submit TMP data for CMS's review. CMS currently makes scaled reductions to Star Ratings for Part C or Part D appeals measures if the relevant IRE data are not complete based on the Timeliness Monitoring Project (TMP). CMS proposes adding an additional provision to assign a 1 Star rating to the applicable appeals measure(s) if a contract fails to submit TMP data for CMS's review to ensure the completeness of their IRE data. WellCare agrees with CMS's proposal and believes it is a positive step towards reducing incentives for health plans to avoid scaled reductions by not submitting their TMP data.

Review of Sponsors' Data

WellCare requests that CMS extend the proposed deadline to include the First Plan Preview. CMS proposes that requests from plans for CMS or the IRE to review contract data must be received no later than June 30 of the following year in order to have time to use accurate information in the Star Ratings calculation. For example, changes to contract year 2018 appeals data must be made by June 30, 2019 for the 2020 Star Ratings. WellCare requests that CMS extend the deadline to include the First Plan Preview (August of the calendar year) so that the health plan can evaluate official Stars data provided by CMS and make any needed changes for measure integrity.

CMS proposes that any requests for adjustments following CMS's Complaints Tracking Module (CTM) Standard Operating Procedures for the complaints measures be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data. For example, changes to contract year 2018 complaints data must be made by June 30, 2019 for the 2020 Star Ratings. WellCare requests that CMS extend the deadline to include the First Plan Preview (August of the calendar year) so that the health plan can evaluate official Stars data provided by CMS and make any needed changes for measure integrity.

Extreme and Uncontrollable Circumstances (page 149)

WellCare appreciates CMS's proposal, but requests guidance in select areas. CMS proposes adjusting the Star Ratings to take into account the effects of extreme and uncontrollable circumstances (e.g. natural disasters) that occur during the performance or measurement period. CMS also proposes that adjustments be tailored to the specific geographic areas experiencing the extreme and uncontrollable circumstance. Overall, WellCare agrees with CMS's proposal, but would request that CMS provide additional guidance on select components of the proposal before implementing.

WellCare requests clarity on whether adjustments can be applied in consecutive years. WellCare requests that CMS provide clarity on whether plans can receive the proposed adjustments in consecutive years. For instance, if a specific geographic area experiences a natural disaster for two years in a row, will CMS make adjustments to Star Ratings in both years? Likewise, does CMS intend to impose caps on how many consecutive years plans could receive such an adjustment? Relatedly, we request that CMS consider and provide additional insight on how adjustments in consecutive years would be accounted for in the aforementioned cut point methodology.

In addition, we ask that CMS consider whether there might be special cases that warrant extending the extreme and uncontrollable circumstance adjustment into the performance year immediately following the originally impacted performance period. For instance, select regions in Florida and Texas are still recuperating from major hurricanes in the last couple years, while regions in California

are recovering from wildfires. In such regions, health plans continue to work to effectively service membership that might still be suffering from displacement and/or need for greater assistance.

WellCare requests clarity on how thresholds were chosen. Lastly, we ask CMS to provide justification on how the threshold of 25 percent of enrollees residing in Individual Assistance areas was chosen for application of the adjustment. In Hawaii, over 20 percent of our membership continues to experience the impacts of flooding and volcanoes, which in turn influences our ability to drive member outcomes. In such an instance, we believe an adjustment from CMS would be appropriate to accurately reflect health plan performance.

2. Improving Clarity of the Exceptions Timeframes for Part D Drugs (page 159)

WellCare agrees with CMS's proposed exceptions timeframes. More specifically, we support the proposal to require that plans notify an enrollee (and prescribing physician or other prescriber involved, as appropriate) of the decision no later than 72 hours (or 24 hours in the case of an expedited decision) of receipt of prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

C. Clarifying Program Integrity Policies

1. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (page 163)

WellCare agrees with CMS's preclusion list proposal. WellCare agrees broadly with CMS proposed revisions and additions to the preclusion list provisions that were finalized in the April 2018 Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS-4182-F) final rule.

Conclusion

WellCare appreciates the opportunity to provide comments on these important issues and to partner with CMS. If your staff would like further detail on any of our information, please feel free to contact me at (202) 902-2918. Thank you.

Sincerely,

Sohini Gupta
Vice President, Federal Government Affairs & Advocacy

TAB 18

Humana Comments

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Humana

December 31, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244
Submitted electronically via www.regulations.gov

RE: CMS-4185-P

Dear Administrator Verma:

This letter is in response to the Centers for Medicare and Medicaid Services (CMS) request for comments regarding the "Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021" proposed rule published in the November 1, 2018 *Federal Register*.

Humana Inc., headquartered in Louisville, Kentucky, is a leading health care company that offers a wide range of insurance products and health and wellness services that incorporate an integrated approach to lifelong well-being. As one of the nation's top contractors for Medicare Advantage (MA) with approximately 3.1 million members and Medicare Prescription Drug Plans (PDPs) with over 5 million members, we are distinguished by an over 30-year, long-standing, comprehensive commitment to Medicare beneficiaries across the United States. These beneficiaries – a large proportion of whom depend on the Medicare Advantage program as their safety net and many in underserved areas – receive integrated, coordinated, quality, and affordable care through our plans.

In summary, Humana is pleased and supportive of the agency's proposals to expand MA coverage of telehealth services and to mitigate large annual swings in Star Ratings cut points. We further commend CMS for preserving a pathway for plans to continue offering Dual Eligible Special Needs Plans (D-SNPs) in states where they do not have a Medicaid managed care contract. While we have numerous technical suggestions, our greatest concerns focus on the following:

- **MA Telehealth Coverage Expansion** – We strongly support CMS's proposed implementation of the Bipartisan Budget Act (BBA) of 2018. If implemented, the agency's proposal will give MA plans sufficient flexibility to expand beneficiary access to telehealth services. The expansion of telehealth coverage in the MA program also has the potential to reduce costs, particularly in geographic areas currently dominated by a small handful of providers. However, in order for plans to fully leverage market forces to drive competition and enhance access to care, we urge CMS to allow telehealth providers to comprise up to 10 percent of a plan's providers per specialty for purposes of meeting network adequacy compliance.

- **D-SNPs** – Humana believes that every dual eligible should have access to a choice of high quality D-SNPs. We are appreciative that CMS is acknowledging the variation in state approaches to managed care. However, we also urge CMS to ensure that the final rule supports integration efforts without the unintended consequence of blocking market access and thus limiting beneficiary choice.

- **MA Risk Adjustment Data Validation (RADV)** - On December 20, 2018, CMS announced that it would release the "data underlying" the Fee-for-service adjuster (FFSA) Study and extend the deadline for comments on the RADV portions of the Proposed Rule until April 30, 2019. Humana supports CMS's efforts to comply with its obligations under the Administrative Procedure Act by making available all of the information on which the FFSA Study relies. Additionally, Humana urges CMS to release this information as soon as possible, because stakeholders will need several months to review and analyze this supplemental information before submitting their comments. We intend to provide extensive feedback on the proposed RADV changes in a future comment letter.

As always, we value this opportunity to provide comments and are pleased to answer any questions you may have with respect to the comments below. We hope that you consider our comments as constructive feedback aimed at ensuring that together we continue to advance our shared goals of improving the delivery of coverage and services in a sustainable, affordable manner to Medicare beneficiaries, focused on improving their total health care experience.

Sincerely,



Mark A. Newsom
Vice President, Public Policy
mnewsom@humana.com

Additional Telehealth Benefits – Clinical Appropriateness and Provider Requirements

CMS proposes to allow Medicare Advantage Organizations (MAOs) to independently determine which telehealth services are clinically appropriate and consistent with professionally recognized standards of health care.

> **Humana comments: We support the CMS proposal to allow MAOs to independently determine which Part B services are clinically appropriate to be provided as Additional Telehealth Benefits consistent with professionally recognized standards of health care.** The agency's proposal aligns with current regulatory requirements at 42 CFR § 422.504(a)(3)(iii), which require MAOs to offer benefits in a manner consistent with professionally recognized standards of health care within existing regulations. Humana is committed to ensuring that our members receive high quality care. Our commitment necessitates staying abreast of the most recent professionally recognized and developing standards of health care, in concert with new advancements in modern medicine. We also monitor and comply with state laws, many of which require that telemedicine services be provided consistent with an in-person standard of care.[1] As a result, we believe that additional requirements would be redundant and unnecessarily burdensome for providers and MAOs.

Additional Telehealth Benefits – Capital and Infrastructure Costs and Investment

Section 1852(m)(2)(A)(ii) of the BBA of 2018 excludes capital and infrastructure costs and investments associated with Additional Telehealth Benefits.[2] CMS did not propose a specific definition of capital and infrastructure costs or investments; rather, the agency provides examples, including high-speed internet installation and service, communication platforms and software, and video conferencing equipment. CMS estimates that 15 percent of Additional Telehealth Benefits net costs will be attributable to capital and infrastructure expenses.

> **Humana comments: Humana recommends that the agency avoid adopting a prescriptive definition of Additional Telehealth Benefits capital and infrastructure costs and investments.** Due to the inevitable variability in plan offerings and the iterative and evolving nature of telehealth technology, a specific definition would be incapable of capturing the myriad of possible capital and infrastructure costs or investments.
>
> **Humana further recommends that CMS implement exclusions consistent with existing Non-Benefit Expense rules as defined in the Instructions for Completing the Medicare Advantage Bid Pricing Tools for Contract Year 2019 (CY2019 MA BPT Instructions).[3]** The CY2019 MA BPT Instructions for Non-Benefit Expenses specify the requirements for

[1] *See* Rule 64B8-9.0141, F.A.C., R.C. § 4731.74, V.T.C.A., Occupations Code § 111.007; https://www.lexology.com/library/detail.aspx?g=0ecc4572-1506-4141-b895-f574a571631b; https://www.texmed.org/Telemedicine/; http://www.ahca.myflorida.com/SCHS/telehealth/docs/TAC_Report.pdf.

[2] Pub.L. 115–123

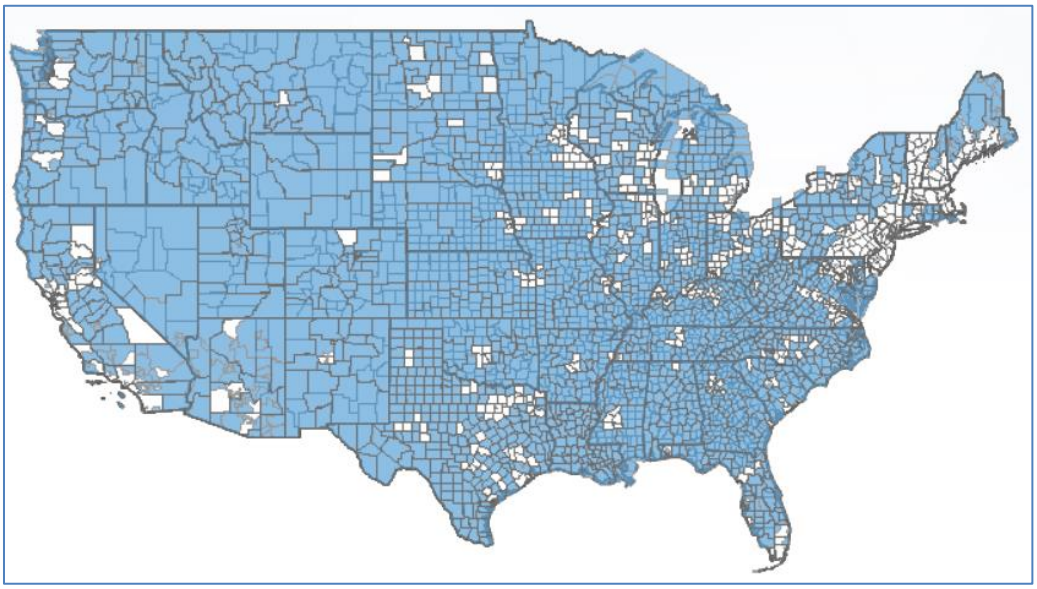
[3] See https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Pricing-Tools-and-Instructions-Items/BPT2019.html

deferring and amortizing capital expenditures which include cost of capital and infrastructure and investments associated with MA plan benefits including telehealth supplemental benefits. We recommend that CMS apply this same standard to Additional Telehealth Benefits.

Telehealth providers will bolster beneficiary access to specialty care

There are substantive mental/behavioral health access issues in the United States. In fact, almost 124 million Americans reside in Mental Health Care Health Professional Shortage Areas (HPSAs).[4] As illustrated by the county map below, outside the large urban centers, most American counties are a Mental Health HPSA.

Mental Health Care Health Professional Shortage Areas (HPSA) County Map[5]



In response to these access issues, Humana recently conducted a telepsychiatry pilot program in San Antonio, Texas, in which patients at certain primary care clinics were given the option of scheduling behavioral health visits from a telehealth provider. The program reduced the average wait time for a behavioral health visit by 47 percent, resulting in early indicators of decreased behavioral health and primary care hospitalizations. Humana agrees with the Assistant Secretary for Planning and Evaluation (ASPE) report that concluded that telehealth "can connect geographically dispersed patients and providers and is a promising approach to expand access and enhance quality of Medication-Assisted Treatment (MAT) for Opioid Use Disorder (OUD)."[6] The Department of Health and Human Services (HHS) has established the

[4] KKF State Health Facts Mental Health Care Health Professional Shortage Areas (HPSAs), available online at https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

[5] HRSA available online at https://data.hrsa.gov/hdw/Tools/MapToolQuick.aspx?mapName=HPSAMH

[6] Using Telehealth to Support Opioid Use Disorder Treatment, available online at https://aspe.hhs.gov/pdf-report/using-telehealth-support-opioid-use-disorder-treatment-issue-brief

reduction of opioid-related morbidity and mortality as a priority goal and has further established that this can be achieved through "improving access to prevention, treatment and recovery support services."[7] We believe that MA policies need to be aligned in support of this worthy objective.

Humana launched a similar pilot project aimed at reducing appointment wait times for dermatologists. The pilot leveraged teledermatology technology in several South Florida primary care clinics to reduce the wait time for a teledermatology consult to less than 24 hours. Independent studies have shown similar success in bolstering access to specialty care utilizing electronic exchange. A 2018 study published in Telemedicine and eHealth Journal, found that wait times for teledermatology consults averaged less than one day.[8] We urge CMS to allow MAOs to count these providers when determining compliance with MA network adequacy standards.

Telehealth providers could potentially inject new competition into highly concentrated health care markets

According to a recent analysis, 77 percent of Americans residing in urban markets live in highly concentrated health care markets.[9] Studies conducted by the Federal Trade Commission and academic researchers have consistently found that health care providers with significant market power can, and often do, demand above-market reimbursement rates, resulting in higher costs for the Medicare program and beneficiaries.[10] More recently, researchers have been able to obtain data to study market concentration among primary care and specialty physicians. For example, Brent Fulton recently calculated the Herfindahl-Hirschman Index (HHI)[11] for both primary care and specialty physicians across all Metropolitan Statistical Areas (MSAs). He found that the average HHI for specialty physicians and primary care physicians grew from 2010 to 2016, with 62 percent of specialty physicians and 35 percent of primary care physicians practicing in highly concentrated markets in 2016.[12] Moreover, a recent analysis by the Commonwealth Fund found that provider systems tend to be bigger, more

[7] Department of Health and Human Services Priority Goal: Reducing Opioid Morbidity and Mortality, available online at https://www.performance.gov/health_and_human_services/APG_hhs_2.html; see also CMS FY 2019 Congressional Justification, available online at https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2019-CJ-Final.pdf

[8] Jay Rajda, Mark P. Seraly, Joaquim Fernandes, Kyle Niejadlik, Henry Wei, Kathe Fox, Gregory Steinberg , and Harold L. Paz, Impact of Direct to Consumer Store-and-Forward Teledermatology on Access to Care, Satisfaction, Utilization, and Costs in a Commercial Health Plan Population (Feb. 2018) available at https://www.liebertpub.com/doi/pdfplus/10.1089/tmj.2017.0078

[9] Mathews AW. Behind your rising health care bills: secret hospital deals that squelch competition. *Wall Street Journal*. September 18, 2018.

[10] Ginsburg, Paul. Wide variation in hospital and physician payment rates evidence of provider market power. Center for Studying Health System Change, Research Brief No. 16. November 2010.

[11] The HHI measures the concentration of level of markets The U.S. Department of Justice considers a market with an HHI of less than 1,500 to be a competitive marketplace, an HHI of 1,500 to 2,500 to be a moderately concentrated marketplace, and an HHI of 2,500 or greater to be a highly concentrated marketplace.

[12] Fulton, Brad. Health care market concentration trends in the United States: evidence and policy responses. *Health Affairs*. 2017;36(9):1530-16538.

consolidated, and have more market share than payers in the same metropolitan areas.[13] **The growing availability and utilization of telehealth providers has the potential to inject new competition into highly concentrated health care markets. However, in order for MAOs to fully leverage this competition, CMS must allow plans to utilize telehealth providers to meet network adequacy requirements.**

Additional Telehealth Benefits – MA Network Adequacy

CMS is requesting stakeholder comments on what impact Additional Telehealth Benefits should have on network adequacy policies, including the degree to which providers should be considered in the assessment of network adequacy (including for certain provider types and/or services in areas with access concerns) and potential impact on rural MA plans, providers, and/or enrollees.

Humana comments: A recent report issued by HHS, the Department of Labor, and the Department of Treasury entitled, "Reforming America's Healthcare System Through Choice and Competition," recommends that the Administration "continue to provide flexible network adequacy standards for Medicare Advantage and other federally sponsored programs and avoid stringent requirements that are not conducive to innovation and modern medicine."[14] Consistent with the Administration's recommendation, we urge CMS to allow MAOs to count Additional Telehealth Benefit providers when determining compliance with MA network adequacy regulations.

Some observers have given the circular argument that telehealth cannot be used for network adequacy standards because those rules have traditionally been based on in-person face-to-face visits.[15] However, these requirements need to evolve with changes in technology and medical practice. CMS has already begun the transformation with the "Expanded Flexibility for Rural Areas" standard that went live in CY2018, where MA plans were allowed "to request an exception if they are using a telehealth or a mobile provider to meet network adequacy requirements" in rural areas.[16] Ongoing movement towards a more comprehensive and flexible network adequacy approach makes sense given that merely looking at time and distance to a physical location provides limited information about actual access. For example, one recent survey found that even in large metro markets with lots of providers within short distances, the average new patient physician appointment wait times have increased significantly (up 30% from

[13] Market Concentration Variation of Health Care Providers and Health Insurers in the United States, available online at https://www.commonwealthfund.org/blog/2018/variation-healthcare-provider-and-health-insurer-market-concentration

[14] Available online at https://www.hhs.gov/about/news/2018/12/03/reforming-americas-healthcare-system-through-choice-and-competition.html

[15] For example, MedPAC's December 19, 2018, comment letter to Administrator Verma on CMS-4185-P

[16] Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance (Last updated: February 20, 2018), available online at https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/2018-Network-Adequacy-Guidance.pdf

2014) to 24.1 days.[17] In mid-sized metro markets the average wait time is 32 days. CMS has acknowledged the role of telehealth and the need for moving beyond just a traditional time and distance standard for network adequacy in the Medicaid program. Given the relative vulnerability of Medicaid recipients, one cannot justify accepting telehealth as part of network adequacy for that population while rejecting it for Medicare beneficiaries. In the November 14, 2018, Medicaid Managed Care Proposed Rule CMS stated the following:

> *As states have worked to comply with the final rule, they have alerted us to increasing concerns about the appropriateness of uniformly applying time and distance standards. In some situations, time and distance may not be the most effective type of standard for determining network adequacy and some states have found that time and distance analysis produces results that do not accurately reflect provider availability. For example, a state that has a heavy reliance on telehealth in certain areas of the state may find that a provider to enrollee ratio is more useful in measuring meaningful access, as the enrollee could be well beyond a normal time and distance standard but can still easily access many different providers on a virtual basis. A 2017 Brookings/Schaefer Center report notes that in some clinical areas, telemedicine could make proximity measures obsolete, or counterproductive.*[18]

Proposed methodology for balancing beneficiary protection and market competition

Humana applauds CMS for requiring that beneficiaries be given the choice of receiving Additional Telehealth Benefits via telehealth or in-person. This requirement ensures that no plan can seek to construct a provider network comprised primarily or solely of telehealth providers. **With this important beneficiary protection in place, we recommend that CMS allow MAOs to include Additional Telehealth Benefit providers in their network adequacy calculations. More specifically, we recommend that CMS revise existing MA network adequacy guidance to allow telehealth providers to comprise up to 10 percent of an MAO's providers per specialty for purposes of meeting network adequacy compliance.** For example, if network adequacy standards require an MA plan to provide access to ten psychiatrists in its network for a particular geographic area, we recommend that MA plans be able to contract with an Additional Telehealth Benefit telepsychiatry provider to serve as one of the required ten providers. **We believe this innovative approach could serve as an important first step in modernizing the traditional MA program's time and distance standards for purposes of network adequacy.** The current metric reflects an in-person system of care and is not readily applicable to telehealth and remote monitoring services. In addition, we

[17] Merritt Hawkings 2017 Survey of Physician Appointment Wait Times, September 22, 2017, available online at https://www.merritthawkins.com/uploadedFiles/MerrittHawkins/Content/Pdf/mha2017waittimesurveyPDF.pdf

[18] 83 FR 57278-9 available online at https://www.govinfo.gov/content/pkg/FR-2018-11-14/pdf/2018-24626.pdf. Note that at least four states – California, Colorado, Hawaii, and Illinois – have passed legislation allowing for telehealth providers to count toward network adequacy requirements, while others are examining granting similar flexibility via regulation.

recommend that CMS allow MAOs to include Additional Telehealth Benefit providers toward network adequacy in Counties with Extreme Access Considerations (CEAC), rural counties, and micro counties as defined in the agency's network adequacy regulations. We note that plans are already permitted to request exceptions to network adequacy requirements in these counties if certain conditions are met.[19] **We recommend that CMS modify the existing guidance to allow plans to count the Additional Telehealth Benefit providers toward network adequacy in these counties without needing to file an exception. We further urge CMS to work with stakeholders to collaboratively develop a new approach to measuring network adequacy – one that better reflects the growing availability and utilization of telehealth.**

Additional Telehealth Benefits – Differential Cost Sharing

CMS proposes to allow MA plans to maintain variable cost sharing for the specified Part B service(s) furnished through an in-person visit and the specified Part B service(s) furnished through electronic exchange. This proposal aligns with how CMS has traditionally interpreted section 1852(a)(1)(B)(i), (iii), (iv), and (v) of the of the Social Security Act to mean that basic benefits must be covered at an actuarially equivalent level of cost sharing from a plan level.

Humana comments: CMS has traditionally allowed plans flexibility in varying cost sharing for providers, including pharmacies in Medicare Part D. CMS ensures beneficiary protections with detailed rules for cost sharing and vigorous oversight of plans.[20] CMS has even, in the case of the Medicare Advantage Value-Based Insurance Design (VBID) Model, waived the uniform cost-sharing requirements at 42 CFR §§ 422.2, 422.100(d)(2), 422.254(b)(2) and 422.262(c)(1).[21] In both the traditional MA program and the VBID demonstration plans have varied cost sharing without a problem, when in compliance with CMS rules. **Accordingly, we recommend that CMS continue to allow plans to vary beneficiary cost sharing for both in-person and telehealth visits.**

Additional Telehealth Benefits – Supplemental Benefits

For those services that do not meet the requirements for Additional Telehealth Benefits, CMS proposes to continue allowing MA plans to offer supplemental benefits via remote access technologies and/or telemonitoring.

Humana comments: We support the agency's proposal. Plans are already leveraging these technologies to support improving access to and timeliness of needed care, increase convenience for patients, increase communication between providers and

[19] Available online at https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/2018-Network-Adequacy-Guidance.pdf

[20] See Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections for guidance https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf; and Part C and Part D Compliance and Audits for oversight background https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/index.html

[21] 2017 VBID request for applications, available online at https://innovation.cms.gov/Files/reports/VBID-RFA-10-9-15.pdf

patients, enhance care coordination, improve quality, and reduce costs related to in-person care.

Studies of remote patient monitoring consistently show the effectiveness of authorizing additional telehealth services under the Remote Access Technology Supplemental Benefit. For example, a 2015 published study on the utilization of remote patient monitoring for chronic obstructive pulmonary disease and heart failure found a 50% reduction in 30-day re-admission and 13-19% reduction in 180-day re-admission.[22] A 2013 study utilizing remote patient monitoring of blood pressure (BP) in conjunction with pharmacist case management found that telemonitoring improved BP control compared to standard care.[23] **Plans should not be prevented from continuing to offer coverage of such services solely because they fail to meet the agency's proposed definition of Additional Telehealth Benefits.**

Additional Telehealth Benefits: Provider Selection & Credentialing

CMS proposes to require that MA plans furnishing Additional Telehealth Benefits may only do so using contracted providers. CMS further proposes to require that MA plans have written policies and procedures for the selection and evaluation of providers. The policies must conform to MA credentialing requirements described in § 422.204.

Humana comments: Humana strongly supports the agency's proposal to limit Additional Telehealth Benefits' services to the plan's participating providers. Humana agrees with CMS that limiting delivery of Additional Telehealth Benefits to contracted providers will help MA plans ensure that providers are sufficiently qualified and capable of providing high quality, clinically appropriate telehealth services.

Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE

CMS proposes several revisions and additions to the preclusion list provisions that were finalized in the April 2018 Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-F) final rule (hereafter referred to as the "2019 Final Rule").[24] CMS proposed to consolidate the revocation and preclusion list appeals processes to run concurrently rather than consecutively and the

[22] Davis, C., Bender, M., Smith, T., Broad, J. (2015). Feasibility and Acute Care Utilization Outcomes of a Post-Acute Transitional Telemonitoring Program for Underserved Chronic Disease Patients. Telemedicine and e-Health, 21(9), 705-713; available at https://www.ncbi.nlm.nih.gov/pubmed/25955129

[23] Margolis, K., Asche, S., Bergdall, A., Dehmer, S., Groen, S., Kadrmas, H., Kerby, T., Klotzle, K., Maciosek, M., Michels, R., O'Connor, P., Pritchar, R., Sekenski, J., Sperl-Hillen, J., Trower, N. (2013). Effect of Home Blood Pressure Telemonitoring and Pharmacist Management on Blood Pressure Control: A Cluster Randomized Clinical Trial. JAMA 310(1):46-56 available at http://web.b.ebscohost.com/ehost/detail/detail?vid=2&sid=227cc6ac-091b-4af9-826de8d8d8cea374%40sessionmgr112&hid=110&bdata=JnNpdGU9ZWhvc3QtbGl2ZQ%3d%3d#db=mnh&AN=23821088

[24] See https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf

prescribers or providers would only be placed on the preclusion list after exhausting their first level of appeal. In addition, CMS proposes changes to beneficiary notification time frames as well as a technical proposal that a beneficiary does not have the right to appeal when payment is denied because a provider or prescriber is on the preclusion list. Finally, CMS proposes a technical correction to the definition of preclusion list to more clearly incorporate the applicability of felony convictions. CMS proposes that the effective date of these additions and revisions, if finalized, would be January 1, 2020 except for the consolidated appeals provisions which would be effective 60 days after the final rule. However, the January 1, 2019 effective date of preclusion list requirements in the final April 2018 rule remain in effect.

Humana comments: We appreciate that CMS believes the preclusion list is necessary to protect the Medicare program and beneficiaries, and generally support such efforts. However, the standards for 2019 and 2020 conflict with each other and with existing plan requirements. They are internally inconsistent and contradictory, and create unnecessary burdens and operational complications for plans. Given the potential for serious operational issues, Humana respectfully requests that CMS postpone implementation of the preclusion list requirements, and engage with stakeholders in a careful discussion to address the challenges discussed in detail below.

Humana strongly urges CMS to delay all preclusion list requirements until January 1, 2020. The proposed rule would significantly change the requirements previously set. In an apparent attempt to bridge the gap between the prior standards and these proposed regulations, CMS issued the HPMS Memo setting forth "recommendations" for 2019 that layer on top of the existing regulations effective January 1, 2019.

However, the HPMS Memo conflicts with the regulations set forth in the 2019 Final Rule, and it will be impossible for plans to both comply with the regulations and follow the "recommendations." For example, the Final Rule prohibits MAOs from paying claims for items and services that were furnished by a provider on the preclusion list, and does not include any requirement that the MAO send notice to the member or otherwise provide for any delay before denying payment.[25] The HPMS Memo, in contrast, "recommends" that MAOs wait for 90 days before denying payment. It will be impossible for MAOs to comply with both the immediate and the 90-day timeframe for claims denials. The notice and other "recommendations" also introduce numerous legal and operational problems, as set forth below.

The HPMS Memo seemingly seeks to impose additional requirements that go beyond the 2019 Final Rule's provisions and that must be promulgated through notice-and-comment rulemaking. For example, the HPMS Memo states that MAOs must remove

[25] The proposed regulations apply to health care items and services furnished by individuals and entities on the preclusion list and to pharmacy claims and requests for reimbursement for Part D drugs prescribed by a prescriber on the preclusion list. For simplicity, Humana refers to these individuals, entities, and prescribers as "providers," except where the context requires otherwise.

precluded providers from their networks as soon as possible. This obligation, along with other "requirements" and "recommendations" in the HPMS memo, are not in the 2019 Final Rule and cannot be implemented through an HPMS memo.

It appears that CMS has attempted to use the HPMS Memo to clarify the agency's expectations for 2019, leaving this proposed rule's regulations to apply in 2020. Critically, however, the HPMS Memo creates inconsistencies and improperly imposes additional obligations. These issues need to be addressed through notice-and-comment rulemaking. For these reasons, CMS should delay the effective date of the 2019 Final Rule, and all preclusion list requirements, until January 1, 2020. At a minimum, CMS should withdraw the HPMS Memo and/or clarify that it does not create binding requirements.

CMS proposes to require that plans deny claims beginning 60 days from the date the plan sends notice to the member. Because CMS proposes to require plans to send the notice within 30 days of the provider being placed on the preclusion list, this means that plans would start denying payments at a certain point 61-90 days after the provider is placed on the preclusion list and that they would be prohibited from issuing denials before that date.

Humana comments: **Humana strongly urges CMS to allow plans up to 90 days to begin denying payments, meaning that plans would be allowed to stop paying the claims immediately, as plans are required for providers excluded by the HHS Office of the Inspector General (OIG), while also providing discretion to begin denials at any point within 90 days if there is no other legal requirement to act immediately.**

Requiring plans to pay claims for a period of time after the provider is placed on the preclusion list conflicts with other requirements that plans must follow and introduces multiple challenges. Specifically, the statute prohibits plans from making payment for services provided by excluded providers (whom CMS intends to place on the preclusion list), and does not allow for any delay between the exclusion and the payment denials. CMS acknowledged this statutory requirement in the preamble to the proposed rule, noting that "section 1862(e) of the Act (42 USC 1395y(e)) is clear that no federal health care program payment may be made for any items or services furnished by an excluded individual or entity, or directed or prescribed by an excluded physician." CMS also indicated that it would issue guidance as to which member notice requirements would apply in the event that a provider is both excluded and precluded. Humana is not aware that such guidance has been issued, and it is not clear that this guidance would eliminate the conflict, as it will address only the notice requirement and leave the prohibition on payment in the regulation intact.

Because the statute prohibits plans from making payment for items and services furnished or prescribed by an excluded provider, CMS cannot impose a separate requirement that plans continue to pay claims for precluded providers (some of whom will also be on the exclusion list) for a particular period of time. As such, Humana

strongly recommends that CMS allow plans to begin denying payment at any point up to 90 days following the provider's placement on the preclusion list. Under this proposal, plans could begin denying some claims immediately (e.g., those associated with providers also on the exclusion list) while paying others for a short period of time. As noted below, **Humana also recommends that CMS limit the preclusion list to providers who are not on the exclusion list so as to avoid conflicts between the exclusion and preclusion requirements.** If such a step is not taken, allowing plans up to 90 days to begin denying payment would allow plans to meet their obligation, under both OIG and CMS regulations, to deny claims for items and services provided by an excluded provider, while also allowing time – where permitted – for members to be notified and transition to a new provider. This would also be more consistent with MAOs' current obligations to provide members with 30 days' advance notice of a provider's contract termination.[26] It is not clear why a provider placed on the preclusion list should continue to be paid for a longer period of time than a provider whose contract terminates for another reason.

The proposed regulations do not contain any requirement to terminate a precluded provider. The HPMS Memo, however, indicates that CMS expects plans to terminate precluded providers as soon as possible.

Humana comments: **If CMS intends to require plans to terminate precluded providers from their networks, the agency should promulgate this requirement through notice-and-comment rulemaking. If CMS undertakes such a step, then Humana recommends that plans be permitted to terminate providers at any point up until plans are obligated to begin denying payments.**

As an initial matter, Humana notes that the requirement to terminate a precluded provider from the network is not part of the existing or proposed regulations. Rather, CMS noted this "requirement" in the HPMS Memo, which (as stated above) CMS should clarify is non-binding. Any such expectation should be promulgated through notice-and-comment rulemaking, thus providing stakeholders with a meaningful opportunity to comment.

If CMS issues such a rule, the agency should clarify when plans should terminate providers. Plans may need or prefer to remain contracted with a provider for a short period of time for multiple reasons. For example, plans that do not offer any out-of-network benefit would have no means of paying claims submitted by or on behalf of a non-network provider. Additionally, plan benefit designs provide members lower cost-sharing and other benefits when care is received through a contracted provider, as compared to receiving services from a non-contracted provider. A requirement to terminate a contract while payments are still being made would unnecessarily complicate delivery of the plan benefit. In addition, plans should be able to retain

[26] See 42 CFR § 422.111(e).

contractual protections for themselves, including contractual obligations imposed on providers and agreed-upon pricing terms, while they are still making payments.

Allowing termination up until denial of the claims would also conform to CMS's requirement to notify members that a plan is terminating a network provider and to similar state laws.[27]

CMS proposes to codify a requirement that an MAO's contract with CMS provide that a member shall not have any financial liability for services or items furnished by a contracted provider on the preclusion list.

Humana comments: Humana recommends that, rather than imposing a hold harmless obligation on plans, CMS directly prohibit the precluded provider from billing or otherwise seeking payment from the member. Alternatively, Humana recommends that CMS clarify that an MAO's obligation to hold the member harmless does not apply once either (1) the precluded provider's contract is terminated or (2) the MAO must deny payment.

Humana is concerned that a hold harmless requirement that applies to plans will result in plans being faced with conflicting requirements – that they not pay claims by providers, while also requiring that they hold members harmless if the provider bills the member. If the provider were to do so, plans might have to pay the provider (in order to hold the member harmless), which would conflict with the requirement not to pay a claim. Alternatively, plans might have to reimburse a member who has made payment to the provider, effectively allowing the provider to evade the impact of the preclusion list.

Accordingly, CMS should prohibit precluded providers from billing members as part of the preclusion process. At a minimum, if CMS does not take this route, Humana encourages CMS to clarify the scope of its proposed regulation. CMS's existing regulation requires that MAOs protect their members from "incurring liability … for payment of any fees that are the legal obligation of the MA organization."[28] To apply this to the preclusion context, CMS proposes to prohibit members from having "any financial liability for services or items furnished to the enrollee by an MA contracted individual or entity on the preclusion list." (This would be codified at 42 CFR § 422.504(g)(1)(iv)). As such, the hold harmless requirement would apply to fees (1) that are the MAO's legal obligation and (2) that result from items or services furnished by contracted providers.

Humana recommends that CMS confirm that the hold harmless requirement does not apply to services and items furnished by precluded providers after their contracts

[27] See 42 CFR § 422.111(e).
[28] See 42 CFR § 422.504(g)(1).

have been terminated. At this point, the provider will no longer be considered to be a contracted provider, and the terms of section 422.504(g)(1)(iv) would not apply.

Similarly, Humana recommends that CMS confirm that the hold harmless requirement does not apply to claims that the MAO is obligated to deny per 42 CFR § 422.222(a)(1). As payment for these claims is prohibited, it appears that any related fees would not be considered to be the legal obligation of the MAO. Accordingly, section 422.504(g)(1) would seem inapplicable. Humana requests that CMS confirm this interpretation.

CMS's proposal does not contain a set "look back" period indicating which members must be notified of a precluded provider. CMS provided some guidance on this issue in the HPMS Memo, which indicates that plans must notify those members who have received care from the provider in the last twelve months.

Humana comments: CMS should revise proposed §§ 422.222(a)(1)(ii)(A) and 423.120(c)(6)(iv)(A) to clarify that plans need only notify a member who has received services furnished by a precluded provider in the twelve months prior to the date the provider was added to the preclusion list.

Codifying a "look back" period in regulation will provide clarity to plans as they operationalize this standard. Without such a standard, plans will not have clear guidelines by which to determine which members they should notify. Although plans could rely on the HPMS Memo's instruction to use a twelve month "look back" period, the HPMS Memo does not clearly indicate when this twelve month period begins. Humana requests that CMS confirm that the period begins on the date the provider is added to the preclusion list. Under this interpretation, the notice requirement would not apply to members who first receive care from the precluded provider after the date the provider is placed on the preclusion list.

As recommended above, payment denials should be allowed to begin at any point up to 90 days after the provider is placed on the preclusion list. Any member notice requirement should be independent of the timing for denying payments.

CMS proposes that plans make "reasonable efforts" to notify precluded providers of the members who were provided with the notice as described above. In the HPMS Memo, CMS states that plans "may" notify precluded providers by copying them on the required notice sent to members.

Humana comments: CMS should remove the requirement that plans notify the provider of the members who were notified of their preclusion. These notification requirements are duplicative of notices provided by CMS, and create unnecessary costs and administrative burden for plans. CMS's proposed regulations would already require that CMS notify a provider to be added to the preclusion list. Creating an additional requirement for plans to provide a similar notice would only duplicate this effort.

> The Final Rule generally prohibits a PDP Sponsor from making payment to an individual on the preclusion list who prescribed a drug to a Part D member. A commenter noted that the Part D preclusion list should also include entities such as pharmacies, as some pharmacies have participated in fraud schemes.[29]
>
> CMS replied to this comment that "this was our intent" and that "[t]he preclusion list will prevent any individual or entity that is able to prescribe or provide services under the Medicare Part C and D programs from prescribing or providing those services….".[30] CMS nonetheless finalized the Part D preclusion list as applicable only to individuals who prescribe.

CMS proposes to revise the scope of the Part D prohibition on payment for a drug prescribed by a precluded "individual" to a precluded "prescriber" as "some states permit pharmacies to prescribe medications." Additionally, CMS notes in the HPMS Memo that it expects a Part D plan to remove a pharmacy from its network "as soon as possible."

> **Humana comments**: Humana requests that CMS clarify the scope of the Part D preclusion list, indicating whether and how it applies to pharmacies. CMS should revise the Part D regulation to extend to precluded entities that furnish Part D drugs, in addition to prescribers, if that is CMS's intent. In the absence of a regulatory provision, CMS should withdraw guidance that appears to require denial of payment to pharmacies furnishing Part D drugs.
>
> CMS's statements to date could be read to suggest that CMS intends to add to the preclusion list pharmacies that do not prescribe drugs to Part D members but do fill member prescriptions. Humana urges CMS to address this in the regulation text. As written, the Part D regulations require denial of payments to precluded "prescribers," and do not extend to include pharmacies that fill member prescriptions.[31]
>
> Despite the clear regulatory language, however, the Final Rule preamble states that CMS intends for the Part D preclusion list to include individuals and entities that provide services under Part D in addition to prescribers and not just those that prescribe.[32] The HPMS Memo also states an expectation that PDP Sponsors remove pharmacies from its network as quickly as possible upon their addition to the preclusion list.
>
> The current guidance is not supported by the regulations. Accordingly, Humana requests that CMS limit the preclusion list, and the related provisions for plans, to those pharmacies that are prescribers, until such time as the regulations are modified. The

[29] 83 Fed Reg at 16651.
[30] Ibid.
[31] 42 CFR § 423.120(c)(6)(i); see also 42 CFR 423.100 (defining preclusion list as a list of "prescribers").
[32] 83 Fed Reg at 16651.

current guidance and inclusion of pharmacies other than prescribers on the preclusion list, risks exposing PDP Sponsors that deny payments to pharmacies on the preclusion list to legal claims in light of the lack of regulatory authority for those denials.

As noted above, CMS proposes to prohibit MAOs from making payment "for a health care item or service furnished by an individual or entity that is included on the preclusion list." CMS also proposes to require the MAO to hold the member harmless for items and services furnished by an MA contracted individual or entity on the preclusion list.

Humana comments: CMS should confirm this payment prohibition applies to requests for reimbursement that are submitted directly by members.

In some circumstances, MA members may submit requests for reimbursement to MAOs. Humana interprets CMS's proposed § 422.222(a)(1) to apply to these member-submitted requests for reimbursement since they are "for a health care item or service furnished by an individual or entity that is included on the preclusion list." Humana requests that CMS confirm this interpretation.

Further, if this interpretation is confirmed, Humana requests that CMS clarify that denial of claims under these circumstances is required irrespective of any hold harmless provisions that may otherwise apply. As noted above, Humana recommends that providers be precluded from billing members; and if CMS adopts that recommendation, there should not be member requests for reimbursement.

CMS proposes to codify a policy denying members the right to appeal a payment denial that is made on the grounds that the provider was precluded.

Humana comments: Humana supports this proposal.

In a FAQ document released on August 2, 2018, CMS indicated that providers "will not drop off the Preclusion List." Rather, the list will indicate the date the provider's preclusion ends. In the preamble to the proposed rule, however, CMS makes several references to "removing" providers from the preclusion list.

Humana comments: Humana requests that CMS provide clarification as to whether providers will be removed from the preclusion list, or whether they remain on the preclusion list with a date indicating the end of their preclusion period.

CMS's statements in the August FAQ and the preamble to the proposed rule appear to contradict each other, and it is not clear whether providers will be truly removed from the preclusion list. In order to operationalize the preclusion list requirements, plans need to know how and whether they should track the end of providers' preclusion periods. For example, will plans need to keep historic preclusion list data in order to determine whether a provider is still precluded?

CMS proposes that providers be added to the preclusion list following either the expiration of the 60-day appeals window (for providers who do not appeal) or the provider's unsuccessful first level appeal (for providers who appeal). CMS proposes one exception for this: OIG excluded providers would be added to the preclusion list effective on the date of the exclusion.

> **Humana comments**: We recommend that CMS clarify that the removal of a provider who successfully appeals his or her addition to the preclusion list would not be retroactive to the date of the provider's original preclusion, and that the plan would not be required to retroactively pay claims for such a provider.
>
> Providers may lose their first appeal (and thus be placed on the preclusion list) but subsequently succeed in overturning CMS's decision to place them on the preclusion list. In the interim, the provider would be on the preclusion list. CMS has not described how plans should implement such a provider's removal from the preclusion list. For example, will the removal apply retroactively? Should plans pay claims if the provider re-submits them?
>
> CMS's statements in the preamble to the Final Rule indicate that the removal does apply retroactively, thus suggesting plans should pay re-submitted claims: "[h]owever a provider or prescriber would need to resubmit any claims denied as a result of the preclusion."[33] Humana notes that requiring plans to pay such claims retroactively may create confusion among members, who may be urged by their precluded providers to continue to see the precluded provider during the appeals. Further, members may be liable for cost sharing associated with the re-submitted claims. Finally, plans would face uncertainty in determining how to pay such claims (i.e., at what payment rate), as the provider contract will likely have been terminated. As such, Humana encourages CMS to reconsider its position stated in the Final Rule, and to issue clarification on this issue.

Consistent with the Final Rule, CMS proposes to include excluded providers on the preclusion list.

> **Humana comments**: CMS should narrow the scope of the preclusion list such that it does not include excluded providers. Per section 1128 of the Social Security Act, the OIG has the authority to exclude providers from participation in any Federal health care program for a variety of reasons.[34] Plans are statutorily barred from paying for services rendered by these excluded providers.[35] CMS's attempt to overlay a set of preclusion standards on top of the existing statutory exclusion requirements is unnecessary, creates numerous inconsistencies, and imposes operational complexities.

[33] 83 Fed Reg at 16663.
[34] 42 USC § 1320a-7.
[35] 42 USC § 1395y(e); 42 CFR §§ 422.224 and 422.752(a)(8).

For example, as described above, the Social Security Act prohibits plans from making payment for services rendered by excluded providers. There is no grace period after a provider's inclusion on the exclusion list during which plans can continue to make payment. In contrast, the proposed rule would require plans to continue making payment for services rendered by precluded providers (some of whom are also excluded) for a period of time to allow for member notice and transition to a new provider. Complying with both of these standards simultaneously is impossible, and CMS cannot create a rule that directly conflicts with the Social Security Act.

Although CMS could potentially create exceptions to the preclusion list requirements for excluded providers or revise the preclusion list requirements to be consistent with those applicable to excluded providers, simply defining the preclusion list such that excluded providers are not included would be administratively cleaner and easier to operationalize. A comprehensive set of statutes and regulations sets forth procedures for handling excluded providers and provides adequate protection for the MA program and Medicare beneficiaries. Overlaying additional requirements is unnecessary and creates challenges for plans. As such, CMS should narrow the scope of the preclusion list such that it does not include excluded providers.

Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

Section 1860D–4(c)(6)(A) of the Social Security Act, as added by section 50354 of the BBA of 2018, provides that the Secretary shall establish a process under which the sponsor of a PDP that provides prescription drug benefits under Medicare Part D may request, beginning in plan year 2020, that the Secretary provide on a periodic basis and in an electronic format, standardized extracts of Medicare claims data about its plan enrollees. CMS outlined the timeline for implementation in which data would be available during the third quarter of 2020 at the earliest.

CMS proposes that plan sponsors will be permitted to use the data to optimize therapeutic outcomes, improve care coordination, or to aid in certain health care operations or fraud and abuse or compliance activities under the HIPAA privacy regulations. Furthermore, plan sponsors would be prohibited from using the data to inform coverage determinations under Medicare Part D, conduct retroactive reviews of determinations related to medically accepted indications, to facilitate enrollment changes to a different Part D or MA-PD plan offered by the same parent organization; and/or inform marketing of benefits.

Humana comments: Humana has long supported and advocated for the policy goals authorized in the BBA of 2018 in which Medicare Parts A and B Fee-For-Service (FFS) claims data can be used by PDP sponsors to improve outcomes, increase care coordination, and support health care operations. **Beyond the uses outlined in the BBA of 2018, we recommend allowing the use of FFS claims data for value-based contracting which aligns with the spirit of the directives of the BBA to improve health outcomes.**

Care Coordination

Humana has demonstrated the value of utilizing FFS Medicare claims data to improve outcomes through care coordination. Humana is currently participating in the Center for Medicare and Medicaid Innovation's five-year Part D Enhanced Medication Therapy Management (EMTM) Model which permits participating stand-alone basic Medicare PDP sponsors a flexible approach to customize MTM services for their population. All PDP members in the five demonstration regions are eligible for MTM services and participating PDPs conduct risk modeling to target members for EMTM interventions. All plans participating in the EMTM demonstration receive Medicare Part A and B FFS claims history extracts for EMTM members on a monthly basis in addition to three years of historical data.

As part of participation in the program, Humana will use the data in plan year 2020 to inform predictive modeling and risk stratification of members into four risk tiers for EMTM targeting that include Monitoring, Low, Medium, and High Risk. The current suite of EMTM services includes Comprehensive Medication Reviews (CMRs), Therapeutic Medication Reviews (TMRs), medication reconciliation, and patient education. All or a combination of these services are deployed depending on the stratification of risk. For example, the cost stratification model utilizes input variables created from the one year of medical and pharmacy claims history (at the time of cost prediction) that characterize the members' conditions, events, and medication utilization. A diagnosis code present in a member's medical claims history will affect specific input variables to our model. For example, suppose an ICD10 diagnosis code of 'A15' corresponding to Respiratory Tuberculosis has appeared in one or more claims within the 1 year claims history for a member. For this member, the indicator variables corresponding to the Level 1 & Level 2 CMS Diagnosis Categorizations of "Certain Infectious and Parasitic Diseases" and "Tuberculosis" respectively will each be set to 1, reflecting this member's history of contracting Tuberculosis. Similarly, the cost variables corresponding to these diagnosis categories would reflect the total allowed costs incurred on the claims with the code 'A15'. Thus, to summarize, diagnoses appearing within the member's claims history affect associated input variables fed into the model, and are not used to represent outcomes.

Purposes and Limitations on the Use of Data

Humana has implemented over 40 value-based contracts for prescription drugs since 2014. In our experience establishing effective value-based contracts, we have found that robust agreements require historical medical claims data to measure the outcome. The lack of historical FFS claims data for PDP members who have enrolled with Humana for the first time creates barriers to negotiating value-based contracts with manufacturers. For instance, in the recent value-based contracts executed by Humana in 2017 and 2018, only a third (4 out of 13) could be applied to PDP utilization due to the lack of FFS Medicare Part A and B claims data. Additionally, manufacturers often require a minimum number of members to qualify for a value-based contract and having

comprehensive FFS claims data on our PDP members would allow for the expansion of value-based contracts, especially in orphan diseases where achieving the minimum number of members is a frequent barrier. We recommend that CMS permit the use of FFS claims data to support these functions which will allow execution of more outcomes-based drug contracting arrangements with manufacturers, ultimately producing higher value and greater affordability for members in the Part D program.

Additionally, the timing and the lookback period of FFS claims data is a critical element in effectively using the claims data to support the execution of value-based contracts. The proposed rule indicates that CMS anticipates that it will be able to start providing data to plan sponsors quarterly on a go-forward basis in the first quarter of 2020 with the first data transmissions to plan sponsors during the third quarter of 2020. For the purposes of value-based contracts, it is often necessary to establish baseline costs (i.e. previous medical events and/or prior treatments) for multiple years prior to the contract year. Therefore, we would recommend that CMS use a similar operational standard that was defined for the EMTM program with a monthly data transmission on all members with at least a one year lookback period for all new members, including a historical transmission for all members in 2019. Without the historical 2019 data transmission, it would be difficult for plan sponsors to use the data in a meaningful way until the 2023 contract year, a full three years after the implementation of the data sharing provisions authorized by the BBA of 2018.

Data Extract Contents

Humana agrees with the proposed list of data elements for all Part A and B services for all seven claims types. In addition to those proposed elements, we recommend the inclusion of additional elements in order to support the evaluation of effectiveness of value-based contracts. In our experience, we have found that the data elements listed below are most effective at increasing the effectiveness of outcome-based contracts, total cost of care reduction guarantees, and resource utilization contracts. As such, we would recommend the inclusion of these data elements:

- **National Drug Code (NDC):** Since some Part B covered drugs share J-codes, NDCs are necessary to understand a member's treatment history.
- **Lab Results**: When available, plan sponsors should be provided with lab results which will help in assessing a drug's effectiveness (e.g., HbA1c for diabetes).
- **Patient Reported Outcomes (PRO)**: To date, CMS is not collecting any self-reported or wearable data from members. However, as new technologies (wearables, apps, etc.) emerge in this area, because CMS may choose to collect it in the future along with the possibility to bill for these services (telehealth/remote monitoring), we would request these data be added when available.

As CMS considers the options for operationalizing the data-sharing mechanisms for sharing the Part A and B data, we provide the following recommendations:

- **Tools:** Through the EMTM program, participating plan sponsors received nine different Part A and B claims files on a fraction of their total beneficiary enrollment. The volume of data made available to PDPs through the authority granted by the BBA is exponentially expanding. We encourage CMS to avail Part A and B data to PDPs through Application Programing Interfaces (APIs). An API is an interface that allows unrelated data within programs to communicate with one another. They act as bridges between two data applications, allowing data to flow regardless of how each application was originally designed. A report released by the API Task Force, along with the Health IT Policy and Standards Committee, found that when properly secured and managed, the benefits of APIs outweigh the risks.[36] We would also recommend leveraging the processes established through Blue Button 2.0 to allow beneficiaries to release Parts A and B claims directly to PDP plan sponsors. This will create another avenue in which plan sponsors can support the adoption of the use of Blue Button 2.0 to support faster data distribution to plans sponsors.
- **Frequency:** As stated above, receiving the first data transmission in the third quarter of 2020 would make it difficult to effectively use the data to meet the goals of the BBA in 2020. **As the data ages, it becomes become more challenging to use it to take actionable steps to support health care outcomes. Given this, we recommend that CMS examine opportunities to provide information in as close to real time as possible.**

Part D Adjudication Timeframes – Improving Clarity of the Exceptions Timeframes for Part D Drugs

CMS proposes to amend 42CFR §423.568(b), 423.570(d)(1), and 423. 572(a) to state that, for an exception request, the plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 72 hours (or 24 hours in the case of an expedited decision) of receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

Humana comments: We appreciate CMS's effort to clarify the requirement for plans to notify the member and prescriber of an exceptions request within 14 calendar days. The proposed timeline of 14 calendar days aligns with Humana's current internal policies and procedures for notifying members and prescribers of the decision on an exception request when tolling occurs due to the need to collect a prescriber statement. However, the proposed standard does not allow the plan an appropriate amount of time to complete clinical analysis on the request in the event that the prescriber statement is received toward the end of the proposed 14-day time period, for example on calendar days 12 through 14. In these instances, the plan would be required to adjudicate the request on the *same day* that the prescriber's supporting statement is received, limiting the timeline to render a clinically valid decision and exacerbating the existing policy

[36] Application Programming Interface (API) Task Force Recommendations, 05/12/2016

issue that CMS is attempting to resolve by establishing a standard 14-calendar day timeline. CMS has acknowledged that they are trying to strike a balance between providing greater certainty to members and the importance of receiving prescriber statements. The approach outlined in the proposed rule greatly compresses the adjudication timeline for the plan in instances where the prescriber statement is received very late in the 14-day period for the plan to effectively review the prescriber statement and issue a decision.

In order to ensure that members receive a clinically valid decision and the plan is provided with enough time to complete the analysis, we recommend that CMS modify the proposed language such that the plan begins the adjudication timeline of 72 hours (or 24 hours for expedited request) on the date that the prescriber statement is *received or when tolling expires* on the 14th calendar day, whichever comes first. We would recommend modifying the language as follows: *For an exception request, the plan must notify the enrollee (and prescriber as appropriate) of its decision no later than 72 hours (24 hours for expedited request) of* ***either the*** *receipt of the supporting statement or* ***at the expiration of*** *14 calendar days after receipt of the request, whichever occurs first.*

Additionally, there are multiple instances in which the plan may need to obtain additional information from the prescriber. There are currently multiple standards and policies throughout the appeals process for what types of requests may be tolled, and the timeline in which tolling is permitted, ultimately creating beneficiary confusion. For example, plans are only permitted to toll while requesting a prescriber statement for formulary exceptions, but not when the appellant is looking to satisfy the coverage criteria or prior authorization. In an effort to minimize that confusion and reduce the burden on plans, we would propose to standardize the policy for 14-day tolling followed by the 72 and 24 hour(s) adjudication timelines across all exception requests, including exceptions related to formulary, tiering, quantity limits, and utilization management.

Star Rewards Program: Measure-Level Star Ratings

CMS proposes to add mean resampling to the current clustering algorithm to reduce the effect of outliers, and to establish measure-specific caps to mitigate against large annual swings in cut points.

Humana Comments: We support and appreciate CMS's efforts to improve the cut-point methodology to reduce the impact of outliers and increase the stability and predictability of cut points.

Of the various approaches listed in the proposed rule, we support mean-resampling and a restricted range cap for all measures. We note that even 0-100 measures may use only a portion of that range. As an example, although Plan All-Cause Readmission (PCR) is technically a 0-100 measure, the range of results for Star Rating Year 2019 was three percent to 17 percent. **Furthermore, although the agency did not propose**

including Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures in the updated cut point methodology, we recommend applying the restricted-range guardrails to the CAHPS cut points as well.

We agree with the agency that the mean-resampling methodology will reduce the impact of outliers, but note single-point clusters may still have an outsized impact. In past years, we have observed cases in which a single contract made up the cluster for one of the Star Rating levels for a measure. For example, a single contract achieved a 1-Star Rating for PCR in the 2018 Star Ratings. The mean-resampling methodology would include that single contract in 9 out of the 10 samples, meaning it would still have a strong overall impact on the Star Ratings. **While this would be mitigated by the proposed guardrails, there is still the possibility that a single contract could influence a three percent or five percent change in a cut point. In order to address this concern, we propose that CMS consider setting a minimum number of contracts needed to determine each cluster.**

Furthermore, we believe the proposed methodology does not adequately address another stated goal of the cut-points, and indeed the Star Rating program overall, which is to avoid misclassifying nearly identical contracts into different Star Rating levels. It is easy to construct examples where a tenth of a percentage point on a single measure, between two otherwise identical contracts, means the difference between 3.5 Stars overall and 4 Stars overall. Since Medicare Plan Finder (MPF) only shows the contract overall Star Rating, beneficiaries, their families, and other stakeholders will likely view these nearly identical contracts as having significantly different overall Star Ratings.

We propose CMS consider a continuous model for the following options: 1) overall contract Star Ratings and rebate payments; or 2) both measure and overall contract Star Ratings, as well as rebate payments. Under either of these two approaches, any potential misclassification, or the risk of misclassification, would be reduced since the two nearly-identical contracts would then receive nearly-identical overall Star Ratings (e.g. 3.74 and 3.75). This would have the further benefit of improving year-over-year benefit stability as contracts would no longer "swing" between 3.5 and 4 Stars.

We further recommend CMS move to full or partial advance notice of cut-points. Having advance knowledge of the gold standard level of a measure will allow plans to better engage the right members, at the right time, for the right measures in order to maximize positive health outcomes. Having a known gold standard will also allow health plans to work with providers to establish stable and transparent multi-year quality improvement programs. **In the past, CMS has expressed numerous concerns with prospective cut-points, but we believe the proposals below address those concerns. In particular, these proposals would strongly encourage continuous improvement in health outcomes.**

We propose a cut-point methodology using a fixed 5-Star cut-point for measures that have stable performance among the top 25th percentile of plans over time, published with advance notice, while keeping the 2 through 4 Star cut-points and any unstable measures variable per the current methodology. In our analysis, in order to be considered "stable" at the top 25th percentile, the following three criteria must be met:

- The average of absolute year-over-year (YOY) change over three years is <= 1%
- The change between Star Rating Year 2018 and Star Rating Year 2019 is <= 1%
- The measure has to have at least three years of history

We propose the 5-Star cut-point be set at the average of the top 25th percentile of plan performance for the most recent Star Rating Year, remain fixed for 3 years, and then reassessed after year 3. Volatility analyses show that about 75% of measures are stable at the top 25th percentile and most of the volatility occurs among plans performing at the bottom 25th percentile. In addition, those plans in the volatile bottom 25th percentile have continued to show significant year-over-year improvement since Star Rating Year 2016. Determining, and publishing, the 5-Star cut-point ahead of time will not eliminate incentives for improvement if the lower thresholds are still variable.

According to the proposed rule, CMS agrees that "the rate of change is less likely to be linear at lower threshold levels where contracts have greater opportunities for improvement" and "the trend in average performance is not always linear," [37] which is why we propose a mixed approach, keeping lower thresholds variable while fixing the 5-Star threshold. **We also agree with CMS that "older data often do not accurately reflect current performance."[38] Therefore, we propose that the fixed 5-Star cut-point be reassessed every three years. We believe three years is a reasonable amount of time to mitigate the impact of data becoming stale, while allowing sufficient time for plans to implement programs with providers.**

Humana, like many other MAOs, has implemented value-based payment programs that link a portion of provider payments to Stars measure performance. Some degree of predictability and stability would help plans build and strengthen relationships with providers by eliminating some of providers' frustrations with working toward unknown targets. Being able to communicate the 5-Star target to providers, while continuing to encourage continuous improvement, would assist MA plans in securing more value-based contracts with providers, which would likely lead to improved quality of care for Medicare beneficiaries.

[37] CMS, Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, PACE, Medicaid Fee-for Service, and Medicaid Managed Care Programs for Years 2020 and 2021 proposed rule. Federal Register. Vol. 83, No. 212. November 1, 2018. p. 55020.
[38] Ibid.

In order to ensure CMS's intent for cut-point methodology to accurately measure true performance is upheld, the 5-Star advance notice cut-point we are proposing should be used only for established measures that have historically shown stability in the top 25th percentile. This will prevent unintended consequences for measures that may experience external or structural factors causing substantial changes from period to period rather than steady, slow year-over-year improvement.

Finally, Humana shares CMS's concern regarding the potential misclassification of plan performance. One potential contributor to misclassification can be rounding of measure scores when the range of plan performance is relatively tight. An example of this would be PCR. For the 2019 Plan Year ratings, there were 358 plans with reported rates ranging from 3% to 17%. Moreover, 346 (or 96.6%) of these plans had reported rates from 5% to 13%.[39] In the case of this measure (which was 3-weighted), a plan with an unrounded score of 10.49% would receive 3 stars after rounding the rate to 10%, while a plan with an unrounded score of 10.50% would receive 2 stars after rounding the rate to 11%. While a discrete 5-star system cannot eliminate the sensitivity of ratings entirely, rounding scores for measures in this category certainly contributes to the sensitivity. **We recommend that CMS consider rounding the score to the next decimal place (tenths of a percent) for measures in this category.**

We further propose CMS implement these proposed changes via the 2020 Medicare Advantage and Part D Rate Announcement and Call Letter in order to make then effective for Star Rating Year 2020.

Proposed Measure Updates (Controlling High Blood Pressure)

CMS is proposing to move the Controlling High Blood Pressure (CBP) measure to the Display Page for 2020 and 2021. The agency's decision is based on a revision to the measure adopted by NCQA that modifies the blood pressure target, along with other structural changes.

Humana Comments: We are concerned that moving CBP to the display page could negatively impact industry focus, provider performance, and more importantly, the overall health outcomes of the millions of Medicare beneficiaries with high blood pressure. The modification made to the CBP measure by NCQA was clinically insignificant and does not warrant removal to the Display Page. Given that plans have already been measured on CBP throughout 2018, we strongly recommend that CMS retain the CBP measure.

We are also concerned that the proposed removal of the CBP measure appears to conflict with the agency's recent regulatory changes to the Stars program. The final rule entitled Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare

[39] See https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2019-Part-C-and-D-Medicare-Star-Ratings-Data-v11-15-2018-.zip

Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-F) stated that plans would receive notice of removal of measures from the Star Ratings prior to the measurement year.[40] **The removal of CBP from the Star Ratings, for a measurement year already in progress and nearly complete (measurement year 2018), does not comply with the agency's regulation.**

Approximately one in every three US adults has high blood pressure, and only half have their blood pressure under control. According to research published in May 2018, national medical costs associated with hypertension are estimated to account for approximately $131 billion in annual health expenditures.[41] Uncontrolled high blood pressure threatens quality of life and is directly correlated to numerous co-morbidities. Often, high blood pressure is not detected and does significant damage to multiple body systems over time and can ultimately lead to heart attack, stroke, heart failure, kidney disease/failure, vision loss, angina, microvascular disease (MVD), and peripheral artery disease (PAD). Simple blood pressure checks and blood pressure control are the first steps to prevention.[42]

Emerging healthcare payment models in MA are rewarding high performance and health improvement outcomes on a set of high-priority cardiovascular measures. The use of blood pressure control in these types of outcome-focused care models plays a vital role in helping health practitioners ensure patients get the care they need to manage their high blood pressure and improve their overall health outcomes.[43]

Proposed Measure Updates (MPF Price Accuracy)

CMS is proposing to make changes to the MPF measure to better measure the magnitude of difference, as well as the frequency of price differences. CMS proposes to increase the claims included in the measure and round a drug's MPF cost to two decimal places for comparison to its Prescription Drug Event (PDE) cost. CMS is proposing the revised measure for the Display Page for the 2020 and 2021 Star Ratings. The legacy measure would continue as a Star measure until it is replaced by the updated measure in 2022 Star Ratings.

Humana Comments: Humana supports this proposal.

Proposed Measure Updates (Plan All-Cause Readmission)

CMS is proposing changes to Plan All-Cause Readmission that include the addition of observation stays as hospital discharges and readmissions in the denominator and the numerator, removing individuals with high frequency hospitalizations, combining the 18-64 and 65+ age groups as the updated measure specifications are adopted and to use NCQA's new recommendation of 150 as the minimum denominator. The proposal is to move the revised

[40] Available online at https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare

[41] Available online at https://www.cdc.gov/sixeighteen/bloodpressure/index.htm

[42] See http://www.heart.org/en/health-topics/high-blood-pressure/health-threats-from-high-blood-pressure

[43] See https://www.cdc.gov/sixeighteen/bloodpressure/index.htm

measure to the Display Page for the 2021 and 2022 Star Ratings. CMS proposes to return the revised measure to the Stars program for the 2023 ratings.

> **Humana Comments:** Humana supports the clinical intent to update the specifications and also the reporting of the entire Medicare enrollee population for this measure.

Proposed Measure Updates (Improvement Measures)
CMS proposes to exclude any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year from the improvement measure(s).

> **Humana Comments:** Humana supports this proposal.

Proposed Measure Updates (Data Integrity)
CMS is proposing to assign a 1-Star rating to the applicable appeals measure(s) if a contract fails to submit Timeliness Monitoring Project (TMP) data for CMS's review to ensure the completeness of their Independent Review Entity (IRE) data.

> **Humana Comments:** Humana supports this proposal.

Proposed Measure Updates (Review of Sponsor's Data)
CMS is proposing that requests for the agency or the IRE to review contract data must be received no later than June 30 of the following year in order to have time to use accurate information in the Star Ratings calculations. Re-openings are not taken into account under this proposed deadline for corrections to the IRE data. When the decision is evaluated for purposes of the appeals measure, if a reopening occurs and is decided prior to May 1, the revised determination would be used in place of the original reconsidered determination. If the revised determination occurs on or after May 1, the original reconsidered determination would be used.

Additionally, CMS proposes that any requests for adjustments following CMS's Complaint Tracking Module (CTM) Standard Operating Procedures for the complaints measures be made by June 30 of the following year in order for the changes to be reflected in a contract's Star Ratings data.

> **Humana Comments: The timeframes/deadlines CMS is proposing do not appear to align with the allotted timeframes CMS allows for plans, and the IRE, to re-open decisions.** Per Chapter 13, of the Medicare Managed Care Manual, plans have 180 days to reopen an IRE decision.[44] Per Section 7.2, of the Maximus Federal Medicare Health Plan Reconsideration Process Manual, the IRE has 120 days for the processing of reopening cases.

[44] See https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c13.pdf

Humana proposes CMS review the IRE reopening process and timeframes to ensure all cases submitted to the IRE, in the measurement plan year, are fully resolved by the first plan preview period. Humana would also propose that if the IRE doesn't meet the IRE reconsideration timeframes, which are outlined in the Maximus Federal Medicare Health Plan Reconsideration Process Manual, then plans would still be held accountable for the outcome of the reconsideration but those cases should not be included in the plan's performance scores since they were not fully resolved.

Extreme and Uncontrollable Circumstances

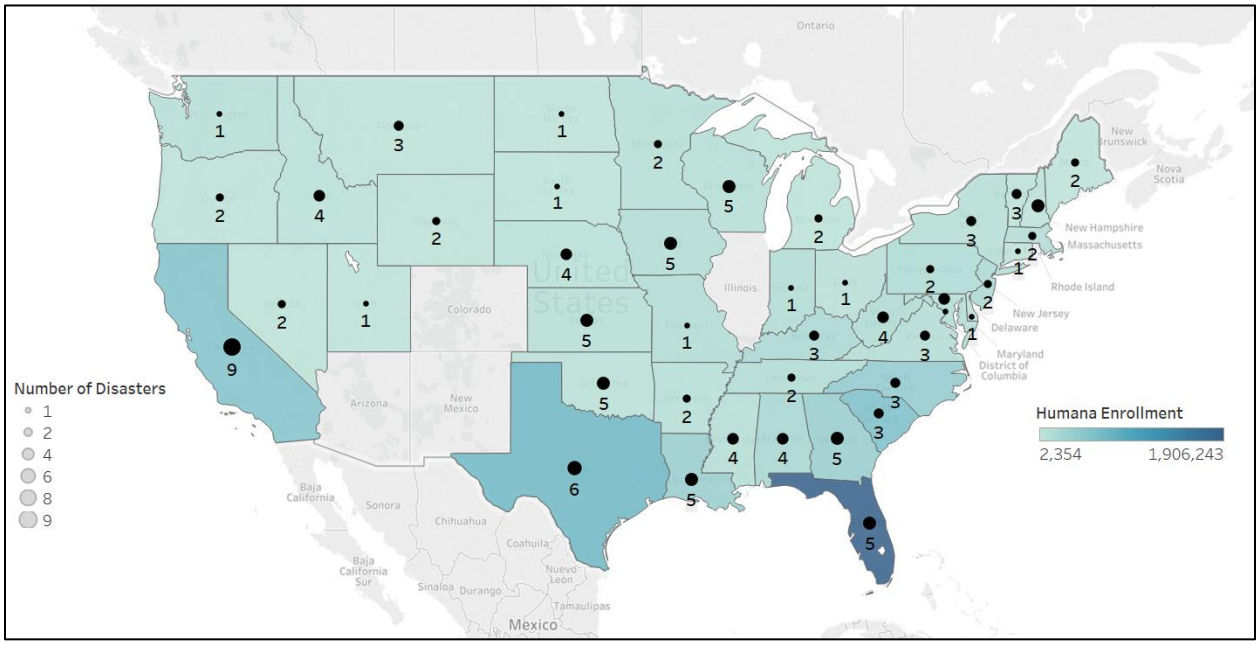
CMS is proposing to codify at paragraphs §§ 422.166(i) and 423.186(i) existing policy for adjusting the calculation of Star Ratings for the Parts C and D organizations who are impacted by extreme and uncontrollable circumstances. The proposed policy would make adjustments to take into account the potential impact on contracts when there are extreme and uncontrollable circumstances during the performance period or measurement period for MA and Part D plans.

Humana Comments: We applaud CMS for codifying a Stars Rating adjustment policy for MA and Part D organizations impacted by extreme and uncontrollable circumstances. An appropriate adjustment is particularly critical for those plans, like Humana, that serve geographic areas disproportionately impacted by natural disasters. Since 2016, the Federal Emergency Management Association (FEMA) has officially declared 119 natural disasters across the U.S., including hurricanes, wildfires and severe storms/flooding.[45] At the time of these disasters, nearly one-third of Humana's MA/MA-PD and stand-alone PDP members (27 percent) resided in counties listed in the disaster declarations.[46] As shown in Figure 1 below, Humana's membership is strongly concentrated in the southeastern region of the country, which has been disproportionately impacted by natural disasters over the past three years. Florida, Georgia, and Alabama alone experienced 14 natural disasters, including Hurricanes Hermine and Matthew in 2016, Irma and Nate in 2017, and Florence and Michael in 2018.

[45] Analysis is based on the Open FEMA Disaster Declarations Summary dataset (as of 10/19/2018), available online at https://www.fema.gov/media-library/assets/documents/28318. Analysis includes incidents beginning on or after 01/01/2016 for which the Public Assistance (PA) program and/or the Individual and Household (IH) program was declared by FEMA. Analysis excludes 328 records for disasters declared on Indian reservations and 571 records without a valid county code. Disasters with the same title that began within 7 days of one another are categorized as a single incident. Additionally, Tropical Storm Harvey and Hurricane Harvey were grouped together.

[46] County-level membership was approximated for the month of each disaster using the publically available CMS monthly enrollment files by contract/plan/state/county, available online at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Enrollment-by-Contract-Plan-State-County.html. To protect the privacy of Medicare beneficiaries, contract/plan/county combinations with between 1 and 10 members are suppressed. A value of 5 was imputed for suppressed member counts.

Humana Membership in FEMA Disaster Declaration Areas (2016-2018)



Sources: Open FEMA Disaster Declarations Summary dataset (as of 10/19/2018); CMS monthly enrollment files by contract/plan/state/county

Based on our experience, we strongly support CMS's Star Ratings mitigation methods for contracts and enrollees materially affected by extreme and uncontrollable circumstances as well as this proposal to codify the mitigation methodology and process for identifying affected contracts. We further recommend CMS finalize the proposed mitigation methodology for implementation in measurement year 2018 in order to avoid a temporary lapse in the application of the proposed policy. According to the 2019 Medicare Advantage Final Call Letter, the existing extreme and uncontrollable circumstances mitigation methodology applies solely to the 2017 performance year, while the current proposal would not codify the methodology until the 2020 measurement period.[47]

Additionally, when a single disaster impacts a service area for multiple years, or multiple disasters impact a service area for consecutive years, we request CMS clarify the eligibility and application of the mitigation methodology. For example, the public health emergency declaration for Puerto Rico due to Hurricane Maria was renewed by HHS Secretary Azar in March 2018.[48] This would appear to meet the definition of an "emergency area" in an "emergency period" as defined by Section 1135(g), satisfying one of the proposed criteria for the use of the mitigation methodology.[49] However, it is

[47] CMS 2019 Final Call Letter (https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf)
[48] Renewal of the Public Health Emergency Declaration for Puerto Rico, March 2018 (https://www.phe.gov/emergency/news/healthactions/phe/Pages/pr-maria-16Mar2018.aspx)
[49] Section 1135 of the Social Security Act (https://www.ssa.gov/OP_Home/ssact/title11/1135.htm)

unclear whether the methodology would be applied since the major disaster declaration for Puerto Rico was issued for an event that occurred in 2017. Furthermore, it's unclear how the hold harmless policy would be applied in the event of consecutive year impacts. We suggest in these cases using the best of current measurement year performance, prior year performance, parent organization average performance, or industry average performance.

Dual Eligible Special Needs Plans (D-SNPs)

Definitions (§ 422.2)

CMS proposes new definitions for the terms "dual eligible special needs plan," "fully integrated dual eligible special needs plan," "highly integrated dual eligible special needs plan," and "aligned enrollment."

Humana comments: We commend CMS for revising the existing definitions and clarifying the varying options for integrating coverage for dual eligible beneficiaries in clear, straightforward terms. The proposed modifications provide far greater clarity for states and D-SNP plans. We believe the proposed definitions provide the appropriate amount of detail to inform agreements between MAOs and state Medicaid agencies. As CMS acknowledges in the proposed rule, states are permitted flexibility in Medicaid program administration. The proposed classification of D-SNPs by level of integration appropriately accounts for the variability across state programs, particularly the varying state adoption of managed care for state-based programs specific to this population.

D-SNPs and Contracts with States (§ 422.107)

CMS proposes to implement the Bipartisan Budget Act of 2018 by requiring that D-SNPs meet at least one of the following three qualification criteria:

1. A D-SNP must either meet the requirements of a fully integrated dual eligible (FIDE) SNP or enter into capitated contract with the state Medicaid agency to provide long term services and supports (LTSS), behavioral health services, or both;

2. A parent organization of a D-SNP that is also the parent organization of a Medicaid managed care organization providing LTSS or behavioral health services must assume clinical and financial responsibility for benefits provided to beneficiaries enrolled in both the D-SNP and Medicaid managed care organization; or

3. Any D-SNP that is not a FIDE SNP or a highly integrated dual eligible (HIDE) SNP is required to notify the state Medicaid agency and/or other designated entities of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full benefit dual eligible individuals, as determined by the state.

CMS is also proposing to give states broad latitude to establish notification procedures and protocols, including the recipients of the admission notifications, timeframes by which a D-SNP must furnish this information directly or indirectly, and how such notification would occur.

Humana comments: Humana believes that CMS has established an appropriate approach to the three qualifying criteria as well as to the latitude afforded to states to implement notifications and protocols. In particular, we appreciate that CMS has acknowledged that there can be alternative approaches to integrating and enhancing coordination of coverage for dual eligible beneficiaries and that it is possible to offer a D-SNP that is not a designated FIDE SNP or HIDE SNP. This is critical for states that have not yet adopted a managed care approach to coverage unique to dual eligible beneficiaries under programs for Medicaid benefits, behavioral health, or separately, LTSS. It also allows for the offering of a broader variety of coverage options to this population by not limiting D-SNPs to those contracted by the state separately to provide managed Medicaid and/or managed LTSS coverage.

Humana also concurs with the CMS proposal to establish a minimum contract requirement that incorporates the notification of hospital and SNF admissions by D-SNPs to states or state designees. We also support CMS engaging states to develop a scalable integration model while focusing initial efforts on initiatives that have the greatest impact on care coordination and health outcomes. Developing the method, timing, and scope of notification permits states the flexibility to incorporate the requirement into existing data exchange methods. Based on our experience working with multiple State Medicaid agencies, we have found substantial differences in how states receive and send data. As the Medicaid and CHIP Payment and Access Commission (MACPAC) points out the "zero-sum nature of state budget decisions creates a powerful incentive for state agencies to limit spending on program administration" including information technology. In particular, "State Medicaid agencies need high-level analytic, financial, and clinical expertise to implement and oversee these modernized systems, yet they struggle to attract and retain staff with the necessary qualifications."[50] Thus, States with less advanced IT infrastructures and smaller budgets could be at a disadvantage if they did not have the capacity to accomplish substantial system changes within the expected timeframe. Given the differences in states' capabilities and current data sharing methods, we do not believe it is practical to enact more prescriptive notification requirements. Doing so may inhibit, rather than promote, integration by forcing states to conform to a model that they may be unable to implement and administer.

Because states have widely varying approaches to managed care and health information management, prescriptive process requirements would be counterproductive. We recommend that CMS instead work with states to develop a

[50] MACPAC Building Capacity to Administer Medicaid and CHIP available online at https://www.macpac.gov/wp-content/uploads/2015/01/Building_Capacity_to_Administer_Medicaid_and_CHIP.pdf

standardized reporting template that specifies the minimum data elements needed to comply with the hospital and SNF notification requirements. A CMS-required template could reduce ambiguity by standardizing the required data across all states. It also would make data sharing easier for both states and plans by providing a roadmap to the requirement, thus making a more immediate impact on efforts to improve care transitions. Alternatively, CMS could build IT infrastructure where States, plans, and ideally, providers could all interface and share data or build off of a Blue Button 2.0 framework and have the data follow the beneficiary.

We fear that some states may elect to stop authorizing D-SNPs if faced with new, overly-burdensome requirements, especially if they place substantive pressures on state administrative budgets. While D-SNP offerings have increased steadily in the past three years, there remains an access issue when looking at D-SNP options geographically. Beneficiaries in nearly 30 percent of U.S. counties will continue to lack access to D-SNPs in 2019, and, in an additional 17 percent of counties, beneficiaries will only have one D-SNP option. Conversely, regular MA plans will be available in all but 115 counties in 2019. According to a recent report from the Kaiser Family Foundation, these counties without regular MA options account for just one percent of beneficiaries, most of whom live in rural areas of California.[51] There are only 57 counties with only one MA plan option, compared to 542 counties with only one D-SNP option.

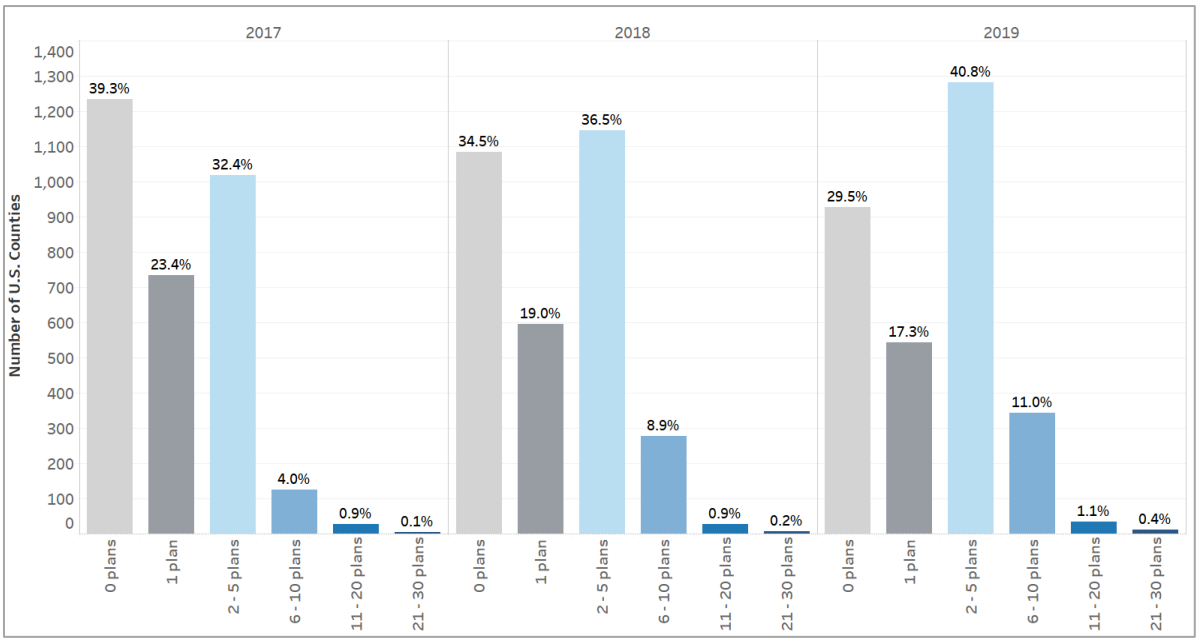
Even in counties with multiple D-SNP options, there are often only a few parent organizations offering plans. Only four percent of U.S. counties have six or more parent organizations participating in the D-SNP market, compared to 21 percent of counties in the base MA market. Furthermore, in the vast majority of states, D-SNP penetration for dual-eligible Medicare beneficiaries is lagging behind base MA penetration.[52] [53] Nationally, about one-third of Medicare eligible beneficiaries are enrolled in MA, but only one-fifth of dual-eligible beneficiaries are enrolled in D-SNPs. Only four states (HI, DC, AZ and TN) have higher D-SNP penetration compared to base MA penetration.

[51] Kaiser Family Foundation's "Medicare Advantage 2019 Spotlight: First Look", October 2018, available online at http://files.kff.org/attachment/Data-Note-Medicare-Advantage-2019-Spotlight-First-Look

[52] To protect the privacy of Medicare beneficiaries, contract/plan/county combinations with between 1 and 10 members are suppressed. A value of five was assigned for suppressed member counts.

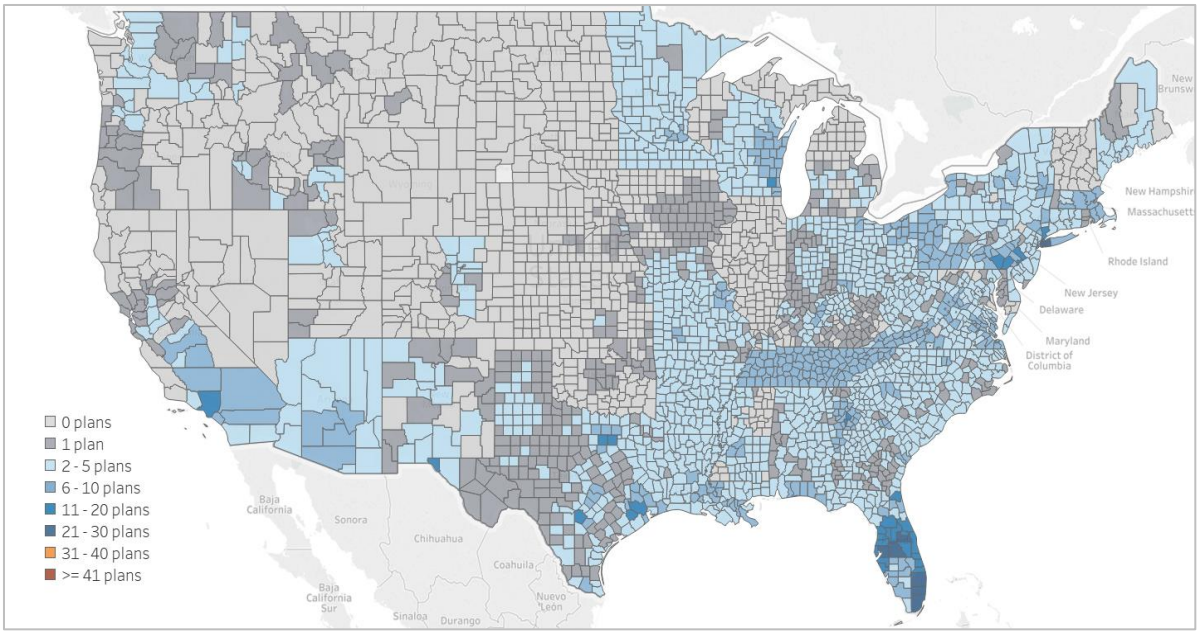
[53] Some D-SNP contracts span multiple states. Membership in these contracts was divided evenly between the states listed.

D-SNP Availability by County, 2017-2019



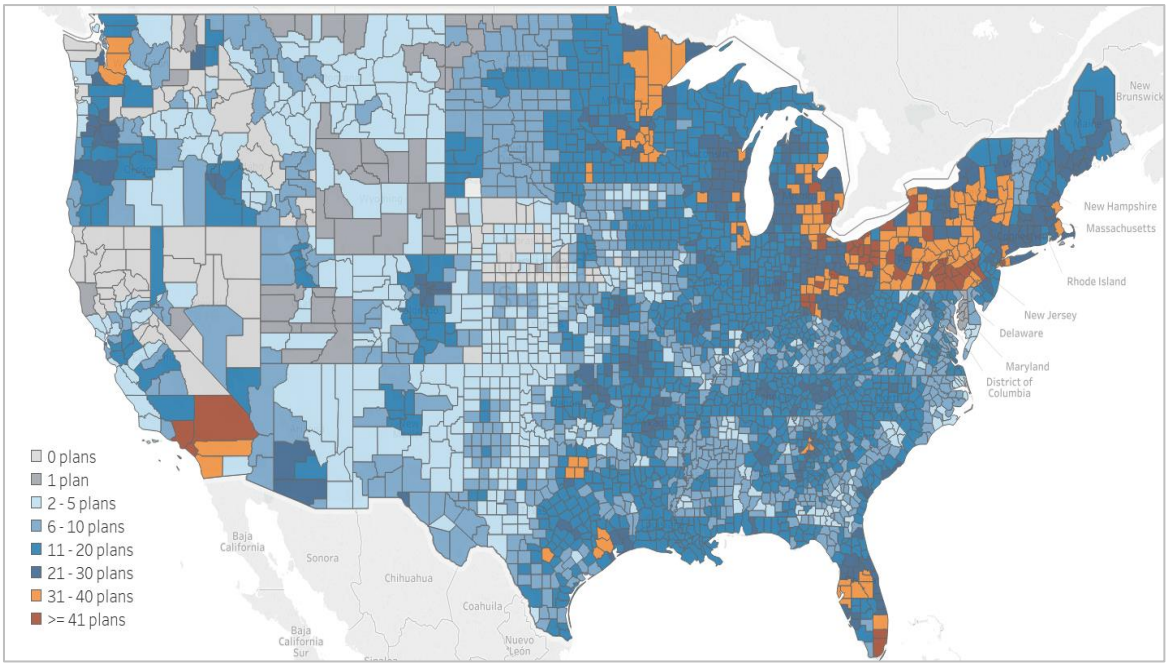
Source: CMS SNP Landscape files for 2017-2019

D-SNPs by County, 2019



Source: Analysis of CMS MA Landscape files for 2019

Non-SNP Medicare Advantage Plans by County, 2019



Source: CMS SNP Landscape file for 2019

Eligibility of Partial-Benefit Dual Eligible Individuals for D-SNPs

CMS notes in the proposed rule that the agency has considered proposing limits on the enrollment of partial-benefit dual eligible in D-SNPs. CMS also questions the benefits that partial benefit dual eligibles derive from their enrollment in a D-SNP relative to the challenges associated with allowing such enrollment.

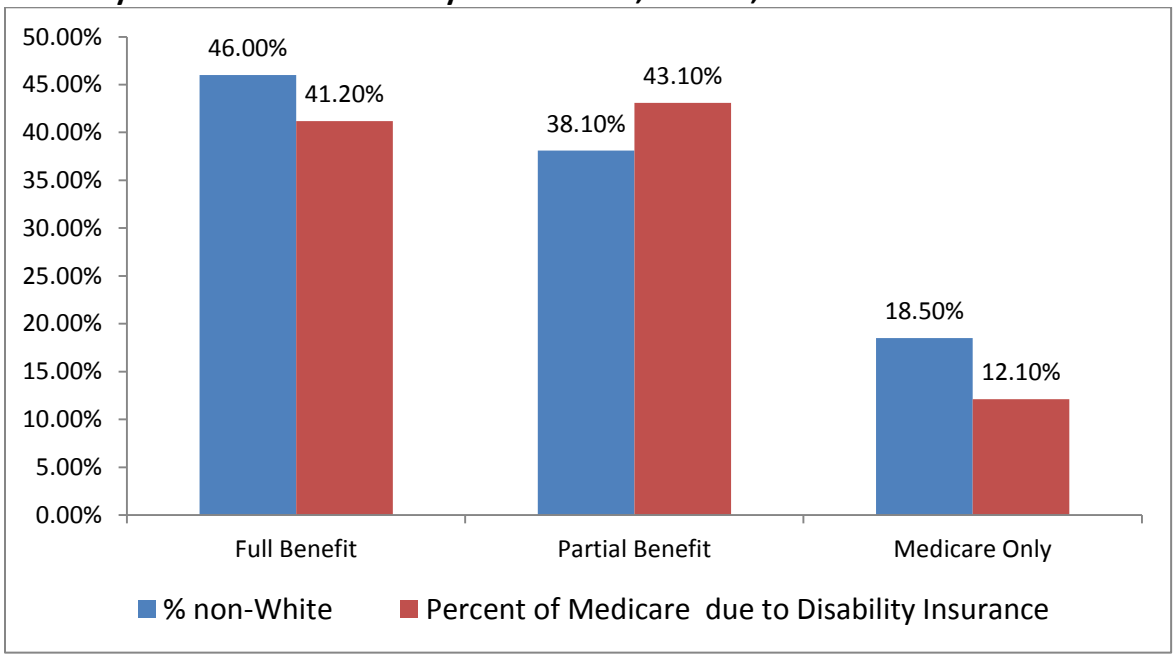
Humana comments: We strongly recommend that CMS preserve partial-benefit dual eligible beneficiaries' access to D-SNPs on the following grounds: 1) partial and full duals are a distinct cohort of beneficiaries from the Medicare-only population; 2) there is significant overlap between partial benefit and full benefit dual eligibles; and 3) Congress did not instruct CMS to prevent partial benefit dual eligibles from accessing D-SNPs.

The evidence suggests that partial and full duals are distinct cohorts of beneficiaries from the Medicare-only population. As illustrated below, the CMS MMLEADS Public Use File shows that both partial and full dual eligibles are more likely to be non-white and have a disability status.[54] Partials and full duals also have similar elevations in behavioral health issues, hospital readmission rates, and emergency room (ER) visits relative to Medicare-only beneficiaries. Humana has observed similar overlap in our partial and full duals enrolled in D-SNPs. We generally see partial and full duals living in similar

[54] Medicare-Medicaid Linked Enrollee Analytic Data Source (MMLEADS) PUF available online at https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/MMLEADS/index.html

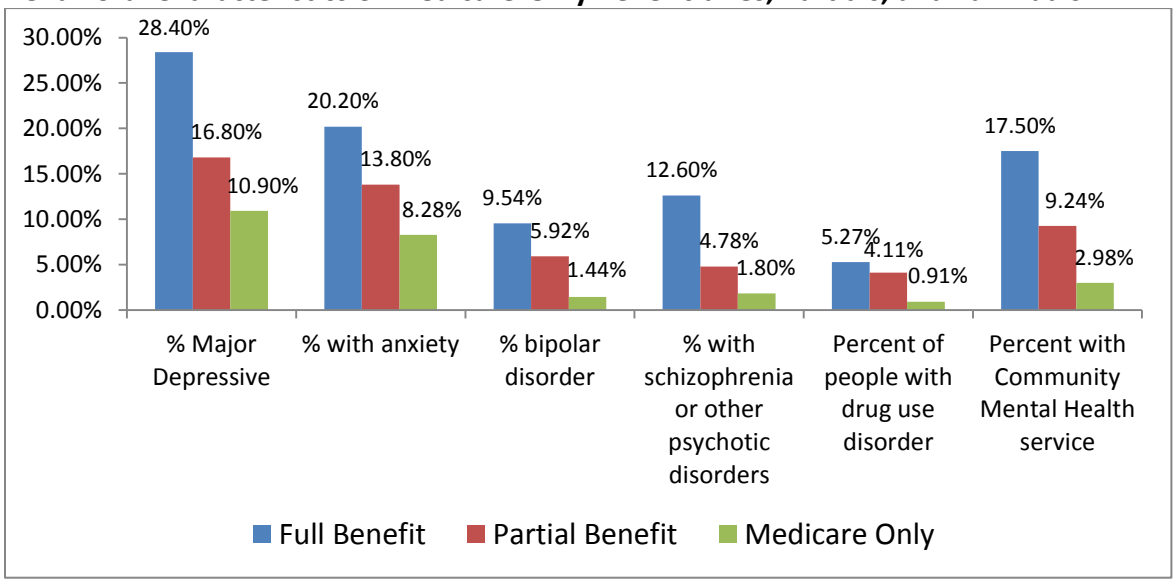
communities with similar issues around the social determinants of health. Moreover, partial and full duals have higher costs relative to Medicare-only beneficiaries by aged vs disability segments.

Disability Status of Medicare-Only Beneficiaries, Partials, and Full Duals



Source: Medicare-Medicaid Linked Enrollee Analytic Data Source (MMLEADS) PUF

Behavioral Characteristics of Medicare-Only Beneficiaries, Partials, and Full Duals



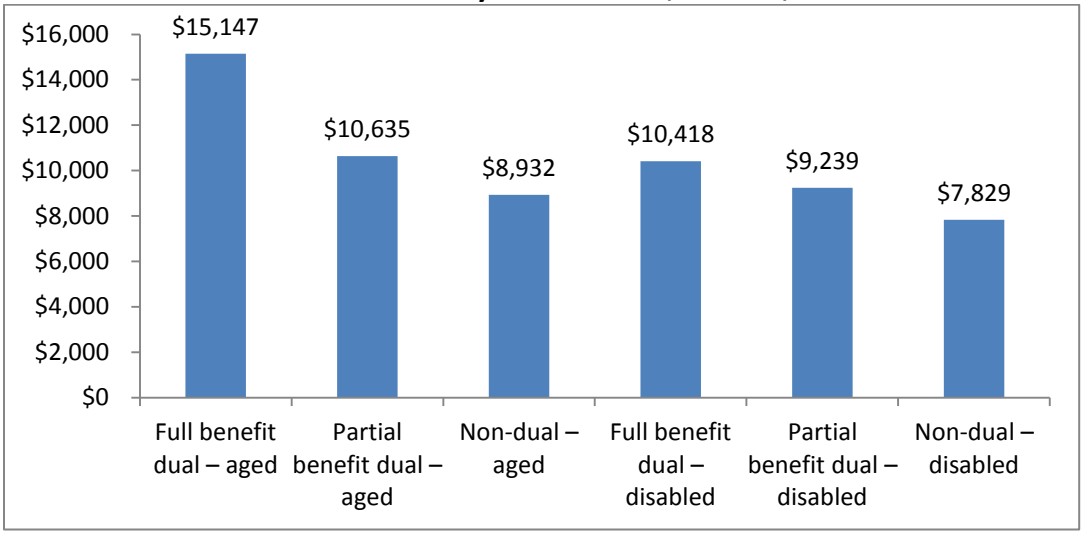
Source: Medicare-Medicaid Linked Enrollee Analytic Data Source (MMLEADS) PUF

Hospitalization Rates of Medicare-Only Beneficiaries, Partials, and Full Duals

Medicare-Medicaid Enrollment Type	Hospital Readmission Rate	ED Visits per 1,000 enrollees
Full Benefit	27.4%	1,491.6
Partial Benefit	24.1%	891.7
Medicare-Only	16.5%	498.1

Source: Medicare-Medicaid Linked Enrollee Analytic Data Source (MMLEADS) PUF

Mean Actual Costs of Medicare-Only Beneficiaries, Partials, and Full Duals



Source: RTI International analysis of 2011-2012 Medicare 100% data for October 28, 2015, HPMS Memo "Proposed Changes to the CMS-HCC Risk Adjustment Model for Payment Year 2017"

The overlap between partial and full dual eligibles is further illustrated by the fact that many partials progress to full dual status and some full duals can lose that status for a period and become a partial. In fact, we have observed that on average at least two percent of our partial duals convert to full dual status every year. This would likely be a higher number, but for the well documented administrative burdens and barriers placed on Americans seeking full Medicaid status.[55] Similarly a joint analysis performed by the Medicare Payment Advisory Commission (MedPAC) and MACPAC found that in one year examined, approximately eight percent of partial duals became full duals and approximately three percent of full duals switched to being partial.[56] **In order to ensure continuity of care, we recommend that CMS continue to allow both partial and full benefit dual eligibles to enroll in D-SNPs.**

[55] See for example, Moynihan, Donald P., Pamela Herd, and Elizabeth Ribgy. "Policymaking by other means: Do states use administrative barriers to limit access to Medicaid?." *Administration & Society*48.4 (2016): 497-524.
[56] MedPAC and MACPAC Data book: Beneficiaries dually eligible for Medicare and Medicaid — January 2018.

Eliminating the ability of partial-benefit dual eligibles to enroll in D-SNP plans also runs counter to congressional intent. We conducted an exhaustive review of the legislative history of the BBA of 2018, including the legislative text and transcripts of the floor debate and related congressional hearings.[57] We were unable to identify any instance where Congress signified its intent to limit or prevent partial benefit dual eligibles from enrolling in D-SNPs.

Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 – 562, 422.566, 422.629 – 634, 438.210, 438.400, and 438.402)

First, CMS is proposing to establish requirements for all D-SNPs, relative to the role they play in assisting full-benefit dual eligible individuals, to assist with Medicaid-related coverage issues and grievances (§ 422.562(a)). Second, CMS is also proposing new requirements in accordance with section 1859(f)(8)(B) of the Act to create integrated grievance and appeals systems for a limited subset of D-SNPs ("applicable integrated plans"), identified using terms and concepts CMS proposes to define in amendments to § 422.561, with the integrated processes established by proposed new regulations (§§ 422.629-422.634). Finally, CMS is proposing a number of changes of a technical and conforming nature to existing provisions in parts 422 and 438 (§§ 422.560, 422.562, 422.566, 438.210, 438.400, and 438.402).

Humana comments: Humana is supportive of the approach CMS is taking for these procedures. We ask that CMS continually seek feedback from all stakeholders during the development of guidance for operationalizing these rules.

Suspension of Enrollment for Non-Compliance with D-SNP Integration Standards (§422.752)

Section 50311(b) of the BBA of 2018 amended section 1859(f) of the Act by creating a new paragraph (8)(D)(ii) to permit the Secretary, for plan years 2021 through 2025, to impose an intermediate sanction of stopping all new enrollment into a D-SNP if the Secretary determines that the D-SNP is failing to comply with the integration requirements set forth in section 1859(f)(8)(D)(i) of the Act. CMS notes that the "statute authorizes this lesser sanction but does not require that it be used, leaving it to" the discretion of CMS. CMS believes it would be appropriate to impose the enrollment sanction for non-compliant D-SNPs before initiating any contract termination or other sanction or enforcement action.

Humana comments: We thank and support CMS for the view that non-compliance with 42 CFR §422.752 should not go directly to contract termination. However, we would note that enrollment sanctions are also at the discretion of CMS. Accordingly, we recommend that CMS not immediately impose an enrollment sanction for minor compliance issues around 42 CFR §422.752. We further recommend that an enrollment

[57] US Senate, Committee on Finance, Hearing: Examining Bipartisan Medicare Policies that Improve Care for Patients with Chronic Conditions, May 16, 2017; US House of Representatives, Committee on Energy and Commerce Subcommittee on Health, Hearing: Examining the Extension of Special Needs Plans, July 26, 2017; Congressional Record, v. 164, no. 193-194.

sanction, for compliance issues related to new integration standards, only be applied when those violations meet the established precedent of posing a serious threat to the health and safety of Medicare beneficiaries or other widespread and systemic failures where there is demonstrated harm to beneficiaries.[58] Lesser violations can be handled via the established mechanisms, such as, notices of non-compliance, required corrective action plans (CAPs), and civil monetary penalties (CMPs).

MA Risk Adjustment Data Validation (RADV)

CMS proposes to use extrapolation in RADV-contract level audits and that extrapolation authority would apply to the payment year 2011 contract-level audits and all subsequent audits. CMS further proposes not to apply a FFS adjustor to audit RADV findings. On December 20, 2018, CMS extended the public comment period on the RADV proposal by 120 days. Comments on the proposal are now due by April 30, 2019.

Humana comments: The Proposed Rule also proposes certain changes to the MA Risk Adjustment Data Validation ("RADV") methodology, including the elimination of a Fee for Service Adjuster ("FFSA"), relying primarily on "a study regarding the presence and impact of diagnosis error in FFS claims data" (the "FFSA Study").[59] On November 26, 2018, Humana sent a letter to CMS expressing concern that CMS had not released all of the data and methodologies on which the FFSA Study relied and explaining that its failure to do so prevented Humana from commenting effectively on the Proposed Rule.[60] Humana requested that CMS: (i) disclose the complete FFSA study, including any underlying data and methodologies on which it relied; and (ii) allow Humana and other interested parties sufficient time to submit comments based on that additional information.[61]

On December 20, 2018, CMS announced that it would release the "data underlying" the FFSA Study and extend the deadline for comments on the RADV portions of the Proposed Rule until April 30, 2019.[62] Humana supports CMS's efforts to comply with its

[58] Some historical examples of CMS enrollment sanctions following the serious beneficiary harm standard include https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/SummaCare-Notice-of-Sanction-8-11-14.pdf; https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/Cigna_Sanction_01_21_16.pdf; and https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/Capital-Blue-Cross-Sanction-05_28_14.pdf

[59] 83 Fed. Reg. 55,040.

[60] Letter from M. Newsom to J. Smith (Nov. 26, 2018); *see also*, *e.g.*, *See Am. Radio Relay League, Inc. v. F.C.C.*, 524 F.3d 227, 236-37 (D.C. Cir. 2008) ("It would appear to be a fairly obvious proposition that studies upon which an agency relies in promulgating a rule must be made available during the rulemaking in order to afford interested persons meaningful notice and an opportunity for comment."); *Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 201 (D.C. Cir. 2007) ("The failure to provide an opportunity for comment on the model's methodology . . . constitutes a violation of the APA's notice-and-comment requirements."); *Chamber of Commerce of U.S. v. S.E.C.*, 443 F.3d 890, 900 (D.C. Cir. 2006) ("Among the information that must be revealed for public evaluation are the "technical studies and data" upon which the agency relies.")

[61] *Id.* at 1.

[62] *See* CMS-4185-P RADV Rule Provision Notice (Dec. 20, 2018)

obligations under the Administrative Procedure Act by making available all of the information and methodologies on which the FFSA Study relies.[63] Additionally, Humana urges CMS to release this information as soon as possible, because stakeholders will need several months to review and analyze this supplemental information before submitting their comments.

[63] *See* Letter from M. Newsom to J. Smith (describing required information); *see also Am. Radio Relay League, Inc.*, 524 F.3d at 237 (partial release of studies does not comply with the APA).

TAB 19

UnitedHealth Group Comments

UNITEDHEALTH GROUP

December 31, 2018

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4185-P
Box 8013
Baltimore, MD 21244–8013
Submitted via: www.regulations.gov

RE: Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

Dear Administrator Verma:

UnitedHealth Group (UHG) is pleased to respond to the Centers for Medicare & Medicaid Services (CMS) request for comments regarding Policy and Technical Changes to the Medicare Advantage (MA), Medicare Prescription Drug Benefit (Part D), Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021.

UHG is dedicated to helping people live healthier lives and making our nation's health care system work better for everyone through two distinct business platforms – UnitedHealthcare, our health benefits business, and Optum, our health services business. Our workforce of over 300,000 people serves the health care needs of 140 million people worldwide, funding and arranging health care on behalf of individuals, employers, and the government. As America's most diversified health and well-being company, we not only serve many of the country's most respected employers, but we are also the nation's largest Medicare health plan – serving nearly one in five seniors nationwide – and are one of the nation's largest providers of Medicare Part D plans on a stand-alone basis, serving over 4.7 million seniors in the U.S. In addition, OptumRx pharmacy care services uses the most frequent health care consumer touch point – the pharmacy – to provide distinctive, whole-person care, turning a traditionally disconnected, transactional experience into one that integrates the entire health care experience.

The MA and Part D programs are public-private partnerships that have proven the ability to improve quality and reduce costs. MA is delivering private-sector best practices and innovations in effective and consumer-friendly ways that are demonstrating sustained, proven results. MA's approach to care results in beneficiaries experiencing 20% fewer hospital readmissions and a 20% increase in annual preventive care visits as compared to beneficiaries in Medicare Fee-For-Service (FFS). During the past 30 years, MA has consistently delivered better benefits, innovation, choice, and affordability to America's seniors, while advancing our health care system at large.

Notably, analysis shows MA delivers medical benefits at approximately 20% lower costs than Medicare FFS and better outcomes, with a 52% lower rate of clinical complications for MA beneficiaries compared to FFS beneficiaries. Additionally, 90% of beneficiaries report their Part D plans provide good value in part due to the Part D program's effective use of Pharmacy Benefit Managers (PBMs). PBMs are effectively delivering value to the health care system and consumers – saving the Federal government and seniors $24 billion in 2015, and estimated to save $900 billion – or 37% of Part D spending – from 2016-2025 according to a June 2017 study prepared by Oliver Wyman.

The CMS Proposed Rule presents an opportunity to build upon the successes of the MA and Part D programs. UHG supports policies focusing on delivering high-quality, coordinated care to MA and Part D beneficiaries, including the following solutions:

Modernize Quality Improvement

Changes to the CMS Star Rating System that enable MA plans and care delivery practices to allocate resources efficiently and drive meaningful improvement in clinical outcomes will improve quality and deliver the maximum value of the program to beneficiaries. The industry performance parity on measurable Star Rating outcomes has put more performance reliance on survey-based, less empirically supported evidence compromising the effectiveness of the Star Ratings System in its entirety, and requiring urgent re-evaluation of its significant impact on beneficiary benefits and MA program stability. Specifically, for 2020 UHG recommends CMS implement the following:

- Allowing MA plans achieving 3.5 Stars to receive a portion of the CMS Star Rating Quality Bonus to support investment in programs and activities intended to improve patient outcomes.
- Moving away from perception-based measurement, such as the Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures, and driving towards measureable improvement in patient clinical outcomes, such as Healthcare Effectiveness Data and Information Set (HEDIS) measures.
- Improving measurement of patient satisfaction by transitioning to a Net Promoter System methodology to more accurately measure consumer preferences.
- Eliminating quality measures focused on administrative collection of data to enable MA plans to focus on measures directly tied to patient outcomes.
- Implementing a rolling three-year average Star Rating threshold to bring predictability to the Star Rating System.

Integrate Dual Special Needs Plans

UHG supports CMS efforts to integrate the Medicare and Medicaid programs for Dual Eligible beneficiaries and efforts to balance the flexibility provided to the States in the Medicaid program with the Federal requirements of the Medicare program. Specifically, UHG recommends CMS implement in 2020:

- Allowing partial Dual Eligible beneficiaries to continue to enroll in D-SNPs to ensure these complex beneficiaries have access to coordinated Medicare and Medicaid benefits.
- Creating options for data sharing among D-SNPs, Medicaid agencies, and Medicaid Managed Care Organizations.

- Integrating the grievance and appeals processes for exclusively aligned D-SNPs and refine CMS integration processes.
- Measuring D-SNPs separately in the CMS Star Rating System and ensuring measurement takes into account the complex clinical profile of the patients receiving care through a D-SNP.
- Prohibiting arrangements that tie carrier participation in D-SNP programs to participate in other State Medicaid programs unless the State demonstrates to CMS it is marketing these programs in an actuarially sound manner. This will improve competition and the actuarial soundness of State Medicaid programs.

Support High-Quality Coordinated Care

We support policies focusing on delivering high-quality, coordinated care to MA and Part D beneficiaries. In order to maximize the value of MA and Part D, we ask CMS to consider focusing on implementing the following policies in 2020:

- Reducing the number of restrictions on beneficiary incentives to enable incentives to be individualized to beneficiaries' unique health care needs, including in Part D.
- Offering additional flexibility for the business comparison test to limit unintended consequences, such as limiting beneficiary choice and access, as well as disincentivizing insurers from expanding to other offerings, like Medicaid.
- Enabling MA plans to offer real-time additional benefits and reduced cost sharing to chronically ill members that will eliminate barriers to care and support the health of members by addressing social determinants and health status.
- Preserving beneficiary choice of outstanding, high-quality plans by eliminating the prohibition on new beneficiaries from enrolling in a MA plan that has missed the MLR target requirement for multiple years.
- Enabling flexibilities in Employer Group Waiver Plans (EGWP) to expand access for seniors by broadening the definition of "employment-based retiree coverage" to allow associations and other types of organizations to collectively purchase offerings, permit simultaneous enrollment, and allow marketing of value-added items and services.

UHG supports CMS' more recent efforts to provide a sustainable and adequate rate environment that will ensure the MA program delivers the high-quality, effective, and innovative health care that seniors expect and deserve. UHG looks forward to partnering with CMS as it works to achieve the highest quality and most cost effective health care for seniors.

Attached are UHG's technical comments and recommendations for CMS opportunities to strengthen MA and Part D in 2020 and 2021.

As always, UHG welcomes the opportunity for constructive discussion and collaboration as part of this comment process, and we look forward to sharing any additional data or information that supports beneficiaries, CMS, and American taxpayers. We are committed to providing Medicare beneficiaries with stable access to care and affordable coverage, and ensuring that our plans continue to facilitate good consumer decision-making, improve outcomes and quality, and provide excellent value to beneficiaries.

Sincerely,



Brian Thompson, CEO
UnitedHealthcare Medicare & Retirement

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Improving Program Quality and Accessibility

The Star Rating program has clearly reoriented the industry to quality; the overall level of quality performance within the industry is both measurably improved, and performance variability within measures materially narrowed. Based on these successes, and the overall maturity of this program, UHG believes it is time for the Star Rating program to re-align program incentives, measure weighting, and threshold calculations in ways that better encourage future capital deployment toward actual/objective quality outcomes, not the increasingly important perception related programs or evidentiary gathering administrative costs.

UHG has four specific recommendations that are aligned to this type of program improvement and evolution: (i) decrease weighting for survey (perception-based) measures and modify those specific measures to more consumer-centric indices (e.g. Net Promoter System (NPS)); (ii) address the Stars cliff and the inherent benefit instability that it creates; (iii) eliminate and/or reduce the weighting for measures in which costs for 'proving' the result exceed the investments in actually impacting results; and (iv) establish a more stable and predictable cut point methodology that accurately represents true performance.

UHG's specific recommendations and responses to CMS's proposed changes are outlined below.

Survey Measures: Decrease Weight and Move to Consumer-Centric Indices

Star Ratings rely on Consumer Assessment of Healthcare Providers and Systems (CAHPS) and Health Outcomes Survey (HOS) survey-based measures, which have been shown to have a weak relationship to the care members receive. By shifting away from administrative measures, and by either **removing or reducing** the weight of CAHPS and HOS survey measures, CMS could drive more investment towards member benefits and direct care, and better align Star Ratings with plan quality.

UHG is committed to its foundation as a customer-centric organization to improve quality and achieve long-term Stars performance. One of the tools used for building a customer-centric organization is the NPS Operating Discipline. NPS is a multi-industry standard that measures the affinity people have for a company and everything that comes with it. NPS tracking and goals are in place for 50+ lines of UHG businesses and customer segments. Customer feedback collected through the NPS are used to inform strategic planning and investment, fuel closed-loop processes to resolve issues and identify systemic opportunities, and mobilize our employee base to drive customer loyalty through employee engagement.

Our experience with NPS has provided insights into the challenges and best practices of capturing and acting upon customer feedback. While CAHPS offers a set of insights, there are outstanding issues with the structure of the CAHPS survey that limits the effectiveness of the data.

These challenges include:

- The CAHPS survey is comprised of redundant questions (e.g., rating of customer service, health plan, drug plan, etc.) that attempt to answer one similar question – how satisfied are MA Plan members with their plan. By substituting a single, proven question like NPS for the multitude of questions that exist today, the CAHPS survey would be easier to administer and answer, reducing

survey administration costs and allowing funds to be allocated to improve MA Plans' member outcomes.

- CAHPS cannot be used to improve plan performance, since CMS does not allow the survey respondents to be disclosed after the survey is completed. This does not allow for identification of root cause or remediation without investing significant dollars to obtain MA Plans' member feedback that may or may not have impacted results.
- A paper-based survey is outdated, skewed and unscientific, while other survey implementations (website and telephone) can lead to quicker data collection and the ability to better manage sample compositions by setting quotas to ensure data are representative of MA Plans' membership.

Currently, these survey measures represent approximately 28% of the Star Rating. UHG suggests that given the challenges with the current survey methods and that these are not clinical measures, this level of weight is too high and recommends that CMS reduce the significance of the survey measures in the overall Star Rating.

In addition, UHG recommends that CMS consider utilizing a streamlined single question to measure customer satisfaction, like NPS, that is more reflective of the MA Plans members' experience than CAHPS and HOS. The Medicare Payment Advisory Commission (MedPAC) commissioners also discussed the possible use of NPS in place of CAHPS survey measures in their November 2018 meeting. UHG welcomes the opportunity to discuss survey methods and use of data in greater detail with CMS and an implementation timeline that would recognize the investments MA Plans have made in the existing processes.

Star Bonuses and Benefit Stability (Stars Cliff)

To maintain the stability of beneficiary benefits, it is important to be able to predict bonus and rebate payments over a multi-year period. UHG recognizes that CMS is working to increase stability in this Proposed Rule by soliciting input on the cut point methodology, and we are providing feedback and recommendations on how to best achieve that goal in this response. However, we believe that addressing the "Stars cliff" is also a crucial step in stabilizing the Star Ratings bonus and rebate structure. Currently, the difference between a 3.74 score (3.5 Stars) and a 3.75 score (4 Star) results in a significant impact on funding that can lead to a 50% reduction in supplemental benefits that may not reflect a commensurate difference in plan quality. This puts MA Plans and Part D Sponsors in a position of diverting investment in member benefits to administrative spending to protect against losing Stars-related revenue. In addition, as the Stars measures continue to have an administrative focus, it further drives more investment towards documentation and capturing "proof of care" and away from enabling direct, better care for an MA Plan's members. It is important that spending on quality is not supplanted by administrative spend.

UHG recommends CMS work with MA Plans and Congress to change the current bonus and rebate retention structure to include a bonus for 3.5 Star plans, dampen the rate differences between 3.5 and 4 Star plans, and reduce the rebate retention difference (15%) between 3.0 and 3.5 Star plans. In the interim, CMS could offer a demonstration to smooth out the bonus payment structure to more accurately reflect plan quality.

CMS could also use its demonstration authority to reinstate rebate retention percentage to 75% for all Star levels. If an MA Plan is driving savings from Medicare Fee-for-Service (FFS) levels at whatever bonus

adjusted benchmark is being used, the Star Rating should not impact how much the MA Plan can use for supplemental benefits. This would also help mitigate the potential for MA Plans' member disruption year over year due to Star Ratings fluctuations.

Star Measures that Emphasize Administration Over Outcomes

The current Star Rating measure set emphasizes administrative measures, which drives more investment towards documentation and capturing "proof of care" and away from direct, better care for members.

UHG believes that early identification of member risk indicators through prospective data collection is essential to provide MA Plans' members with medical and social services needed to improve health outcomes. However, retrospective chart review does not allow MA Plans to act effectively to better influence prospective appropriate medical protocols and interventions. UHG supports National Committee on Quality Assurance's (NCQA's) recent proposal for data collection that would reduce provider burden by allowing for electronic submission that would replace chart retrieval on all hybrid measures and urges CMS to give this proposal serious consideration in light of its expressed desire to reduce provider burdens and paperwork.

UHG further recommends eliminating or modifying the following administrative measures that do not directly address the drivers of health outcomes.

- **Osteoporosis Management in Women Who Had a Fracture**: Screening with bone ultrasound after a fracture has occurred does not consistently lead to therapy for the member. UHG recommends screening for osteoporosis prior to fracture, consistent with how Medicare covers screening for osteoporosis.
- **Disease-Modifying Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis (RA)**: Verification of diagnosis and related claims correction is the primary cost driver for this measure. The medications in scope for gap closure are not routinely administered by primary care physicians (PCPs). These identified factors impact treatment protocol administration and adoption. UHG recommends that the measure numerator be limited to RA patients under treatment with Rheumatologists (with a minimum number of claims per year, perhaps 3, to avoid including misdiagnoses) in order to more effectively reflect health outcomes for this population set.

In addition, certain measures should be restructured to ensure that they do not inadvertently penalize MA Plans for actions that do positively impact the member:

- **Members Choosing to Leave the Plan:** Ensuring MA Plan members have freedom of choice and access to the best plan available for their needs as those needs evolve and change is a foundational priority, and should not negatively impact performance on the C30 measure. UHG recommends that CMS exclude MA Plans' member switching between any plans within the same parent organization from the disenrollment calculation, whether or not on the same contract.

  MA Plan members may switch contracts between the UHG commonly owned contracts for a number of reasons, including a change in special needs status or the decision to switch to a MA Plan with benefits, premium, or network that better suits their healthcare needs. An MA Plan member's choice to move to another plan within the parent organization reflects member satisfaction with the organization and should not lead to a negative impact on the disenrollment

measure.

- **Complaints about the Health/Drug Plan:** CMS allows Medicare beneficiaries to submit CTMs about MA Plans or Part D Sponsors that restrict their opioid access, impacting performance on measures C28 and D04. CMS should modify Measures C28 and D04 to exclude MA Plan or Part D Sponsor member complaints about MA Plans or Part D Sponsors that appropriately restrict their opioid access. CMS should also change patient surveys to ensure responses from beneficiaries who are misusing opioids do not have an inappropriate impact on a Part D Sponsor's Star Ratings.

CMS should also consider eliminating duplicative administrative measures in order to redistribute weight to those measures that reflect improved health outcomes – such as:

- **C34 – Call Center Foreign Language Interpreter and TTY Availability and D01 - Call Center Foreign Language Interpreter and TTY Availability:** UHG recommends that CMS combine the call center sampling for C34 – Call Center Foreign Language Interpreter and TTY Availability and D01 - Call Center Foreign Language Interpreter and TTY Availability. These two measures are highly correlated (90%) and therefore should be treated as one measure.

Measure-Level Star Ratings - Stabilizing Cut Points

UHG agrees with CMS that stabilizing the cut points is important to accurately measure quality and ensure that benefits are reasonably stable to protect beneficiaries. However, UHG believes that CMS's proposal to add resampling and guardrails to the current hierarchical clustering methodology is not the most effective method for improving stability and measuring true performance. The MedPAC commissioners are also discussing these same issues, including most recently in their November 2018 meeting, and we will continue to follow their discussions and monitor their recommendations.

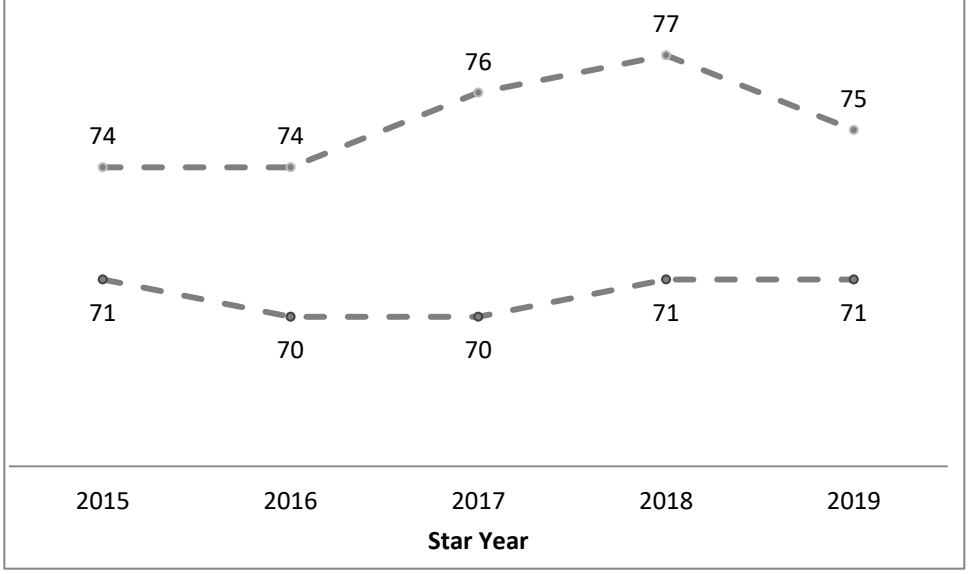
UHG has specific feedback on CMS's proposed changes and our own recommendations below related to the cut point methodology.

Concerns with Resampling

CMS has proposed implementing "mean resampling" to improve the stability of cut points by reducing the sensitivity of the clustering methodology to outliers contracts. UHG recognizes and supports CMS's effort to minimize the impact of outliers without removing them. UHG believes it is important to not remove the outlier contracts since the outlier data is real and should be addressed in a thoughtful manner.

UHG's simulation analysis shows that the resampling approach is not as effective at achieving stabilizing the impact of outliers as suggested, because it still results in a larger than expected range of possible cut points. Also, the observed cut point variability is only partially attributed to outliers, while the rest is related to SAS-documented clustering limitations related to ties when merging clusters. This can cause a randomization effect, resulting in increased variability in each resample. For example, a simulation analysis on the Breast Cancer Screening measure from a previous Star year resulted in 130 unique sets of cut points based on 1,000 separate runs of the resampling method. Each resampled run creates a new set of data resulting in a different set of ties to be resolved during the clustering algorithm. CMS's methodology would select just one of the 130 potential cut points in the example of the Breast Cancer Screening measure, and as Graph 1 shows, cut point 4 could be anywhere across a wide range from 71 and 77 .

Graph 1. **Resampling variation too high**. Results based on resampling method with Breast Cancer Screening for Cut point 4. Lines represent minimum and maximum values across 1,000 resampling runs.



Another concern with the resampling method is the amount of data eliminated at each clustering calculation. Ten percent (10%) of industry data is eliminated at each run and can create unexpected gaps in the data that may result in additional variability related to the issue of clustering ties.

While UHG recognizes that outliers contribute to cut point variability, and that the resampling method lessens the size of that variability, UHG recommends that outliers be addressed more directly by measure developers. We have provided more detail on this recommendation below.

Concerns with Guardrails

CMS has also proposed implementing guardrails, a 5 percent cap that would restrict movement both above and below the prior year's cut points. UHG believes that guardrails could potentially serve as a safe-guard, but are not the most effective means of stabilizing cut points. In addition, they come with a risk of capping real industry performance improvement. UHG proposes an alternate approach to stabilizing cut points that avoids capping improvement as detailed below.

UHG Recommends Alternative Approaches

1. Three-Year Rolling Average with Fixed Threshold for Topped Out Measures

UHG's analysis has shown that using a three-year rolling average, with fixed thresholds for "topped- out" measures, would be more effective at achieving stability, improving quality, and measuring true performance than the resampling with guardrails that CMS has proposed. In addition, we suggest specific stabilization methods, including cut point re-ordering and increasing data reliability by measure design modifications.

In the November 16, 2017, "*CMS Proposed Rule: CMS Policy Changes and Updates for Medicare Advantage and Prescription Drug Benefit Program for Contract Year 2019*," CMS asked stakeholders to consider a moving average of the cut points over the two or three most recent years as a possible cut point methodology. As communicated in our response to that Proposed Rule, UHG supports that approach and specifically would recommend a three-year rolling average to increase stability. As CMS has recognized, the current clustering methodology is highly sensitive to the movement of even a single contract. At present, it is very common for an improving raw score to produce a declining Star Rating year over year due to the sensitivity of the clustering methodology. Additionally, the year-to-year variation creates a "moving target" for processes and clinical goals. Resources that could have been deployed more effectively on clinical programs are instead utilized to work toward Star Rating goals that are subsequently changed. With a three-year rolling average, extreme fluctuations will be stabilized and MA Plans can deploy more resources to measures that would benefit from increased focus, rather than devoting those same resources to measures where high performance has already been achieved.

CMS cites the Technical Expert Panel's ("TEP") concerns that fixed, pre-announced cut points would eliminate the incentive for MA Plans to continue to focus on improvement once the fixed threshold had been achieved. The three-year rolling average will continue to promote industry improvements, and the steady rate of increase will allow for long-term planning strategies instead of short-term wins. CMS also pointed to the TEP's concerns that fixed cut points would not adjust to reflect structural factors that might change scores, such as the adoption of Electronic Health Records. Cut points based on a three year rolling average would reflect broad industry shifts of this kind while dampening the effects of outliers to the trend. Finally, CMS pointed to the fact that newer measures tend to show more rapid improvement, and fixed cut points based on this early period of improvement could artificially inflate future cut points and lower Star Ratings. Again, a three-year rolling average would be influenced by the pace of improvement without shifting dramatically year over year. Overall, UHG believes that a three year rolling average for measures that have not yet topped out strikes the right balance between the concerns raised by CMS and the TEP while still providing increased stability and predictability.

Fixed Cut Points for Topped Out Measures

Applying one cut point approach to all measures provides a simplified methodology. However, given that not all measures behave the same, it is more appropriate to consider special methodologies for some measures. CMS already recognizes this in the case of CAHPS measures, where a separate percentile approach is applied since survey measure results follow a more symmetric distribution. Other special measures to consider are those that have "topped out." As CMS and UHG have observed, longer standing measures have exhibited a tendency to flatten out, as higher levels of improvement are not sustainable. Because these measures have less room for improvement, it would be better to shift focus to areas where performance is lagging, instead of using additional resources on measures that are already performing well. This "race to the top" approach "may not yield the greatest clinical benefit and may lead to overtreatment of patients."[1] A large percentage of contracts perform well for these skewed measures, and the lowest 5-10% contracts are the ones that show larger improvement as they "catch-up" to the majority of contracts. An unintended consequence of this bottom upward shift is that the cut points 4 and 5 may shift over, requiring already high performing contracts to perform even higher. The additional resources

[1] *Measuring Success in Health Care Value-Based Purchasing Programs*, RAND 2014

needed for "over the top" improvement on high performing measures would be better allocated to measures needing more improvement.

Therefore, for these topped out measures, UHG proposes fixed cut points based on the most recent year when the measure is categorized as topped out. For example, topped out measures could be identified by examining industry average performance for the last five Star years. When the industry average starts to improve at a reduced rate for a few years in a row, it could be classified as a topped out measure. Some current examples are: the Adult BMI, Plan Makes Timely Decisions about Appeals/Reviewing Appeals Decisions, Call Center Foreign Language/TTY Availability, About the Health/Drug Plan, Diabetes Care-Kidney Disease Monitoring, MPF Price Accuracy, and the Care for Older Adults measures.

CMS has previously proposed removing topped out measures from Star Ratings, and UHG believes that this should only be done with careful review. CMS should not remove measures where maintaining a high level of quality is still important. Removal should be limited to measures that are no longer clinically appropriate, and special analysis is needed so that too many topped out measures are not removed as that will unintentionally disrupt overall performance significantly. By applying a fixed cut point to topped out measures, CMS can achieve many of the same goals as in removing these measures, while maintaining the stability of the Star Ratings program and beneficiary benefits.

We are proposing two additional methods below – reordering and improving measure reliability - that could be used in conjunction with the three-year rolling average of cut points to most effectively increase stability. Alternatively, any of UHG's recommended methods for improving stability could be implemented independently.

2. Reordering

In place of resampling, we recommend reordering. Reordering solves a documented issue within the SAS clustering algorithm by running clustering repeatedly, sorting the data randomly each time, and choosing the set of cut points derived most frequently. UHG simulations based on 1,000 random permutations resulted in a reasonable range of cut points with the most frequent set generally near the middle. Breast Cancer Screening for Star Year 2019, for example, resulted in four sets of unique cut points after running 1,000 random permutations:

Cutpoint Scenario	ctp2	ctp3	ctp4	ctp5	Probability of Selection	
low	47	62	72	82	27%	
mid1	47	64	75	82	23%	
mid2	47	66	75	82	25%	
high	47	68	76	82	25%	<--Published Cut points

The source of the variation in these cut points is the random aspect for breaking ties. Cut points 2 and 5 are the same in all four sets, but the range in possible values for the remaining cut points is 4 points. That is a significant level of variation. The actual selected set of cut points is equally as likely as a set of cut points where the 3 and the 4 star cut point are 4 points lower. UHG shared this recent discovery with CMS

during plan preview. This example shows the variation in cut points that is currently being attributed towards suspected outliers.

3. Improving Measure Reliability

UHG recommends that any attempt to stabilize cut points include addressing data reliability via the measure design. Ensuring the use of reliable data is crucial for the overall integrity of the Star Ratings system, because if unreliable data inappropriately distorts industry performance for cut point calculations, then it would also distort the measure and overall ratings for the suspected outlier contracts. Instead of attempting to reduce the impact of extremely large or small measure rates for cut point calculations through resampling, UHG recommends these suspected outliers be reviewed more thoroughly by measure developers. In most cases, outliers can be attributed to: contracts with smaller enrollment; data that is not clinically appropriate; contracts that are not eligible for an overall rating; or reliability levels that are not appropriately set at higher levels.

For example, Breast Cancer Screening during Star Year 2017 had four outlier contracts identified which were contracts that had a population that is not clinically appropriate for such a screening, such as the institutional population enrolled in an Institutional Special Needs Plans (ISNP) contract. NCQA and CMS correctly modified the measure specification to exclude these members from the measure for future years. This example provides a template to address root causes of outliers in the future.

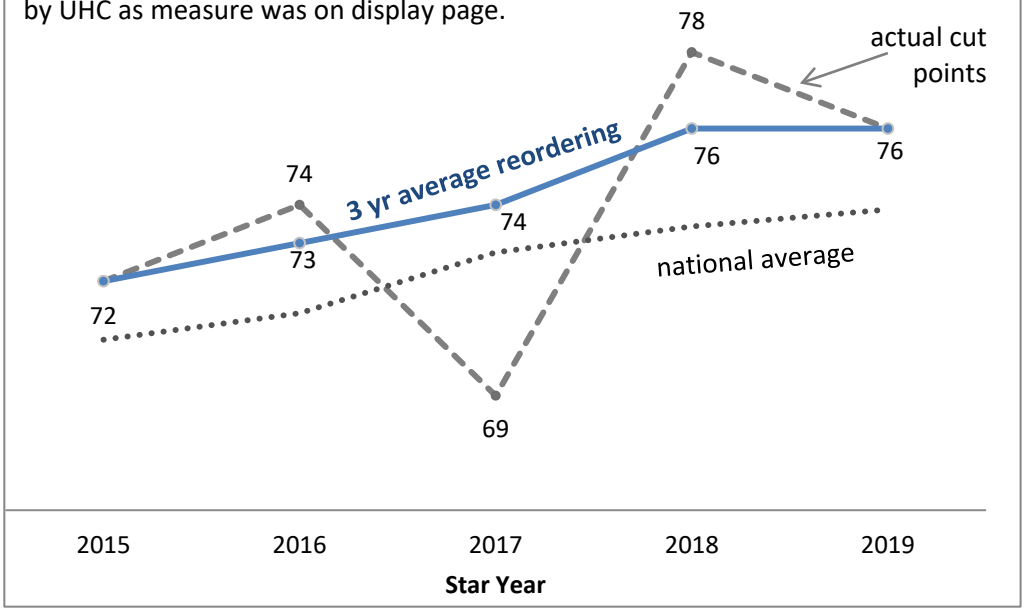
> **Breast Cancer Screening** suspected outliers - clinically inappropriate and lack financial incentives
> H0710: Rate = 32, 2015 enrollment= 2,877, 100% ISNP (not clinically appropriate)
> H1777: Rate = 14, 2015 enrollment= 1,582, 100% ISNP (not clinically appropriate)
> H2406: Rate = 30, 2015 enrollment= 881, 100% ISNP (not clinically appropriate)

UHG recommends that measure methodology be reviewed by measure developers to set more appropriate rules to define reliable data when needed. These recommendations may include increasing the minimum denominator or enrollment threshold to ensure that measure data is reliable and that it excludes members for which the measure may not be clinically appropriate or applicable, such as the example of exclusion of institutional members for Healthcare Effectiveness Data and Information Set (HEDIS) measures.

Illustrative Examples

We provide the two graphs to help describe the concepts discussed above. Graph 1 (above) “Resampling variation too high” illustrates the amount of variation that can occur with the resampling method. The dotted lines represent the range of all runs. CMS only proposed running the resampling method once, which could result in a set of cut points that lands near the maximum or minimum values and may not result in more stable cut points. Averaging across many resampling runs would mimic the reordering method proposed to fix the issue with clustering ties. Although the resampling method does lessen the sensitivity of outliers, UHG still recommends that outliers be addressed directly earlier in the process by measure developers instead of dealt with partially in cut points.

Graph 2. Three-year average with reordering trending same as industry average. Results based on the three-year average for cut point 4 where each yearly run is based on 1,000 random reordering runs with exlusions applied to mimic exlclusion of non-clinically appropriate data. *2015 cut points estimated by UHC as measure was on display page.



Graph 2, "Three-year average with reordering trending same as industry average," illustrates the recommended reordering approach. This approach also applies exclusions to mimic exclusion of non-clinically appropriate data. To further smooth any remaining variability, a three-year average was applied. This set of cut points appropriately follows the industry national average and also significantly reduces the variability when compared to actual cut points.

Additional Recommendations Related to Cut Points

Special Cut Point Methodology Case - New Measures

UHG recommends that CMS consider new measures be considered for special cut point methodology. As noted by CMS, new measures demonstrate significant improvements in the few first years. However, prior to the first Star year as a measure, there are no published thresholds made available and also due to significant industry increases, it is difficult to determine an appropriate target to measure success. For these measures, UHG proposes advance notice of thresholds for the first three Star years so that long-term strategies can be implemented. After the third year, cut points based on a three-year average can be provided under the normal timeline for non-new measures.

Increase Calculation Transparency

UHG recommends that CMS provide full industry data used for cut point calculations for the last five years, as well as providing it going forward. This will allow UHG and other organizations to fully validate cut point calculations, as well as research proposed enhancements. In order to validate fully, UHG recommends that de-identified industry data be provided during the plan preview period so that cut points can be recalculated and compared with CMS-derived cut points. An increased level of transparency surrounding

calculations will allow organizations to discover errors more easily and contribute to Star Ratings enhancements in a more meaningful way.

Proposed Measure Updates

UHG supports the proposed changes to the Controlling High Blood Pressure, MPF Price Accuracy, and Plan All-Cause Readmissions measures.

Extreme and Uncontrollable Circumstances

UHG supports the efforts CMS has made to adjust the Star Ratings program for contracts and beneficiaries impacted by severe natural disasters. However, we request CMS delay codifying the current disaster logic, as we believe additional modifications to the policy are needed.

First, UHG recommends that CMS reconsider the 25% threshold with individual assistance and a Section 1135 waiver that a contract must meet in order to receive any adjustment. Given that each natural disaster produces a unique set of impacts, the 25% threshold used for previous natural disasters may not be a meaningful threshold for assessing whether a contract is impacted. In fact, our analysis of the 2018 measurement year indicates that there are a number of contracts that are close to the 25% threshold and the 'natural break' in the data will not occur at 25%. Additionally, there are a number of beneficiaries who are impacted by natural disasters who do not meet the current disaster criteria. For example, beneficiaries who were ordered to evacuate, an often costly and disruptive event, may have trouble affording or getting back in the habit of filling their prescriptions if they feel they have more immediate needs. We propose that CMS consider a lower threshold of beneficiaries impacted, or a more inclusive definition of beneficiaries impacted for the better of two years adjustment.

Next, for contracts that have membership impacted by the disaster, but do not meet the minimum percent impacted to warrant the "better of two years" adjustments, UHG proposes CMS work toward a proportional adjustment to prevent adding an additional payment "cliff' to the Star Ratings program. UHG recommends CMS calculate measure rates with and without disaster impacted beneficiaries and take the better of the two rates. This would hold plans impacted by a disaster harmless, while still measuring the plan for their current year performance and allowing for improvements made in disaster impacted regions before the disaster occurred. This would also allow MA Plans to focus on helping their members with their immediate needs following a natural disaster.

Finally, the current disaster policy does not have a specific adjustment for contracts that are too new to be measured, but are considered impacted. UHG recommends that these contracts remain as "Plan too new to be measured" for an additional year if the contract meets the disaster criteria.

Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits (§§ 422.100, 422.135, 422.252, 422.254, and 422.264)

UHG supports CMS's proposed implementation of the provision in the Bipartisan Budget Act of 2018 (BBA 2018), which allows MA Plans to provide additional telehealth benefits to Medicare beneficiaries and treat them as basic benefits. UHG believes expanding coverage for services obtained through telehealth will improve Medicare beneficiaries' access to care and potentially help them better manage their health and lead to better outcomes. We appreciate CMS's recognition of the need to allow for flexibility in the implementation of the telehealth benefits, but believe there are areas where additional flexibility will

significantly improve MA Plans' ability to offer and manage these additional benefits. As proposed, some of CMS's operational rules could create administrative burdens, resulting in unnecessarily restricting telehealth access because MA Plans may decide not to offer the benefit. UHG has specific recommendations and requests for clarification.

Benefit Disclosure

UHG appreciates that MA Plans would need to disclose to their members that telehealth is a covered benefit. However, UHG believes it is overly restrictive to require MA Plans to identify in the Evidence of Coverage (EOC) each specific service that will be covered through telehealth. UHG recommends CMS provide more flexibility in how MA Plans are able to disclose and describe the offering of telehealth benefits so that MA Plans could add coverage mid-year for services not initially available through telehealth to account for situations such as providers adopting new telehealth technology and practices. For example, a provider group may only support primary care services through telehealth at the time the EOC is printed. Later in the benefit year, that group may add mental health services to their supported telehealth services. Accordingly, we recommend CMS allow MA Plans to describe additional telehealth benefits in general terms in the EOC and other materials, without explicitly listing each service that is offered as an additional telehealth benefit.

Provider Directories

UHG does not support CMS's proposal to require MA Plans to use their provider directories to identify the specific providers offering services for additional telehealth benefits and in-person visits or offering services exclusively for additional telehealth benefits. This requirement would be onerous for both the MA Plan and the providers offering telehealth services. The specific providers offering services through telehealth could change frequently, as providers develop a better understanding of the types of patients and conditions they feel comfortable assessing through telehealth. It could also be difficult for provider offices and group practices that are implementing telehealth technology to appropriately identify which individual providers are offering the services. Similarly, to accurately reflect an individual provider's status may also require MA Plan oversight of each telehealth provider's technical capabilities to avoid inaccuracy in the directory. Requiring providers and each MA Plan contracted with these providers to track these changes in real-time would require a significant amount of time and undue administrative effort.

Alternatively, we suggest CMS allow MA Plans to use the EOC to describe how members can obtain information on how to access telehealth services through available providers and vendors of telehealth services. This could include listing the telehealth provider or vendor website addresses in the EOC or other plan materials. It would be administratively easier and less confusing for MA Plans to direct their members to a website or telephone number to access the service—the website address and telephone number would not change even if the provider roster staffing the service were adjusted.

Provider Networks

CMS requested comments on what, if any, impact additional telehealth benefits should have on MA network adequacy policies. UHG supports CMS considering telehealth providers in the assessment of network adequacy. In addition, we encourage CMS to take a broader view regarding the current time and distance criteria. If CMS were to broaden its evaluation of network adequacy and availability beyond just the current time and distance requirements, UHG believes that telehealth professionals could be accounted for within the health service delivery (HSD) tables.

In the event that CMS maintains the current HSD time and distance standards, UHG supports the utilization of telehealth providers in areas where there is currently a shortage of specialty providers. Specifically, UHG recommends that CMS allow MA Plans to list telehealth providers serving Medicare beneficiaries in a particular service area in their Network Adequacy Exception Requests and count them as providers in that particular network for the purposes of determining network adequacy.

We also suggest CMS clarify in guidance that when MA Plans offer a telehealth benefit supported by local providers in the medical network, those providers may limit access to their telehealth services to members of the MA Plan who are patients of their medical group and not require those providers to make the telehealth service available to all members of an MA Plan. In this situation, we believe the benefit offering is consistent with the uniform benefit rules because all MA Plan members are free to choose a provider that supports telehealth, even though MA Plan members who choose a different provider group that does not support telehealth may be unable to access any telehealth services.

Bidding Requirements

UHG requests greater clarity on how CMS expects MA Plans to file the additional telehealth coverage in the bid and plan benefit package (PBP), including whether CMS will require MA Plans to account for differences in their member cost sharing between telehealth services and in-person services.

Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

UHG agrees with CMS that integration for dual eligible beneficiaries across Medicaid and Medicare is important, and we support holistic programs that include long-term services and supports (LTSS), as well as behavioral health (BH). We applaud CMS for developing Dual Eligible Special Needs Plan (D-SNP) integration requirements in a manner that acknowledges and respects the flexibility provided to states under the Medicaid program. State Medicaid program designs necessarily vary by state due to local delivery systems, county programs, state budgetary and political pressures, and other factors. By allowing states to contract with one or more of the integrated SNP types, CMS ensures that states have flexibility to determine the form(s) of integration that will best serve their dual eligible beneficiary population considering the many factors at play in their Medicaid program. We appreciate that this approach gives states the ability to promote integration in a manner that is incremental and minimizes the disruption to Medicare beneficiaries, state Medicaid programs, and D-SNPs.

UHG cautions that the alternative interpretation considered by CMS, namely, that in states with Medicaid managed care for dual eligible beneficiaries, only Medicaid managed care plans could offer a D-SNP – would likely result in significant disruption to beneficiaries who are currently enrolled in unaligned D-SNPs. In addition to the initial disruption in 2021, requiring strict alignment wherever state Medicaid program design permits it, would create a cycle of regular D-SNP market exits to align with Medicaid Managed Care Organization (MCO) procurement changes. This would reduce competition in the D-SNP marketplace, as well as discourage D-SNPs from investing in their care models and infrastructure.

Hospital and Skilled Nursing Facility Admissions

We support CMS's decision to promote integration for non-aligned D-SNPs via a state Medicaid agency contract requirement to provide notice in the event of a hospital or skilled nursing facility (SNF) admission,

and believe this is consistent with the intent and language of the BBA 2018. This approach will facilitate care transitions for dual eligible beneficiaries in instances where they are not enrolled in an aligned D-SNP product and provides a framework upon which states can advance integration in the future. We also appreciate CMS providing states sufficient flexibility to implement this requirement as appropriate to their state needs and readiness to share information and data. As we further note, we are concerned with states' ability to implement appropriate data sharing mechanisms, particularly by 2021. We request that CMS take a lead role in facilitating the data sharing that will be necessary to support this Proposed Rule's changes, and be expansive in how it determines compliance with this requirement for 2021.

State Burdens

As a general matter, UHG is concerned that increased regulatory or administrative burdens for states, for example in the transfer of hospital and SNF data, may discourage states from pursuing or continuing D-SNP programs. To that end, we encourage CMS to consider increasing the Federal Medical Assistance Percentage (FMAP) states receive for activities related to dual eligible beneficiary integration and in particular, for programmatic or system changes to come into compliance with D-SNP integration. We would encourage CMS to extend the increased FMAP to care coordination and appeals and grievances (A&G) requirements as well (e.g., developing systems to provide line of sight to D-SNPs and MCOs), in instances where this development does not already fall under that "design, development, and implementation" category for information technology (IT), or for resources a state expends to intake and analyze Medicare encounters and utilization. This approach could mitigate state financial burdens related to this Proposed Rule and expedite state efforts around dual eligible beneficiary integration.

We also recommend CMS consider developing resources to facilitate efficient data sharing between D-SNPs, Medicaid agencies, and Medicaid MCOs. Data sharing will be central to the success of many of the proposed requirements, including SNF and hospital admission notifications, "arranging for benefits" for full dual eligible beneficiaries, and providing integrated A&G, as well as assistance with Medicaid A&G processes. Having an effective means to share data is particularly crucial when a Medicare beneficiary is enrolled in separate organizations for his/her Medicare and Medicaid benefits. In most states, there is no centralized, automated method to share information about a beneficiary's coverage, or to provide notification of admissions.

We believe that direct data sharing between the D-SNP and Medicaid agency or the MCO will allow for the timeliest action following a care transition or other significant event. To facilitate this with minimal burden to states, the most robust and effective option for data sharing is a CMS-managed portal that could allow for real time data from providers regarding admission, emergency department and discharge dates, and could be used by state Medicaid plans, Medicaid MCOs, D-SNPs, external health homes, and providers to exchange information necessary for coordination of care. We believe a central database is the ideal approach, but as an alternative, UHG recommends that CMS modify the Transformed Medicaid Statistical Information System (T-MSIS), or other existing state Medicaid program to CMS feed, to include the same information. CMS should then filter that information into its MARx system so that it is visible to the MA Plans providing the D-SNP coverage. CMS and states also could consider allowing D-SNPs enhanced access to T-MSIS systems, such that D-SNPs would have non-blinded line of sight into the Medicaid experiences of their members. Second, CMS could modify the format of the nationwide standard 834 file to include fields for the state to add in the name of the Medicare beneficiary's Medicaid carrier, their Medicaid aid category, the Medicaid MCO contact name, and the Medicaid MCO agency contact telephone number. In addition to reducing state burden, this approach would allow for consistency across markets and should

facilitate interaction across CMS and states.

We also support efforts focused on prohibiting arrangements that tie carrier participation in D-SNP programs to participate in other State Medicaid programs unless the State demonstrates to CMS it is marketing these programs in an actuarially sound manner. This will improve competition and the actuarial soundness of State Medicaid programs.

Notification Requirement Implementation Timeline

UHG supports CMS in deferring to state Medicaid agencies on the method by which hospital and SNF admission notifications occur. Depending on when CMS finalizes these requirements, it is plausible that some states may need time to test and implement automated notification technology. UHG urges CMS to consider this integration component to be met, as long as the notification requirement language is in the 2021 State Medicaid Agency Contract (SMAC) with full implementation no later than the 2022 plan year. For such situations, the D-SNP should be allowed to continue to operate in 2021 without enrollment sanction.

Promoting Integration

UHG also believes that CMS should provide incentives and flexibilities to D-SNPs to make them the most attractive and appropriate products to dual eligible beneficiaries. We encourage CMS to consider these flexibilities for all D-SNPs, not just highly integrated dual eligible (HIDE) and fully integrated dual eligible (FIDE) SNPs. Such an approach would maximize Medicare beneficiary access to integrated and robust products regardless of whether a state has pursued managed LTSS and/or managed BH program for dual eligible beneficiaries. Example incentives include the following:

- D-SNPs that meet 2021 integration requirements should be allowed to market to new Medicare beneficiaries year round, irrespective of a 5-Star Rating. Should CMS desire to maintain a Star Rating link to annual marketing, UHG recommends that D-SNPs be allowed to qualify at 4 Stars.
- CMS should allow dual eligible beneficiaries to use a monthly special election period (SEP) in instances where they are electing enrollment into a D-SNP (i.e., an “integrated plan”).
- CMS should consider approaches to apply frailty payments at the individual level in all D-SNP products; for example, any individuals enrolled in a D-SNP that meet the state’s nursing facility level of care (NFLOC) criteria.
- CMS should measure D-SNPs separately in the CMS Star Rating System to ensure measurement takes into account the complex clinical profile of patients receiving care through a DSNP and the various State and Federal requirements that DSNPs have to meet.

Supplemental Benefits Flexibility

We appreciate CMS’s expansion of supplemental benefits available to MA Plans and believe this expansion will further the ability to meet the broader social and unmet needs of members that impact their health. We encourage CMS to allow maximum flexibility of the 2019 and 2020 supplemental benefits. In particular, we recommend that CMS interpret the new supplemental benefits flexibility to allow all MA Plans to include benefits such as nutrition benefits and non-health-related transportation. Alternatively, we believe that CMS could permit some new types of additional benefits under the supplemental benefits flexibility available to HIDE and FIDE plans.

Supplemental Benefits – Definition of Chronically Ill

The BBA 2018 expands supplemental benefits for chronically ill individuals beginning in 2020 such that these benefits no longer will be limited to "primarily health related" benefits. We applaud Congress and CMS for movement in this direction. An individual's health is heavily influenced by factors that exist outside the healthcare they receive, and we anticipate this expanded supplemental benefit flexibility will facilitate MA Plans' ability to address the myriad of factors which influence an individual's overall health and well-being. We recognize that the BBA 2018 limits such expanded flexibility to individuals with medically complex chronic conditions, and encourage CMS to define medical complexity expansively to maximize the impact of this new supplemental benefit flexibility. For example, researchers have defined medically complex patients as "those exhibiting patterns of use of care demonstrating lack of coordination," inclusive of individuals who access emergency departments for primary care or who have inconsistent drug use and adherence patterns.[2] "Chronic condition" also is defined in various ways, including conditions that "require ongoing medical attention and/or limit activities of daily living."[3]

UHG recommends that CMS consider these broad definitions as it develops guidance for expanded 2020 supplemental benefits. For example, CMS might include ICD-10 Z-codes reflective of "health hazards related to socioeconomic and psychosocial circumstances" as acceptable medically complex chronic conditions.

We also recommend CMS allow all MA Plans to utilize multiple data sources in determining whether a Medicare beneficiary has a medically complex chronic condition. This approach would capture individuals with conditions potentially not identified in claims data, in particular individuals with mental illness. For example, MA Plans might use self-reported conditions gleaned from health risk assessment (HRA) completion or other beneficiary assessments. In addition, once the Medicare beneficiary belongs in a category for which flexibility should be applied, an MA Plan should have the flexibility to treat the same beneficiary as such in subsequent years.

Partial Duals

We encourage CMS to continue to allow D-SNPs to serve partial dual eligible beneficiaries. This population is vulnerable to many of the same social and healthcare complexities that full dual eligible beneficiaries experience, and as a result, they benefit from the clinical model that D-SNPs are able to provide. For example, D-SNPs can prevent or delay functional decline among partial dual eligible beneficiaries through robust supplemental benefits such as in-home supports that decrease reliance on institutional settings. Moreover, because partial dual eligible beneficiaries do not have access to Medicaid benefits, they benefit from the targeted "Medicaid-like" supplemental benefits in D-SNPs such as non-emergency medical transportation, home-delivered meals, dentures and eyeglasses.

Additionally, the higher touch approach of D-SNPs (e.g., HRAs and Individualized Care Plans) can better identify unmet needs, as well as individuals incorrectly categorized as "partial" who meet a state's requirements to be a full dual eligible beneficiary. As an example, if a Qualified Medicare Beneficiary (QMB) is identified through an assessment process as meeting a NFLOC, a D-SNP can work with the state

[2] The Healthcare Imperative, funded by the National Institutes of Health. Lowering Costs and Improving Outcomes, Institute of Medicine (US) Roundtable on Evidence-Based Medicine Workshop Series Summary. 2010

[3] 4 Warshaw G. Introduction: advances and challenges in care of older people with chronic illness. Generations (2006) 30(3):5–10

to allocate a Medicaid "home and community-based waiver slot" and move that individual into full Medicaid benefits for LTSS, because NFLOC financial eligibility standards are higher than standard Medicaid. A traditional MA Plan generally would not have this state relationship to advocate on behalf of the Medicare beneficiary. Whether fully integrated or not, all D-SNPs can provide assistance navigating complex state programs and a model of care that is responsive to the higher complexity of dual eligible beneficiaries. Allowing partial duals to continue enrolling in D-SNPs will help ensure they are receiving a level of care appropriate to their needs.

Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 – 562, 422.566, 422.629 – 634, 438.210, 438.400, and 438.402)

Assisting with Medicaid Coverage Issues and Grievances

UHG understands CMS's desire to have D-SNPs provide assistance to their members with their appeals and grievances regarding their Medicaid coverage. To ensure that D-SNPs are not penalized when good faith assistance is provided, but the result is ultimately unfavorable, UHG recommends that CTMs associated with assistance with Medicaid coverage issues and grievances be added to the exclusion list for the Complaints Against the Health Plan and Complaints Against the Drug Plan Star Rating measures .

Additionally, as with the proposed SNF and hospital admission notification requirement, effective data sharing will be necessary to allow D-SNPs to effectively assist a Medicare beneficiary with a Medicaid coverage issue. Without knowledge of the Medicare beneficiary's Medicaid enrollment and their specific set of Medicaid benefits, a D-SNP will have limited ability to provide the kind of detailed assistance that CMS proposes. As previously discussed, UHG encourages CMS to consider facilitating options for direct data sharing between D-SNPs, Medicaid agencies, and MCOs.

Integrated Grievances and Appeals for Exclusively Aligned Plans

Overall, UHG supports CMS's proposal to integrate the grievance and appeals process for exclusively aligned FIDE and HIDE SNPs ("applicable integrated plans"). Based on our review of the proposed integrated process and our experiences integrating grievances and appeals in our Medicare Medicaid Plans (MMPs), we are providing a number of technical recommendations and comments to ensure that the integrated process meets CMS's goal of simplifying navigation for Medicare beneficiaries.

Integrated Grievances

UHG requests clarification regarding when the timeline begins for the extension notification deadline. UHG recommends that CMS use the MA guideline that the extension notification deadline timeline begins at the end of the 30 day resolution deadline.

In addition, UHG has one recommendation that we feel will reduce Medicare beneficiary confusion. In some cases, a grievance is both filed and resolved within a single telephone call. However, at 42 CFR 422.629(g), CMS would require that applicable integrated plans send the Medicare beneficiary an acknowledgement of receipt in writing for all integrated grievances and integrated reconsiderations. While we understand CMS's intent to provide written documentation of all filed grievances to a Medicare beneficiary, mailing an acknowledgement letter after the grievance has been verbally resolved leads to confusion. We often hear from our members that they do not understand why they are receiving an

acknowledgement letter regarding a concern that was already wholly addressed in a single telephone call. Therefore, we ask that CMS clarify at 422.629(g) that no written acknowledgement is required in this circumstance.

Integrated Organization Determinations

UHG has previously commented on the Medicare beneficiary confusion that results when a service is denied under Medicare, but is covered under Medicaid, and the Medicare beneficiary receives the required Integrated Denial Notice (IDN). For example, a home health benefit may not meet Medicare coverage criteria, but meets Medicaid coverage criteria and is therefore approved. It has been our experience that mailing an IDN in this situation leads to confusion, as the Medicare beneficiary often focuses on the notice's header, "Integrated Denial Notice" and may not read the content stating the benefit has been approved under Medicaid. This leads to a Medicare beneficiary to mistakenly believing that the service is being denied, when it has actually been approved.

UHG asks that CMS require the use of the IDN only when the requested benefit is being denied or limited by both Medicare and Medicaid. Alternatively, UHG recommends that applicable integrated plans be allowed to send an integrated approval notice instead of the IDN when the service is completely covered under Medicaid. This notice could provide the Medicare beneficiary with their Medicare appeal rights, a key function of the IDN in the circumstance described, but would more clearly inform the Medicare beneficiary that his/her service has been covered.

Integrated Reconsiderations

UHG requests that CMS clarify in the proposed section 42 CFR 422.633 who may request and be a party to an integrated reconsideration. The existing rule for a standard reconsideration is found in 42 CFR 422.582 and contains a section on "parties to the reconsideration." A similar, corresponding section in 422.633 would add clarity and consistency to the new rule. UHG requests that a new section on parties to an integrated reconsideration specify that the parties are the same as they are for a standard reconsideration, as reflected in 42 CFR 422.582 and the Medicare Managed Care Manual Chapter 13, section 70.1. In particular, because the proposed rule governs integrated plans, such guidance in a new section on parties to an integrated reconsideration will provide clear direction to all stakeholders, including states, which may assert that their state-specific rules apply. Consistent with the existing guidance, CMS should make clear that a party to an organization determination, such as a Medicare beneficiary, their representative, or a non-contract physician or provider to the MA Plan, may request that the determination be reconsidered, but that contract providers do not have appeal rights in an integrated reconsideration. Contracted providers should instead follow the process they negotiated with the health plans in their contracts.

For expedited reconsiderations, UHG recommends CMS add clarifying language to align with current MA guidance and explicitly state that applicable integrated plans have three calendar days to mail written notification when verbal outreach to a member is successful.

Finally, UHG recommends that CMS clarify when the timeline begins for the extension notification deadline. UHG recommends CMS use the existing MA guideline which "starts the clock" at the end of the 72 hours or 30 calendar day resolution deadline.

Unifying Medicare and Medicaid Appeals Subsequent to Integrated Reconsideration

UHG supports CMS's proposal for a unified system for appeals processes by applicable integrated plans as modeled after the New York Fully Integrated Duals Advantage (FIDA) process. We recognize the resources and commitment needed, and the potential that only a limited number of states may choose to participate initially. However, the FIDA process resolves the current timing conflict between the Medicare and Medicaid processes, preventing Medicare beneficiary confusion and missed deadlines. This would also improve coordination within the MA Plans, and increase the MA Plan's ability to assist Medicare beneficiaries in the external appeals process. Finally, we believe this would also speed up the results of the external review process and potentially reduce wait time for Medicare beneficiaries should a benefit decision be reversed.

UHG offers one recommended modification to the potential integrated external review process: when the Medicare beneficiary receives the notification of the external review, we recommend that the notice provide the option for the Medicare beneficiary to either attend in person or telephonically. The notification would also inform the Medicare beneficiary that should he/she choose not to attend in person or telephonically, the external agency will review the case with no additional information. If the Medicare beneficiary chooses not to participate, then the MA Plan also may also decline to attend.

Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§ 423.153)

UHG appreciates CMS's proposed efforts to supply requesting Part D Sponsors with Parts A and B claims data extracts on a voluntary basis. We look forward to CMS releasing more specific guidance to Part D Sponsors regarding what the data will include (e.g., sample file layout) and how the data could potentially be used. In particular, we request that CMS clarify whether the data extracts "from all seven claim types, including inpatient, outpatient, carrier, durable medical equipment, hospice, home health, and skilled nursing facility data" will be comprised solely of FFS claims data, or will the data also include Parts A and B claims data furnished by MA Plans. UHG recommends that CMS allow for additional comment opportunities on this topic so that Part D Sponsors can share feedback on the data's usefulness with CMS.

Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE

Appeals Process for Individuals and Entities on the Preclusion List

UHG supports CMS's proposal to consolidate a prescriber or provider's Medicare revocation and preclusion list appeals processes so that they run concurrently. Effectively this means that if a prescriber or provider is placed on the preclusion list in conjunction with the revocation of their Medicare enrollment, no more than 5 months will expire before they are placed on the preclusion list. UHG also supports not placing prescribers and providers on the preclusion list until their first level of appeal is exhausted because it limits the possibility of an individual or entity being added and then subsequently removed from this list due to the outcome of an appeal. This will result in fewer claims being denied or paid incorrectly. We also support making the updated appeal process effective 60-days after publication of this final rule.

Claim Denials and Beneficiary Notification

CMS proposes to add a new paragraph at 422.222 (a)(1)(ii)(C) to state: ''Must not deny payment for a

service or item furnished by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph(a)(1)(ii)(A) of this section.''

In November 2018, CMS provided an updated preclusion list file layout to the industry, in which it has added a new field, "CLMREJECTDATE". CMS defines this field as the date by which all MA Plans and Part D Sponsors must deny claims, which is 90 days after the Exclusion Date. Prior to receiving this file, it was not clear on what the claim denial date was. The file layout and field definition, as well as clarifying regulatory language is appreciated. UHG supports this clarification, as it will provide a more consistent member experience, especially if members utilize multiple or different carriers to support their Part C and Part D needs. The expectation regarding claims denial date is consistent for Part C and Part D.

Finally, UHG does not support CMS's proposal to require MA Plans and Part D Sponsors to make reasonable efforts to notify an individual or entity included on the preclusion list of the patients of that individual or entity that the MA Plan or Part D Sponsor provided notice to regarding that individual or entity's addition to the preclusion list. We do not believe it should be the responsibility of MA Plans and Part D Sponsors to send an additional notification to providers and entities, as CMS is already adequately notifying them of their placement on the preclusion list. We believe it would be duplicative and a further administrative burden for MA Plans and Part D Sponsors to notify providers and entities of their patients impacted by CMS's preclusion decision. This proposed change would result in thousands of additional letters being sent to precluded providers and entities who were already notified by CMS of their placement on the preclusion list. In addition, this expectation runs afoul of CMS's Patients Over Paperwork initiative. We expect this will cause provider abrasion and frustration. We do not see any additional value that further notices from MA Plans and Part D Sponsors would satisfy. Furthermore, CMS stated in their preclusion list FAQ (dated 12/14/18) that the rationale behind this additional notification is "to emphasize which patients in their practice are impacted by their inclusion on the preclusion list". Precluded providers and entities should be able to identify their impacted patients and should not need to receive this information from MA Plans and Part D Sponsors. The ultimate goal is to provide adequate notification to members so that they can find an alternative provider or prescriber prior to their claim(s) rejecting; MA Plans and Part D Sponsors should not bear further cost and administrative burden in order to assist bad actors with managing impacted patient populations within their practice. Accordingly, we recommend CMS not proceed with the requirement for MA Plans and Part D Sponsors to also notify providers and entities of their placement on the preclusion list.

Medicare Advantage Risk Adjustment Data Validation Provisions

In the proposed rule, CMS included a section relating to Risk Adjustment Data Validation (RADV) provisions, including a Fee-for-Service Adjuster study that CMS used to propose significant changes in the RADV methodology. On December 20, 2018, CMS announced an extension of the public comment period by 120 days, until April 30, 2019. CMS also indicated that it plans to release data underlying the study. Given the extension of time for public comment and the anticipated release of additional information, UHG will review the additional information and submit its comments on the RADV proposal in April. Due to the complexity of this issue and the paramount importance to the MA program, UHG respectfully requests that CMS release a full explanation of the methodology used in the study, the assumptions made, and the data upon which the study is based. Moreover, we ask that this information be released as soon as possible to permit interested parties a full opportunity to evaluate the proposal and provide meaningful comments.

Additional Recommendations for Future Rulemaking

In addition to the comments and recommendations above, we are providing the following recommendation for CMS to consider for future rulemaking.

Maintain a Consistent, Stable Payment Environment

For 2020, UHG encourages CMS to implement a stable, adequate overall rate environment to ensure that the MA program is well positioned to provide high-quality, effective, and innovative health care that seniors deserve. UHG values long-term payment stability and looks forward to partnering with CMS as it works to achieve the highest quality health care system for seniors. Additionally, UHG requests CMS consider the following specific policies to promote stability:

Business Comparison Requirements (Non-Medicare Margin Test)

MA and Part D bid instructions require the aggregate margin of plans to be within 1.5 percent of the plan's margin on fully insured health insurance business other than MA and Part D. This requirement increases the regulatory burden on MA Plans and Part D Sponsors and creates unintended consequences, making it more difficult for insurers to offer valuable programs across Medicare, Medicaid, Medicare Supplement, and commercial lines of business. This test could discourage insurers from participating or expanding in Medicaid, for example, if the low margins in other lines of business limit the ability of MA Plans and Part D Sponsors to offer competitive plans. Similarly, if an MA Plan or Part D Sponsor were making substantially more in commercial plans than it was in MA or Part D, the MA Plan or Part D Sponsor would likely either stop offering the MA or Part D plan, or raise margins in the MA or Part D plan by reducing benefits. Neither result is in the interest of CMS or beneficiaries.

CMS previously offered more flexibility related to margin relativity by:

- Indicating the numerical comparison was an example of what would be in a reasonable range.
- Making clear that "comparisons to other lines of business must take into account the degree of risk or surplus requirements of the business."[4]
- Allowing plans to meet the test over a multi-year period.[5]

UHG recommends that CMS create more flexibility in meeting the corporate margin requirements by:

- Allowing corporate margin requirements to be measured over a longer timeframe such as three to five years. This allows MA Plans and Part D Sponsors to provide more stability in benefits since there would be no need to change benefits every year due to variable, short-term changes in the margin levels of its other lines of business.
- Reconsidering what is included in the non-Medicare margin and including only lines of business with similar risk profiles, (i.e., those with products where the plans have discretion in rate setting and that are priced annually and include full medical risk). For example:

[4] 2009 MA BPT Instructions, Page 37
[5] CMS Office of the Actuary (OACT), CY2010 Actuarial Bid Questions. Page 19, Line 16.
https://www.cms.gov/Medicare/HealthPlans/MedicareAdvtgSpecRateStats/Downloads/ActuarialBidQuestions2010.pdf

  - The Medicare Supplement business should be excluded from the non-Medicare margin because Medicare Supplement has a different level of risk than MA and is rated over a beneficiary's lifetime.
  - Medicaid business should be excluded from the non-Medicare margin because the rates are largely set by the state and as a result health plans have less control over their profit margins.

- Individual Exchange plans should be excluded from the non-Medicare margin because that product continues to evolve and therefore may have unsustainable and below-market rates.
- Eliminating the corporate margin requirement for Part D Plans (PDP). Due to the risk sharing arrangement around the PDP benefit, PDP business does not have a similar degree of risk as other lines of business. Therefore, it should not require the same level of surplus requirements. Also, due to the risk corridors, CMS already has a mechanism to control how much margin plans make on PDP business.
- CMS should change the way it addresses sequestration in the margin comparison. Sequestration is unique to Medicare and does not affect commercial insurance. If sequestration results in an MA Plan making less than appears in the bid, it does not make sense to compare the pre-sequestration margin of an MA Plan to non-Medicare business that is not affected by sequestration. The bid pricing tool (BPT) instructions indicate that MA should account for the potential impact of sequestration in their risk margin, as a temporary increase. The medical expenses are also reduced for the probability of reduced payments to providers. UHG thinks it would be more appropriate to increase administrative expenses (similar to how the insurer fee is included in the bid) rather than increasing gain/loss margin in the BPT so that the resulting projected bid margin more accurately reflects expected results. Alternatively, CMS could reduce expected revenue in the margin calculation by the amount of sequestration to address this issue.

UHG believes that these recommended changes could be achieved by revising the MA BPT Instructions.

Medical Loss Ratio (MLR) – Enrollment Penalty and Other Reforms

MA Plans are required to report and track the government prescribed MLR, and CMS imposes an enrollment penalty if an MA Plan misses the MLR requirement of 85 percent for three consecutive years. If an MA Plan misses the threshold for five consecutive years, the MA Plan is terminated. Due to the timing of the bid submissions and the availability of data, as well as funding changes, ensuring that an MA Plan meets the threshold can be difficult particularly when they are beyond the MA Plan's control.

For example, the tax relief provided to MA Plans through the Tax Cuts and Jobs Act (TCJA) was implemented well after 2018 bids were due and could create an unintended consequence for MA Plans' 2018 MLR, including the closure of high value plans (if year 5) or preventing them from enrolling beneficiaries (if year 3).

Additional program changes in risk adjustment, the Health Insurance Tax (insurer fee), and the Encounter Data System create greater uncertainty because they can have unpredictable impacts on a given year's MLR. For example, if MA Plans bid assuming the insurer fee applies to the following year and the insurer fee is subsequently repealed or further delayed, MLR calculations should be adjusted to reflect the impact of the insurer fee on the MLR based on what the MA Plan assumed in its bid pricing. Similarly, temporary funding changes in a year could create a funding increase that is unsustainable over time, and would either

result in offering benefits that would have to be removed the following year or could cause an MA Plan to miss the MLR requirement.

UHG is not trying to avoid paying CMS a rebate that may be owed as a result of not achieving the MLR requirement; UHG simply believes the enrollment penalty is unnecessary. Moreover, the Part D program has risk corridors that already limit each plan's profits. This is likely why the statute does not require CMS to apply MLR rules to Part D.

UHG recommends the following:

- CMS support elimination of the enrollment penalty in its entirety.
- In the interim to address these uncertainties, UHG recommends CMS conduct a demonstration and leverage its discretionary authority to delay implementation of any three- or five-year enrollment penalties that are triggered as a result of 2018 rebates, that were impacted by the tax code changes adopted after the 2018 bids were submitted, while still assessing rebates from the MA Plan for contracts that do not meet annual requirements. This demonstration project would maintain beneficiary choice.
- UHG recommends MLR not be applied to standalone Part D, or if it remains, the MLR calculation should include all payments received by Part D Sponsors –Low Income Subsidy payments and a credit for the funds attributable to filling the Coverage Gap Discount.

Part B Drugs – New to Market and High Cost Drug Threshold

Currently, CMS cannot make a determination that a new drug therapy meets the significant cost threshold unless it issues an National Coverage Decision (NCD), which is a lengthy process rarely used for drugs. As a result, MA Plans are paying for new high cost drugs that are more appropriately paid for by original Medicare.

When new drugs are released mid-year, their costs have not been factored into the MA Plan's bids for that plan year. The policy behind the significant cost threshold determination is to protect MA Plans from the financial impacts of high cost therapies until these therapies are appropriately included in the benchmark and MA Plans can incorporate their costs into their bids.

UHG suggests that if CMS were to make the determination that a drug meets the significant cost threshold without going through the lengthy process of issuing an NCD, the policy behind the significant cost threshold would be better fulfilled.

Under the current regulation, CMS does not make a significant cost threshold determination until it determines and announces that an individual NCD or legislative change in benefits meets the criteria for significant cost. UHG recommends that CMS develop a method for making a determination that a covered Medicare item or service, including Part B drugs, meets the "significant cost threshold" without first issuing an NCD.

End Stage Renal Disease (ESRD) – Increased Enrollment for MA

A provision in the 21st Century Cures Act (Act) allows for Medicare beneficiaries with ESRD to choose to enroll in an MA Plan beginning in 2021. Prior to the passage of this Act, ESRD beneficiaries were excluded

from enrolling in MA Plans; however, MA beneficiaries who developed ESRD post enrollment in an MA Plan were permitted to remain enrolled. The Act also excludes the cost of kidney acquisitions from capitation rates and MA benchmarks; the cost of kidney acquisitions will be covered under FFS beginning in 2021. By December 31, 2018 the Secretary of Health and Human Services is to release a report on the risk adjustment model for ESRD under MA.

Because the number of ESRD members in MA Plans will likely now increase, UHG recommends that CMS update the Bid Pricing Tool (BPT) instructions so that the ESRD subsidy falls under Medicare covered benefits instead of Mandatory Supplemental benefits as it is today. Since the vast majority of the ESRD expenses are Medicare covered, MA Plans should not have to use rebate dollars to fund ESRD expenses.

In addition, as CMS reevaluates and revises the ESRD risk adjustment model under MA, UHG recommends that the impact of any changes on benchmarks, the current bidding structure, benefit plan, and eligibility status all be seriously considered. For example, CMS should adjust the benchmark to reflect the fact that as a result of the enrollment of more ESRD members, more members in total will reach the out-of-pocket maximum. Thoughtful consideration of these items, as well as stakeholder feedback and engagement, should be key components in the crafting of a detailed, appropriate model. UHG welcomes the opportunity to have a discussion with CMS on this issue.

Reflect Value of A/B Savings in Pricing of Supplemental Benefits

As outlined in the 2019 MA BPT Instructions, CMS allows MA Plans to offer as a supplemental benefit a waiver of the 3-day inpatient hospital stay prior to coverage of a SNF and price the benefit as a Medicare-covered benefit, even though it would not be covered under FFS. UHG believes that CMS has taken that approach because the waiver results in an A/B cost-savings: waiving the three day hospitalization can avoid unnecessary hospital admissions when the person really needs to be admitted to a SNF, which is less expensive than a hospital admission.

UHG recommends that this approach be applied more broadly for other situations where offering a supplemental benefit results in a likely reduction in A/B costs. UHG recommends that MA Plans be allowed to offer additional benefits and include the costs in their A/B bids when the additional benefit is offered primarily to lower other A/B costs. For example, if an MA Plan offers a zero-dollar in-home physician visit within 3 days after an inpatient or SNF discharge of members likely to be at risk for readmission, the rate of readmission would likely drop and the A/B savings would pay for the program. UHG recommends that the cost listed in the bid for that supplemental benefit is included in A/B costs. Additional examples include: transportation benefits targeted for PCP visits post-discharge, on call in-home physician visits for high emergency room (ER) utilizers, and meals following inpatient or SNF discharges. This change would incent MA Plans to offer benefits that reduce Medicare program expenditures by providing the right care in the right setting at the right time.

Additional Related Party Cost Method

The 2019 MA BPT Instructions require that the MA Plan disclose whether or not they are in a business arrangement with a related party. In addition, the 2019 MA BPT Instructions require that the financial arrangement between the MA Plan and the related parties are not significantly different from the financial arrangement that would have been in place for third parties. MA Plans can meet this standard by showing, for example, that the amount they pay to a related party is within 5% of the amount the related party receives from a third party. If the MA Plan cannot meet the related party standard, it can only include the

actual cost paid to the related party in the bid, even if a higher amount would be reasonable.

UHG recommends that CMS provide additional comparison methods for MA Plans when the market comparison is not within 5% of the third party payment, instead of requiring that MA Plans only use the actual cost paid to the related party. In addition to using the actual cost paid to the related party, CMS should:

- Allow MA Plans to include a rate within 5% of what a third party pays for the same services even if the amount the MA Plan pays the related party is not within 5%. For example, if a plan pays a related party $10 PMPM (Per Member Per Month) for a service and a third party pays the related party $8 PMPM for the same service, the MA Plan should be able to include between $7.60 and $8.40 PMPM.
- Allow MA Plans to include the actual cost incurred by the related party plus a reasonable margin, such as 2% or 3% of cost.
- Allow MA Plans to use as a comparison a medical agreement with a third party that is not in the bid's service area, or a medical agreement between the related party and a third party that is not an MA Plan.

Allowing plans to choose among these alternative comparison methods would produce bids that were more in keeping with true market value of services provided by related parties. As it stands now, two otherwise similar bids could have substantially different bid amounts based only on whether the MA Plan uses substantial services from related parties. While we understand the need to ensure that MA Plans do not overpay for related party services, the changes suggested here would still meet that goal.

Advance High-Quality, Coordinated Care

UHG supports policies that focus on delivering high-quality, coordinated care to MA and Part D beneficiaries. UHG's focus on care coordination has helped us close more than 2 million gaps in care for MA members beneficiaries in 2017 and achieve more than 85% of MA members in Four-Star plans or higher for the 2018 payment year. In order to build on these successes and maximize the value of MA, we ask CMS to consider focusing on effectuating the following policies in 2020.

Supplemental Benefits – Flexibility for Individual Needs

Historically, supplemental benefits must be defined at the time of bid filing and must be offered uniformly to all beneficiaries. UHG appreciates CMS's decision to provide some flexibility in this area by allowing MA Plans to reduce cost sharing for certain benefits or tailor supplemental benefits for enrollees based on health status or disease state, as implemented in the CY 2019 Final Rule.

UHG recommends that CMS provide more flexibility in this area by allowing MA Plans to file supplemental benefits in the bid that are not defined at the time of bid filing or in plan materials, but are administered during the plan year pursuant to plan clinical policies. MA Plans would file the projected cost of the undefined supplemental benefits and would have the ability to offer additional benefits or reduced cost sharing throughout the plan year based on clinical policies and the needs of beneficiaries.

Examples:

- Individualized determinations to waive co-pays or offer additional benefits for members with multiple chronic conditions, clinical needs, and financial barriers to receiving care.
- Provider-based programs to reach out to members with specific chronic conditions and provide additional care without copays.
- Copay waivers for members participating in pilot programs designed to test effectiveness of a more intensive care model.

The ability of MA Plans to offer real-time additional benefits and reduced cost sharing to chronically ill members will eliminate barriers to care and support the health of members by addressing social determinants of care. By filing as supplemental benefits, MA Plans still must use savings to pay for the benefits, so CMS would not have an increased cost.

This recommendation could be implemented by amending the applicable regulation: 42 CFR 422.102(a).

Member Incentives

A well-designed member reward program can incentivize members to improve their health while mitigating increasing health care and prescription drug costs. UHG believes that member reward programs can make a difference in engaging members in their health care, promote disease management and prevention, and improve the efficient operation of the Medicare program.

UHG recommends that CMS allow additional flexibility to innovate and create additional member reward and incentive programs and makes specific recommendations below:

- **Rewards Targeted at Enrollees Who Need Encouragement.** Currently**,** MA Plans are not allowed to limit rewards to members who have a history of not utilizing a recommended service. For example, MA Plans cannot limit rewards to those who have a history of not checking their blood glucose (A1c) levels. In the spirit of the new guidance that limits Part B drug rewards to those not currently using the preferred drug, UHG recommends that CMS allow MA Plans to design reward programs to efficiently improve care. MA Plans should be allowed to offer rewards targeted to a subset of eligible members who are not currently engaging in desired activity.

  Examples:
  - Rewards of $10/month for members testing their A1c levels, but limited to those with a history of uncontrolled A1c levels.
  - Rewards to members who switch to a cheaper drug, but limited to members currently using a more expensive drug.
  - Rewards to frequent ER utilizers for regular appointments with their PCP.

  CMS would need to amend its guidance issued in 2014 related to Rewards and Incentives and Chapter 4 of the Medicare Managed Care Manual to allow MA Plans to distinguish members based on their medical history or other factors to design more efficient programs.

- **Rewards Tied to the More Efficient Delivery of Health Care**. Currently, MA Plans can offer rewards for activities that focus on promoting health, preventing injuries and illness, and promoting the efficient use of health care resources. There are numerous ways that a beneficiary can help an MA Plan operate more efficiently, thus ensuring that Medicare program funds are more efficiently

used to delivery health care and improve health outcomes. For example, if members agree to receive required plan materials electronically, plans can save millions of dollars that are better used towards improved health outcomes. Although the current guidance allows rewards designed to promote the efficient use of health care resources, it is not clear that these rewards can be for changes in administrative activities. MA Plans should also be allowed to reward activities that save administrative costs for the MA Plan.

Examples:
- Rewards for agreeing to accept required materials electronically.
- Rewards for agreeing to autopay for MA Plan premiums.

CMS could revise the regulation to more clearly allow MA Plans to offer rewards tied to administrative savings. Alternatively, CMS could revise the 2014 guidance on this topic.

- **Rewards Based on Improvements in Measures.** MA Plans should be able to offer reward programs to encourage member healthy behavior, including programs that set reasonable goals and offer rewards for obtaining those goals. While MA Plans should not be allowed to limit rewards to those who meet an inflexible, one-size-fits-all measure, such as a particular BMI, MA Plans should be allowed to offer a reward for members engaging in a clinical program designed to promote healthy behavior and obtaining reasonable improvements in their health statistics.

  Examples:
  - Rewards targeted to members with initial BMI in excess of XX, who enroll in a healthy living clinical program and reduce their BMI by X% quarterly.
  - Similar programs tied to reduced blood pressure or improved A1c blood sugar level control.

  Incentives tied to specific outcomes are more effective at changing behavior. Additionally, MA Plans can offer higher rewards by limiting them to members fully engaged in the program. CMS would need to amend the 2014 guidance to allow rewards based in part on specific health outcomes.

- **Rewards for New Members.** UHG recommends that CMS allow MA Plans to offer different or higher rewards to new members.

  Examples:
  - Rewards for providing survey information to the MA Plan, allowing better care coordination.
  - Higher reward for Annual Wellness Visit in the first year of enrollment compared to subsequent years.

  Rewards limited to or modified for new members allows MA Plans to jump start their engagement and gain early information to more efficiently manage their care. CMS would need to amend the 2014 guidance to allow MA Plans to offer different or higher rewards for new members.

- **Rewards in the Form of Credit.** While UHG agrees that MA Plans should not offer monetary payments; it supports allowing MA Plans to offer rewards that are credits against amounts owed.

  Examples:

- Reward of $2 per month as credit against member premium for members who agree to autopay or to receive required materials electronically.
- Reward of $5 per visit as credit against member cost sharing for monthly PCP visit if a member engages in requested program or activity.

Based on member feedback, they would like to get a credit against an amount due rather than a gift card. It also eliminates the waste of unused gift cards, and these types of credits do not count as income and therefore do not have tax or Social Security implications. CMS could revise the regulation to replace the term "monetary rebate" with "monetary payment." CMS could also accomplish this by revising the 2014 guidance to make clear that MA Plans are permitted to offer a credit against amounts owed.

- **Rewards for Part D Members.** MA Plans and Part D Sponsors should be able to offer rewards related to Part D benefits. This reward would be more effective if MA Plans and Part D Sponsors were allowed to target rewards for members who were not currently compliant with prescribed medications.

  Examples:
  - Reward Part D members by $X/quarter if they adhere to their prescribed medications.
  - Reward in the amount of the member's copay / cost-share for the last three months of the plan year if he/she was adherent (i.e., picked up the medications every month) for the first nine months.

  The current prohibition limits the ability of MA Plans and Part D Sponsors to incent positive behavior around the use of Part D benefits, resulting in lost opportunities to improve care and control costs. CMS could adopt a separate Part D regulation allowing for reward programs related to Part D benefits. Alternatively, CMS could revise the 2014 guidance to allow for Part D reward programs. CMS allowed reward programs prior to the adoption of the regulation, so a regulation should not be needed to allow for Part D rewards.

Allow Prior Authorization for Non-Contracted Providers for (PPO) Plans

Existing regulations do not allow PPO (Preferred Provider Organization) plans to require non-contracted providers to obtain prior authorization. However, implementing such a requirement could decrease program costs and better ensure members are getting only medically necessary care.

UHG recommends that CMS allow PPO plans to require non-contracted providers to obtain prior authorization before providing certain services, but hold the member harmless if the provider does not comply. For example, if MA Plans could require out-of-network durable medical equipment (DME) providers to obtain prior authorization, MA Plans would be in a better position to address fraud and abuse.

Currently, CMS's sub-regulatory guidance prohibits PPO plans from requiring non-contracted providers to submit prior authorization requests prior to rendering services. Similarly, 42 CFR section 422.4(a)(1)(v)(D) currently prohibits an MA Plan from reducing a member's cost share if the non-contracted provider voluntarily notifies the PPO plan prior to receiving plan-covered services. UHG recommends that Section 422.4(a)(1)(v)(D) be deleted and the sub-regulatory guidance revised.

EGWP Policy Changes to Allow for Growth

Retiree health coverage is a valuable component of the benefit packages that employer groups and unions offer their workers. Yet, today, only 25 percent of employers with 200 or more employees offer health benefits for their retirees — a decrease from 40 percent in 1999 and 66 percent in 1988.[6] The employers that continue to provide coverage are seeking innovative ways to manage costs while offering high-quality retiree benefits and Employer Group Waiver Plans (EGWP) are an increasingly attractive option.

UHG has several recommendations, described in detail below, that CMS can implement within its current regulatory authority that would enhance the offerings currently available in the EGWP program while expanding the population it serves.

Simultaneous Enrollment – EGWP MA and Individual PDP

UHG submitted a waiver request to CMS in April 2018 regarding simultaneous enrollment in an EGWP MA and individual PDP. CMS denied that request, stating it would not be in the best interest of beneficiaries due to the requirement for coordinated care plans offering Part D to coordinate the Part C and D benefits.

We respectfully request that CMS reconsider their position. We share our rationale as to why this waiver request will be beneficial for employers, Medicare beneficiaries and CMS. We have also responded to the concern about coordination of care and benefits.

As we stated in our waiver request, the request for the ability to enroll in an EGWP MA plan while maintaining prescription drug coverage in an individual PDP plan came to our attention through discussions with existing and prospective employer group clients. These employer groups have retirees who are currently enrolled in individual PDPs and an employer-sponsored group Medicare supplement plan. The majority of these employers have never offered group pharmacy coverage to their retirees. They have instead chosen for many years to offer only a supplemental medical plan. As a result, the covered retirees have likely enrolled in individual PDPs to obtain pharmacy coverage.

Employers in this situation see the opportunity to offer their retirees an EGWP MA plan and are attracted to the superior clinical outcomes[7], member experience, and affordability these plans allow compared to their current supplement plans. In other words, the employer group wants to offer Part C EGWP medical coverage to its retirees, while allowing their retirees to keep the individual PDP plans that they already have in place.

Under the current regulations, the employer group can only select an EGWP MA Plan for their retirees if they also elect to offer an EGWP PDP, not an individual PDP. Some employers are therefore choosing to not offer EGWP MA Plans, because it would disrupt retirees who have already enrolled in individual PDPs. The current restriction would mean that in order to offer a valuable retiree plan option under Part C through an EGWP, an employer would have to add/offer a new employer sponsored benefit that the

[6] *Claxton G, Rae M, et al. 2017 employer health benefits survey. Kaiser Family Foundation. September 2017.*
[7] "The Future of the Medicare Advantage Employer Group Waiver Plan Market." Aetna/Avalere report. February 2018 Available at: https://news.aetna.com/wp-content/uploads/2018/02/20170129-Aetna_EGWP_FINAL.pdf

employer had never promised. Essentially, the current regulation restricts the options that employer groups have in offering benefits to their retirees. As result, it forces these retirees to stay in their uncoordinated supplemental medical plans and does not allow them the benefits of clinical programs offered by Part C plans.

This waiver, if implemented by CMS, will allow more flexibility for employer groups to continue to offer, or to consider offering in the future MA EGWP plans, contributing to CMS's goal to grow MA. In a recent speech on the Value-Based Transformation of America's Healthcare System, HHS Secretary Azar said that one of the key engines for transformation is "addressing any government burdens that may be getting in the way of integrated, collaborative and holistic care for the patient, and of structures that may create new value more generally." Updating the enrollment restrictions for EGWPs is a prime example of an opportunity to create a structure that drives more value for beneficiaries while reducing burden on plans. UHG estimates that there are about 200,000-250,000 retirees who would potentially benefit from this waiver.

UHG agrees with CMS on the importance of coordination of care for beneficiaries and offers the following comments:

- **Medical Care Coordination**: UHG agrees with CMS on the importance of coordination of care for Medicare beneficiaries; but we recognize that coordinating care specific to each member between an EGWP MA plan and numerous individual PDPs is not realistic. However, UHG has demonstrated that the opportunity for retirees to be enrolled in an EGWP MA Plan improves care coordination. EGWP MA Plans provide important quality improvements that are not available in the other options available to these employers. Under the current restrictions, a retiree wanting to keep his/her individual PDP must stay with Original Medicare with a Medicare supplement or select an MA Private Fee for Service (PFFS) plan or a Medicare Medical Savings Account (MSA) plan. No care coordination is required or provided in any of those alternative options between the medical plan and the PDP plan, or even within the medical plan alone. UHG believes that the comprehensive care coordination provided by an MA coordinated care plan is beneficial for retirees. This waiver, if granted, would allow for that.
- **Access to Data via CMS system.** While UHG believes that the comprehensive care coordination provided by the MA Plan is beneficial in and of itself, having data on prescription drug utilization would be beneficial to the overall care coordination. One possibility is to leverage the prescription drug event (PDE) data or other mechanisms for CMS to share the prescription drug data with carriers. UHG would be interested in working with CMS to explore these possibilities.

For the reasons stated, UHG recommends CMS issue a waiver to allow for the simultaneous enrollment in an EGWP MA coordinated care plan and individual PDP Plan by adding a Section to Chapter 9 of the Medicare Managed Care Manual and to Chapter 12 of the Prescription Drug Benefit Manual (PDBM).

Expanding Employment-Based Retiree Coverage Definition

CMS currently has a narrow definition of "employment-based retiree coverage" for determining eligibility for an EGWP plan, when compared to the Department of Labor (DOL) definition, which CMS recently helped redefine. One of the key elements of the October 12, 2017, Executive Order Promoting Healthcare Choice and Competition Across the United States was to direct the Secretary of Labor to expand access to Association Health Plans (AHPs) by expanding the definition of an "employer" for these purposes.

On June 19, 2018, the DOL issued a Final Regulation entitled, *"Definition of Employer" under Section 3(5) of ERISA – Association Health Plans"* designed to expand access to Association Health Plans (AHPs) for a broader set of employer groups and self-employed individuals. This rule was developed in consultation with HHS, CMS, the Department of the Treasury, and the Internal Revenue Service.

Similar to the broader definition of employer group under the DOL rule, UHG recommends that CMS broaden the definition of employment-based retiree coverage to allow greater flexibility for small employers, self-employed individuals, and profession-based associations to sponsor EGWPs.

Specifically, UHG recommends changing the language in Medicare Managed Care Manual Chapter 9 Section 30.1 to allow for inclusion of an individual whose employment is (or was) linked to the industry association by which they are a part of as a sole proprietor or small business member. This would allow, for example, for individual farmers who are members of a farm bureau to have an EGWP plan. By focusing on "employment-based" coverage rather than focusing on employer-based coverage, individuals would be treated equally by more precisely linking AHP access to association-related employment. A change in definition would also align with the recent DOL final rule decision which finalized a broader "commonality of interest" standard to allow a group of employers to be treated as a single employer sponsoring an AHP.

This interpretation would also align with CMS's current guidance as it relates to school districts: *"We also clarify that we believe that employers, such as school districts, could form an association for the purpose of purchasing employer coverage on behalf of retirees from the school districts and that this would be acceptable because, independently, each school district would be eligible to enroll its retirees in an EGWP or individual MA plan. Therefore, for example, two or more school districts could combine to form an association for the purpose of purchasing retirement coverage for their retired employees."*
In short, this change would facilitate the offering of these valuable MA Plans to more Medicare beneficiaries.

Communicating Value Added Items and Services (VAIS)

Many EGWP sponsors choose to include Value Added Items and Services (VAIS) for EGWP members. Under the current Medicare Managed Care Manual, Chapter 4, EGWPs may not market VAIS prior to enrollment.

Since the employer group has narrowed the options available for their retirees through the request for proposal (RFP) process to one, or perhaps a few MA Plan options, the employer group has already determined the plans available for their retirees. UHG believes that describing VAIS before enrollment is not a potential inducement in these situations; the limitation on describing them means that retirees receive an incomplete picture of the coverage negotiated by their former employer prior to enrollment. Many retirees would find it beneficial during their transition to an EGWP MA Plan to have transparency to the VAIS that are available.

In situations where an EGWP MA Plan is offered alongside other plan choices (i.e., Original Medicare plus secondary coverage), the inability to describe VAIS before enrollment prevents the retirees from having the full information needed to make an appropriate enrollment choice. The plan options are not on a level playing field if a member is weighing their options between a Medicare Supplement plan and an MA Plan.

UHG recommends that CMS provide the flexibility for MA Plans and employer groups to communicate VAIS

to prospective EGWP members prior to the coverage effective date, including in retiree re-enrollment educational meetings, beneficiary-initiated pre-enrollment phone calls, and pre-enrollment written materials.

Benefit Flexibility: Permit EGWPs to Set Member Coinsurance Amounts

Many employer groups who purchase EGWPs seek to mirror the benefits for their retirees that they enjoyed as active employees. One common benefit design MA EGWPs choose is to use coinsurance to determine a beneficiary's share of the cost of a covered service.

CMS currently sets service category cost sharing limits on MA Plans (including EGWPs) in addition to a global, annual beneficiary Maximum Out-of-Pocket (MOOP). Complying with both the global, annual beneficiary MOOP and the service category limits complicates certain claim adjudications and can cause the EGWP to deviate from the employer's benefit intentions. For example, an employer intending for retiree plan beneficiaries to pay 10% of the MA Plan allowable amount for inpatient hospital visits, up to an annual beneficiary MOOP of $3,500, is required to cap a beneficiary's share of the cost at $1,801 for a 6-day inpatient stay. This causes undue confusion and frustration for some EGWP beneficiaries in attempting to understand their MA Plan benefits, as they deviate from the benefits they had as active employees.

UHG recommends that CMS allow MA EGWPs to establish coinsurance amounts that exceed the annual fixed limits CMS establishes through the annual Rate Notice and Call Letter process, provided that the EGWP actuarial equivalence standards are met, and the modification does not deny or discourage access to covered medically-necessary health care items and services. This would allow the EGWP to better deliver an employer's intended benefits and increase simplicity and MA Plan understandability for MA Plan members.

In addition, UHG has concerns with the manner and timing of the changes to cost share and MOOP limits as they apply to EGWPs. By the time the Final Rate Notice and Call Letter are released each year, almost 50% of our employer group plans for the following year have been quoted. Requiring plans to change benefits after quoting can be disruptive. Historically, these changes have been minimal, but large changes would be problematic. UHG recommends that CMS provide more advance notice of any mandated MOOP and cost share changes for the upcoming year, or waive the applicability of these amounts for EGWPs.

UHG believes that this change could be made within the current regulations.

Copy of the Record Prior to an Administrative Law Judge (ALJ) Hearing

Before an ALJ hearing, UHG requests a copy of the record. In cases where a beneficiary is relying on new evidence that was not presented to the Independent Review Entity (IRE), it is critical that UHG obtain a copy of the record prior to the hearing so it can evaluate whether a different coverage decision should have been made. However, in certain regions, the ALJ claims he/she cannot provide the additional information without written consent from the patient due to HIPAA protections. For all practical purposes, this means that UHG does not obtain a copy of the record prior to the ALJ hearing. This prevents UHG from being able to make a different coverage decision, where appropriate, prior to the hearing and requesting that the hearing be canceled. It also leads an ALJ, in some cases, to reschedule a hearing to allow UHG to review the evidence submitted by the beneficiary.

There are a number of reasons why the ALJ should provide this information without obtaining consent from the appealing party. As the party from whom the member is seeking payment (*see* § 422.602(c) identifying the MA organization as a party to an ALJ hearing where member is seeking payment from the MA organization), UHG should be entitled to review the evidence being submitted in support of the member's claim without having to seek written consent from the member. The ALJ proceeding concerns UHG's legal rights with respect to whether payment must be made, and UHG should be entitled to view the evidence presented against it. Further, the member has already submitted the information to the ALJ in an effort to compel payment by the MA Plan and it seems unlikely a member would think this information would not be shared with the MA Plan. Finally, the HIPAA rules do not support the position that this information should not be provided without consent from the member. HIPAA allows MA Plans to use protected health information to facilitate payment, and the ALJ process is part of process to determine whether payment is due. 45 CFR § 164.506(c)(1).

In order to have a consistent approach to this situation, UHG recommends CMS revise the current regulation related to the party requesting a copy of the record to allow for the ALJ to provide a copy of the record without the consent from the appealing party. This would require a revision to *42 CFR § 405.1042 and 422.602.* It is our understanding that Office of Medicare Hearings and Appeals (OMHA) is in the process of hiring a number of new ALJs in order to address a large backlog of cases. We believe this rule will help facilitate a smoother process by eliminating the need for unnecessary hearings in some cases and avoiding delays caused by the MA Plan not having access to the evidence prior to the ALJ hearing.

TAB 20

Centene Corp. Comments

CENTENE Corporation

December 31, 2018

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare and Medicaid Programs; Policy and Technical Changes for Years 2020 and 2021 (CMS 4185-P)

Dear Administrator Verma:

Centene Corporation (Centene) appreciates the opportunity to provide feedback on CMS' Proposed Rule: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS 4185-P), published November 1, 2018. We appreciate CMS' efforts to ensure the delivery of quality services to Medicare beneficiaries enrolled in Medicare Advantage (MA) and Medicare Part D. Centene looks forward to working with CMS to further beneficiaries' access to robust medical and prescription drug coverage in the Medicare program.

Founded in 1984, Centene Corporation (hereinafter "Centene") has established itself as a national leader in the healthcare services field with over 14 million members across the country. Centene provides health plans through Medicaid, Medicare, and the Health Insurance Marketplace and other Health Solutions through our specialty services companies. Centene covers 400,000 Medicare (including Special Needs Plan) beneficiaries across 19 states, and 50,000 Medicare-Medicaid Plan (MMP) beneficiaries in six states, and approximately 440,000 dually eligible beneficiaries enrolled in our Managed Long-Term Services and Supports (MLTSS) or Aged, Blind and Disabled (ABD) product lines in 18 states.

Centene prides itself on providing health care access to the most vulnerable populations of our country, with a focus on meeting the needs of our members with high-quality and affordable coverage. Centene believes the dual-eligible population particularly benefits from the enhanced care management and coordination associated with managed care. CMS has made great strides in promoting integration and alignment between Medicare and Medicaid in this proposed rule; nonetheless, we encourage CMS to advance these efforts further. Centene has included several comments to the proposed rule that we believe would advance integration and coordination. We look forward to working with CMS to further improve the way in which these public programs interact.

CENTENE Corporation

Overview

- Centene supports CMS' efforts to advance the utilization of telemedicine in Medicare Advantage. We believe that this will improve the quality of care while also lowering costs and improving efficiency.

- Centene applauds CMS efforts to further the integration requirements for D-SNPs. Without increased alignment between Medicare and Medicaid, many of the administrative, communication, oversight and clinical efficiencies potentially made possible under integration cannot practicably be achieved. Centene's experience with at-risk populations helps us to see the broad integration of medical, LTSS, behavioral health, and social services through plan coordination that can be achieved by greater alignment between Medicare and Medicaid. While there are portions of this proposed rule that advance integration, there remain areas that can be strengthened to better serve at-risk individuals or those who use and access health care differently (e.g., rural beneficiaries), including where additional flexibility could directly benefit care to our members.

- Centene appreciates CMS' efforts to develop and test multiple products and programs for serving dual-eligible beneficiaries—Centene supports the continuation of all of these efforts; however, as the market currently operates, the variety of options creates confusion for beneficiaries about which product best meets their needs. Additionally, the different administrative requirements that apply to each of these products make it administratively burdensome to offer multiple options. As CMS undertakes efforts to reduce regulatory burden and improve beneficiary experience, we encourage the development of a common regulatory framework across federal health programs and within the same program that serves dual beneficiaries (e.g., amongst PACE, Special Needs Plans (SNPs), MMP etc.) to ensure dually-eligible individuals receive the same beneficiary protections regardless of which program they choose, and that the programs are on a level playing field administratively.

- Centene appreciates the CMS' willingness to provide plans additional time to review section II.C.2 *Medicare Advantage Risk Adjustment Data Validation Provisions*. We are committed to submitting accurate diagnosis coding as part of its CMS-HCC data submissions. We look forward to working with CMS to productively develop a policy that maintains program integrity while also recognizing underlying data accuracy issues that occur in provider claims both in FFS and MA.

Our specific comments are organized in the order that issues appear in the proposed rule:

REQUIREMENTS FOR MEDICARE ADVANTAGE PLANS OFFERING ADDITIONAL TELEHEALTH BENEFITS (II.A.1)

Centene supports the Agency's approach to implementing the telehealth provisions of the Bipartisan Budget Act (BBA) specifically allowing plans to offer, as part of the basic benefit package, a category of benefits called "additional telehealth benefits". Centene is very supportive of leveraging telemedicine innovations and applauds CMS for its efforts to allow MA plans and their provider partners to innovate as these technologies advance.

Centene supports the idea of maintaining adequate access to in-person services given the current limited scope of telehealth benefits. Nonetheless, where MA plans can demonstrate that access to certain, specific specialties

would be otherwise problematic without telehealth (e.g. where provider shortages or exclusive contracting arrangements limit the ability to form networks) we ask CMS to consider exceptions that would allow for consideration of telehealth in the overall network adequacy assessment. Such flexibility will allow for more competition and more attractive MA plan options to those communities that today have fewer MA choices.

Centene also encourages CMS to allow for flexibility regarding the inclusion of providers offering telehealth services in its provider directories. Our experience is that a common industry approach to telehealth services is through vendors that contract with licensed providers to provide telehealth services for limited shifts or on a part-time basis. The list of providers that support these platforms is not static and such platforms may not allow for selection of all available providers at all times (a request goes to those providers 'on call'). To accommodate these situations and other provider contracting innovations that may support telehealth innovations, we encourage CMS to allow MA plans to make determinations regarding the inclusion of telehealth providers in their directories in the way they believe optimizes clarity for beneficiaries.

We also support the Agency's approach to utilizing state-based credentialing standards for telehealth services as opposed to a federal approach for MA provider participants. At this time, having a single approach in each state for determining a provider's requirements to deliver and their permitted scope of telehealth service delivery is most likely to encourage more rapid adoption and innovation versus creating possibly misaligned or conflicting requirements based on the beneficiary's product or coverage.

Centene seeks clarification regarding the application of cost-sharing for telemedicine services, based on the manner in which CMS currently allows differential cost sharing under MA plans for original Medicare-covered benefits. It remains unclear if the proposal would allow MA plans to maintain different cost sharing for Part B service(s) furnished through an in-person visit and Part B service(s) furnished through the new telehealth flexibility.

Finally, Centene asks that the proposal to not allow capital and infrastructure costs as part of the bid for telemedicine services be interpreted to align with a traditional understanding of capital or infrastructure costs: those items that would add permanent or depreciable value to the plan or beneficiary and conversely would not include necessary support items or services for telehealth delivery. For example, such permitted expenses could include cellular service associated with a monitoring device, temporary internet service associated with the provision of home-based services limited to the use of those services, and access to devices that communicate telehealth information. If the definition was too inclusive then plans could be restricted in providing non-medical services that enable telemedicine; we believe this would result in reduced access to these services for those with lower income and/or less technological sophistication, greatly limiting the value of these additional benefits in a way that could exacerbate health disparities and limit coordination for vulnerable populations.

INTEGRATION REQUIREMENTS FOR DUAL ELIGIBLE SPECIAL NEEDS PLANS (II.A.2.A)

Centene is supportive of CMS' approach to establish new requirements in accordance with section 50311(b) of the BBA to require that all D-SNPs meet certain new minimum criteria for Medicare and Medicaid integration for 2021 and subsequent years. In the short-run it creates reasonable and necessary requirements for unaligned D-SNPs, while simultaneously creating pathways for more aligned products through the highly integrated dual



eligible special needs plan (HIDE SNP) and fully integrated dual eligible special needs plan (FIDE SNP) categories. We recommend that the new D-SNP minimum requirements be seen as the floor to ensure better alignment; CMS should build upon these requirements in the future to continue to facilitate this transition towards integration.

DEFINITIONS OF A "DUAL ELIGIBLE SPECIAL NEEDS PLAN", "FULLY INTEGRATED DUAL ELIGIBLE SPECIAL NEEDS PLAN", "HIGHLY INTEGRATED DUAL ELIGIBLE SPECIAL NEEDS PLAN", AND "ALIGNED ENROLLMENT" (II.A.2.a.(1))

Centene supports the approach taken by CMS in defining D-SNPs, FIDE SNPs, HIDE SNPs, Arranging of Benefits and Aligned Enrollment. Specific comments on these definitions are as follows:

DUAL ELIGIBLE SPECIAL NEEDS PLAN DEFINITION

Centene supports the BBA's goal of establishing new standards for the integration of Medicare and Medicaid benefits for dual individuals through seamless, high quality, and cost-efficient care, and believes the proposed D-SNP definition represents a good first step in meeting that goal, but that more work needs to be done. Truly meaningful integration for unaligned dual individuals using LTSS and/or behavioral health services requires a whole host of additional requirements and activities in key areas, including, but not limited to: integrated administrative, information technology, communications, reporting, and financial systems; integrated assessment and care coordination processes and data sharing; and integrated transition activities.

ARRANGING FOR BENEFITS DEFINITION

Centene applauds CMS for interpreting the phrase, "arranging for benefits," as requiring a D-SNP to, at a minimum, *coordinate* the delivery of Medicare and Medicaid benefits by, for example, verifying dual individuals' eligibility for LTSS or BH, determining how the individual receives such services, and making arrangements with the LTSS or BH payer for the provision of services. As proposed, this could encompass a wide range of activities that a D-SNP may engage in for their dual eligible members. Specifically, for all enrollees who are eligible for Medicaid services, the D-SNP must fulfill its statutory responsibility to arrange for the provision of Medicaid benefits by facilitating a beneficiary's meaningful access to such benefits. Additionally, Centene encourages CMS to emphasize that coordination for D-SNPs with *aligned* members that require LTSS or BH services includes assessment and care planning that is, at a minimum, in compliance with the person centered requirements of the HCBS Settings Final Rule and incorporates the provision of the needed LTSS and/or BH services either directly or in close coordination with the entity owned or controlled by the D-SNP's parent organization that has contractual responsibility for MLTSS and behavioral health benefits.

HIDE SNP DEFINITION

Centene believes the proposed definition of HIDE SNP is appropriate because it allows for the inclusion of both LTSS and BH services and provides states some flexibility to define inclusion based on the specific use of managed care arrangements.

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ALIGNED ENROLLMENT DEFINITION

Centene supports the proposed definitions of "aligned enrollment" and "exclusively aligned enrollment," and the application of integrated grievance and appeal requirements to plans with exclusively aligned enrollment, as that is a best practice already in place in many of Centene's Medicare Medicaid Plans (MMPs). Furthermore, by including the following language "another entity that is owned and controlled by the D-SNP's parent organization", Centene believes CMS has adequately accounted for all the Medicaid managed care organizations (MCO) arrangements that should fall under "aligned enrollment."

INTEGRATION REQUIREMENT FLEXIBILITY

Centene supports the alternative interpretation discussed in the proposed rule which holds that "in states that have Medicaid managed care programs for dual eligible individuals, all MA organizations seeking to offer a D-SNP could do so only if they were under contract with the state to offer a companion Medicaid managed care plan that aligns all covered Medicaid services in that state, on the grounds that such an opportunity is permitted under state law." We believe that this interpretation would lead to more integrated products being offered in the market and ultimately more beneficiaries experiencing the benefits of these products. Furthermore, Centene recommends CMS consider adding a requirement that D-SNPs in MLTSS (managed long-term services and supports) states must meet the definition of a HIDE SNP or FIDE SNP, or not be allowed to continue. This restriction would only apply to states that have integrated LTSS into managed care.

DUAL ELIGIBLE SPECIAL NEEDS PLANS AND CONTRACTS WITH STATES (II.A.2.a.(2))

Centene believes the proposed notification represents a good first step in meeting the integration intent outlined in the Bipartisan Budget Act, but respectfully requests that CMS add language requiring that a D-SNP member's unaligned Medicaid MCO also be notified (in addition to the state) in the event of a hospitalization or SNF admission by any full benefit D-SNP member that receives Medicaid LTSS or BH services (and not just for one group of "high-risk duals" identified by the state, which could, but may not necessarily, include members receiving LTSS or BH services). This is particularly important for Medicaid managed care organizations that coordinate LTSS, BH, and other services that help prevent re-admission, and that have to report outcome measures related to inpatient admissions and discharge.

Centene agrees with the decision to not require notification of every emergency department visit for *every* D-SNP member, but encourages CMS to require notification (to the state and health plan) of ER visits for unaligned, full-benefit D-SNP members receiving LTSS and BH services from FFS or another MCO.

CMS considered, but chose not to include, a requirement that the notification occur not later than 48 hours after the D-SNP learns of the admission or discharge. Centene highly recommends that CMS include the 48-hour requirement as a federal minimum, and allow states to implement more stringent time requirements if desired to allow for the timeliest action following a care transition or event.

CENTENE Corporation

Finally, Centene agrees that unnecessary and duplicative assessments are conducted because of overlapping requirements for D-SNPs, LTSS and BH services. To this end we ask CMS to encourage D-SNPs to coordinate HRA administration and care plan development with LTSS and BH service payers. This could also be an area for future integrated requirements for Exclusively Aligned organizations.

Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid

Centene supports the new definition of "applicable integrated plans," and agrees that "exclusively aligned enrollment" (when a state Medicaid agency limits a D-SNP's membership to full benefit duals who receive Medicaid benefits either directly from the D-SNP or from a Medicaid MCO that is the same organization as the MA offering the D-SNP, its' parent organization, or another entity that is owned and controlled by the D-SNP's parent organization) adequately captures the optimal universe of managed care arrangements for such unification.

Definitions of "Applicable Integrated Plan", "Integrated Appeal", "Integrated Grievance", "Integrated Organization Determination", and "Integrated Reconsideration," and General Requirements for Applicable Integrated Plans (II.A.2.b.(3))

Centene is supportive of the effort CMS has undertaken in this proposed rule to align the definitions for appeals, grievances, reconsiderations, and organization determinations for integrated plans along with the efforts to create unified timeframes that are the most favorable to the beneficiary.

Authorization for Filing Appeals (II.A.2.b.(4))

Centene supports CMS' intent to combine the MA and Medicaid requirements for authorization for filing appeals but, in order to ensure that the beneficiaries' interests are being represented, believes the enrollee should always be required to provide written consent when someone other than the enrollee is requesting an appeal on their behalf, unless the person has a dually appointed legal guardian or a signed health care power of attorney on file.

Integrated Grievances (II.A.2.b.(5))

Centene supports:

- Allowing grievances to be filed at any time (Medicaid standard) versus within 60 days (MA standard);
- Allowing for expedited grievances that parallel the MA requirements (no federal requirement for Medicaid); and
- Applying the MA standard of 30-days for a grievance resolution (90-days for Medicaid).

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EFFECT (II.A.2.B.(9))

Instead of requiring that D-SNPs assist with filing of Medicaid-related grievances and appeals with, in some cases, a competing entity (which questions the integrity of the grievance or appeal), Centene recommends that D-SNPs be required to make a written referral for the member to the state's Medicaid managed care ombudsman office. D-SNPs should also be required to refer members to a Medicaid managed care ombudsman or Medicare beneficiary ombudsman for assistance when the D-SNP has a financial and/or clinical responsibility for the disputed services. Medicare beneficiary and Medicaid managed care ombudspeople are specifically funded to assist beneficiaries in filing grievances and appeals, and frequently coordinate with State Health Insurance Program (or SHIP) offices, another state-level resource for beneficiaries. Community-based organizations, such as Centers for Independent Living, also already receive federal funding to provide coaching to promote self-advocacy, and D-SNPs should not duplicate these services, but rather refer members to CILs.

MEDICARE ADVANTAGE AND PART D PRESCRIPTION DRUG PLAN QUALITY RATING SYSTEM (II.B)

Centene continues to support CMS' codification and update to the methodology for the Star Ratings system through regulation. Centene supports this year's proposals that include (1) enhancements to the cut point methodology for non-CAHPS measures, (2) measure updates; and (3) rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances. Below we have included additional requests for clarification on these issues along with minor enhancements.

Additionally, we continue to observe that the Categorical Adjustment Index (CAI) has not provided the level of relief necessary to level the playing field for those organizations that provide service to those most in need. We appreciate that CMS continues to explore this issue and look for the best ways to incorporate demographic and other health determinates into its Star Rating methodology. As part of this ongoing effort we ask CMS to specifically explore income and regional differences and also ensure that the CAHPS case-mix adjustment also adequately adjusts for LIS/DE membership.

MEASURE-LEVEL STAR RATINGS (§§ 422.166(A), 423.186(A))

CMS is proposing a change in how it calculates Star Rating cut points for non-CAHPS measures by use of mean resampling and guardrails for inter-year cut-point changes. Centene supports the proposed changes to the cut point calculation including the use of mean resampling and installing a bi-directional guardrail on measures that have been part of the Part C and D Star Rating program for more than 3 years. We suggest using a guardrail of 3 percent for non-CAHPS measures. This would adequately balance predictability while allowing cut-points to continually improve year to year as national performance improves. We also ask that if CMS expands or contracts the bi-directional guardrails to accommodate changes in industry-wide performance, that any such adjustments be made along with a hold harmless provision.

CENTENE Corporation

UPDATING MEASURES (II.B.1.d)

In this rule, CMS is proposing measure changes to the Star Ratings program for performance periods beginning on or after January 1, 2020 and performance periods beginning on or after January 1, 2021. The following are our specific comments on several of the measures being updated:

Controlling High Blood Pressure (Part C) – The new measure will incorporate the new standards under HEDIS 2019. The measure will be moved to the display page for the purposes of the 2020 and 2021 Star Ratings. CMS proposes this measure to return to the Star Rating for 2022 with a weight of 1 and a weight of 3 for subsequent years. Centene agrees with this proposal; however, we recommend leaving it at a weight of 1.0 for a minimum of two years prior to increasing the weight to 3.0.

MPF Price Accuracy (Part D) – CMS proposed a new measure for display in the 2020 and 2021 Star Ratings and inclusion for the 2022 Star Ratings. The new measure will include both the magnitude and direction of pricing inaccuracies. Centene is supportive of the proposed changes.

Plan All-Cause Readmissions (Part C) – CMS is updating this measure for HEDIS 2020 to add observational stays and removing individuals with high frequency hospitalizations. CMS proposes that this measure be moved to the display page for 2021 and 2022 Star Ratings, returning in 2023 with a weight of 1 and then have a weight of 3 for subsequent years. Centene agrees with this proposal; however, we recommend leaving at a weight of 1.0 for a minimum of two years prior to increasing the weight to 3.0.

Furthermore, our experience indicates that the Categorical Adjustment Index is insufficient to appropriately offset the differences in performance which result from enrolling special needs, and beneficiaries with disabilities. By including this population in this measure an undue penalty will be placed on plans who serve these members. Thus, until adequate adjustment is applied, the measures should remain as a 65+ only.

Improvement Measures (Part C & D) – Centene agrees with CMS' proposal to exclude measures impacted by data integrity concerns from the Quality Improvement measures. We ask that CMS exclude measures impacted by the Timeliness Monitoring Project (TMP) scaled reductions of the appeals measures.

EXTREME AND UNCONTROLLABLE CIRCUMSTANCES (II.B.1.e)

CMS proposes to adjust the Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance or measurement period. CMS is also concerned that certain natural disasters and emergencies may interfere in plans' abilities to provide services for their enrollees.

Centene is supportive of CMS' efforts to make Star Rating accommodations for plans serving areas affected by natural disasters. To this end, we look forward to additional guidance in CMS' advanced notice to clarify which ratings would be used for markets with consecutive disaster relief adjustments and when markets have no prior ratings history but are eligible based on disaster relief definitions.

CENTENE Corporation

Specifically, we ask CMS to consider dropping the threshold for relief below 25 and 60 percent for contracts that have had two consecutive years of disaster impact. There may also be lasting years of impact to beneficiaries and their plans as they recover from the disasters. If plans have had consecutive years of impact due to disasters, they should receive the best score of three prior years (including the most recent period NOT impacted by a natural disaster), this should apply to all measures which could be impacted by the natural disaster. Several HEDIS Measures have multi-year lookback periods and CAHPS and HOS may also be impacted by previous year implications of unforeseen circumstances.

ADJUDICATION TIMEFRAMES FOR PART D EXCEPTION REQUESTS (II.B.2)

CMS proposes to state that, for an exception request, the plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 72 hours (or 24 hours in the case of an expedited decision) of receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first. Centene seeks to confirm that this requirement does not impose an obligation on the plan to outreach and obtain the prescriber's supporting documentation within the 14-day timeframe—compliance with such a requirement within that timeframe would be operationally difficult.

Centene appreciates the opportunity to provide feedback on this proposed rule. We welcome the opportunity to work with CMS to discuss any of the issues described above in further detail. If you have any questions, please contact me at jdinesman@centene.com.

Sincerely,



Jonathan Dinesman
Senior Vice President, Government Relations

TAB 21

Magellan Health Comments

Magellan HEALTH

Filed electronically via regulations.gov.

Dec. 31, 2018

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health and Human Services
Attention: CMS-4185-P
200 Independence Ave., SW, Room 600E
Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-4185-P
P.O. Box 8013
Baltimore, MD 21244–8013

Re: Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly, Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS-4185-P)

Dear Secretary Azar and Administrator Verma:

Magellan Health, Inc. (Magellan) welcomes the opportunity to comment on the "Medicare Advantage (MA), Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service (FFS), and Medicaid Managed Care Programs for Years 2020 and 2021; Policy and Technical Changes" notice of proposed rulemaking (NPRM or proposed rule) as published in the *Federal Register* (83 FR 54982) Nov. 1, 2018.

The November 30 NPRM memorandum proposes significant policy and technical changes to the MA and Medicare Prescription Drug programs for contract years (CYs) 2020 and 2021. We thank the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) for soliciting public comment on this significant proposal.

Magellan is a leader in managing the fastest growing, most complex areas of health, including services for special populations, complete pharmacy benefits, and other specialty healthcare services. Through Magellan Rx Management, the full-service pharmacy benefit management division of Magellan, we specialize in solving complex pharmacy challenges for Medicare, Medicaid and other state programs, health plans and managed care organizations, and employers. With more than 40 years' experience supporting states and 30 years supporting self-funded employers, we deeply appreciate the opportunity to bring our pharmacy benefits experience to Medicare, including through our Medicare Basic Prescription Drug Plan (PDP) and through our Dual Eligible Special Needs Plans (D-SNPs).[1]

1. Senior Whole Health, LLC is an affiliate of Magellan. Senior Whole Health serves Medicare-Medicaid enrollees in Massachusetts and New York; Senior Whole Health of New York also offers a Fully Integrated Duals Advantage plan (Medicare-Medicaid Plan).

Magellan HEALTH

In our comments, we note provisions we believe advance the agency's goals with respect to implementing certain provisions of the Bipartisan Budget Act (BBA) of 2018—promoting affordability and meaningful competition in these programs and reducing unnecessary regulatory complexity to ensure the MA and Prescription Drug programs meet the healthcare needs of its diverse beneficiaries. While we appreciate HHS' and CMS' advancement of these proposals that, we agree, will promote affordability and competition in the MA and Prescription Drug programs, we also have concerns with others, including proposed elements around Part D access to Medicare Parts A and B claims data, the Star Ratings program, exceptions timeframes for Part D drugs, and preclusion list requirements.

We appreciate the opportunity to share Magellan's comments and recommendations in response to the NPRM, which is presented first in summary format and followed by a detailed discussion of the issues in the order they appear in the proposed rule.

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Executive Summary of Magellan's Comments

- **Requirements for MA Plans Offering Additional Telehealth Benefits.** Magellan commends CMS for making this long-sought change, and appreciates the flexibility afforded to MA plans to determine which "additional telehealth benefits" to provide; allowing plans to determine the clinical appropriateness of telehealth services and to offer additional telehealth benefits as supplemental benefits; inclusion of these benefits in the Evidence of Coverage; and, the broad definitions utilized in the proposed rule. Magellan encourages that CMS consider the following proposals for future policy development: permitting some services be offered either in person or via telehealth (i.e., not requiring both); CMS recognition of telehealth benefit providers and the services they offer in their assessment of network adequacy in rural and urban areas; and, inclusion by CMS of specific language allowing Medicare beneficiaries to be served by credentialed providers with licensure under different states. We also continue to encourage HHS to issue regulations aligning 42 C.F.R. Part 2 with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of treatment, payment, and healthcare operations.

- **Dual Eligible Special Needs Plans.** Magellan thanks CMS for the approach outlined in the proposed rule for new D-SNP integration requirements, which closely adheres to the intent of the BBA. We request additional clarifications and examples in several requirement areas to better enable states, plans, and other essential stakeholders to achieve the agency's goals of integration.

- **PDP Sponsors' Access to Medicare Parts A and B Claims Data Extracts**. While we support finalizing the permissible uses as proposed and thank CMS for its efforts to advance this new data access avenue, Magellan encourages CMS to reaffirm and leave open flexibility for other uses of Parts A and B data, specifically to clarify claims data otherwise permissibly obtained by PDP sponsors are <u>not</u> subject to the proposed limits. We also request CMS clarify whether PDP

sponsors' access to the data is single point or multiple, and request the agency make the claims data available more frequently and timely than proposed (i.e., as close as possible to real time).

- **MA and Part D PDP Quality Rating System**. Magellan recommends CMS provide simulation data related to the proposed changes to the cut point methodology and provide pre-determined cut points in advance of the measurement period. We encourage CMS consideration of an alternative algorithm to better address the outlier issues the agency has identified (i.e., k-means clustering with outlier removal). We also encourage CMS to consider further refinements to the proposed methodologies beyond the algorithm, including a restricted-range cap and caps for new measures. We urge CMS to consider how these methodological changes and refinements may impact or necessitate adjustments for socio-economic factors. We also urge CMS to be mindful of the impact of the repeated removal of certain contracts under the Extreme and Uncontrollable Circumstances proposal on the overall cut-point thresholds, which may result in incremental volatility. We also request CMS confirm when the proposed changes would be applicable, discourage the proposed addition of a frequency component to the Medicare Plan Finder Price Accuracy Measure, and support the recommendation for updates to the Improvement Measures.

- **Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE**. Magellan urges CMS not to implement this proposal. Alternatively, we recommend the effective date be delayed until the preclusion list – as envisioned in the proposed rule and in other related guidance – can be implemented in alignment with agency intent or, at minimum , until Jan. 1, 2020. As a further alternative to delay, CMS may consider committing to exercise enforcement discretion against plans until Jan. 1, 2020 for such plans that make a good faith effort to comply with the rule.

- **Improving Clarity around Exceptions Timeframes for Part D Drugs**. While we appreciate continued efforts to improve clarity, particularly regarding tolling of exceptions requests, Magellan asks CMS to provide clear, consistent, and timely guidance in both the pending new appeals chapter and the rules set forth in this NPRM.

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Magellan's Detailed Comments and Recommendations

Requirements for MA plans offering additional telehealth benefits (§§422.100,422.135,422.252, 422.254, and 422.264)

CMS proposes to allow additional telehealth covered benefits as part of Medicare basic benefits as well as continuation of supplemental benefits with an option for beneficiary choice of in-person or telehealth. Such services would be financed via inclusion in capitated payments. Capital and infrastructure costs continue to be excluded.

Magellan HEALTH

DEFINITION OF ADDITIONAL TELEHEALTH BENEFITS

CMS proposes to define "additional telehealth benefits" as services furnished by a MA plan that are available under Medicare Part B but are not payable under section 1834(m) and are clinically appropriate to be delivered, as determined by the plan, via telehealth.

Magellan commends CMS for making this long-sought change, and appreciates the flexibility afforded to MA plans to determine which "additional telehealth benefits" to provide via telehealth. We also support the continued authority to allow plans to offer supplemental telehealth benefits if those services do not meet the requirements of additional telehealth benefits.

Magellan's Comments: Magellan supports the proposed definition of "additional telehealth benefits." We believe these provisions will help increase access to behavioral health and other essential healthcare services, assist with early identification of chronic disease, and, specific to behavioral health, help address some of the workforce capacity challenges that exist.

DETERMINATION OF CLINICAL APPROPRIATENESS OF THE TELEHEALTH BENEFIT

CMS proposes to allow MA plans to "independently determine which services each year are clinically appropriate to furnish in this manner." CMS believes that MA plans are in the best position to make such determinations with respect to additional telehealth benefits. As with other benefits, MA organizations must agree to provide all benefits covered by Medicare "in a manner consistent with professionally recognized standards of health care." CMS further requires that additional telehealth benefits that have been deemed clinically appropriate must be identified on Evidence of Coverage (EOC) documents provided to all enrollees. CMS seeks comment on whether it should place limitations on the types of Part B services and items that may be considered additional telehealth benefits by MA organizations.

Magellan's Comments and Recommendations: Magellan appreciates the CMS proposal allowing plans to determine the clinical appropriateness of telehealth services and to offer additional telehealth benefits as supplemental benefits. We support inclusion of these benefits in the EOC and consideration of which services should be included on an annual basis.

DEFINITION OF ELECTRONIC INFORMATION AND TELECOMMUNICATIONS TECHNOLOGY

CMS is proposing to keep the definition very broad. Allowable modalities include, but are not limited to, secure messaging, store and forward, telephone, videoconferencing, and "other evolving technologies as appropriate for non-face-to-face communication."

Magellan's Comments and Recommendations: Magellan appreciates the broad definitions utilized in the rule which allow for evolution of future technology advancements and the opportunities provided for alignment with clinical best practices and discretion of the clinical provider. We would recommend

against limitations on specific services allowed to be provided through telehealth, especially because service access can be highly variable, and limiting services may curtail additional choices for access.

ENROLLEE CHOICE AND NETWORK ADEQUACY

If an MA plan covers a Part B service as an additional telehealth benefit, enrollees must also have access to that same benefit in-person. If plans want to offer telehealth options to beneficiaries beyond network adequacy, they must be classified as supplemental benefits. CMS also solicits comment on the degree to which additional telehealth benefit providers should be considered in the assessment of network adequacy.

While we appreciate and understand the current need to provide enrollees with an option to receive telehealth services in-person and not just via telehealth, Magellan encourages CMS to consider, in the future, providing some flexibility to plans for certain services, to offer services either in person or via telehealth, and not requiring both options be offered for all services as the Medicare program has more experience with telehealth and telehealth gains greater acceptance.

Magellan strongly supports consideration by CMS of additional telehealth benefit providers in the assessment of network adequacy. As telehealth progresses and, increasingly is seen as a vehicle to deliver care to individuals who may not have a provider easily accessible to them or may not be able to leave their home to access services, such evolution may give rise to further discussion of how telehealth can supplement current network standards. Inclusion of telehealth benefit providers in a plan's network and the provision of additional telehealth benefits will improve access to treatment in underserved communities – both rural and urban – and vulnerable beneficiaries, particularly with respect to behavioral health services and other services with identified access limitations and/or workforce capacity constraints.

Magellan's Comments and Recommendations: Magellan encourages future CMS consideration of permitting some services be offered either in person or via telehealth (i.e., not requiring both). We also encourage CMS to recognize telehealth benefit providers and the services they offer in their assessment of network adequacy in rural and urban areas. Specifically, we recommend CMS provide plans with more flexibility to meet network adequacy requirements with the use of telehealth benefit providers and other high-value care and delivery system innovations and approaches.

ENROLLEE COST SHARING

CMS currently allows MA plans to engage in differential cost sharing for original Medicare benefits. This flexibility would be extended to additional telehealth benefits, meaning that MA plans could offer telehealth services for free should they choose to do so.

Magellan's Comments and Recommendations: Though our D-SNP members do not face cost sharing due to their dual eligibility and enrollment in Medicare and Medicaid, we appreciate the flexibility

extended to MA plans to engage in differential cost sharing for these additional telehealth benefits, as CMS currently allows for original Medicare benefits.

CONTRACTED TELEHEALTH PROVIDERS

CMS proposes to require that MA plans furnishing additional telehealth benefits may only do so using contracted providers. MA plans must have written policies and procedures for the selection and evaluation of providers. Telehealth services furnished by a non-contracted provider may only be available as a supplemental benefit, not a basic benefit. CMS is soliciting comment on whether to require just preferred provider organizations, instead of all MA plan types, to use only contracted providers for additional telehealth benefits.

Magellan's Comments and Recommendations: We support requiring all MA plan types to use only contracted providers for additional telehealth benefits, with the flexibility to furnish telehealth services by non-contracted, but credentialed, providers as a supplemental benefit.

PHYSICIAN/PRACTITIONER QUALIFICATIONS

CMS proposes to require MA plans offering additional telehealth benefits to comply with existing MA provider selection and credentialing requirements. The MA plan must ensure through its contract with the provider that the provider meets and complies with applicable state licensing requirements and other applicable state laws. CMS also seeks comment on whether to impose additional requirements for qualifications of providers of additional telehealth benefits.

Magellan recommends against placing additional requirements for qualifications on providers of additional telehealth benefits. We believe the proposed requirements related to existing provider selection and credentialing are sufficiently protective and provide plans with the flexibility to apply their own additional network rules and conditions, as they determine necessary, to ensure enrollees receive high-quality care.

While we support leveraging existing MA provider selection and credentialing requirements, we recommend CMS include specific language allowing Medicare beneficiaries to be served by credentialed providers with licensure under different states (i.e., the provider is licensed in the state in which the provider resides), versus requiring they live, work, and are credentialed and licensed in the state in which the beneficiary resides. We also encourage CMS to ensure providers are given clear guidance on new requirements used to identify providers who offer telehealth services to streamline current processes for ensuring provider directory accuracy and to work toward harmonizing different state licensure rules around delivery of care and issuing of prescriptions via telehealth, which may impede development of telehealth options for providers and beneficiaries.

Magellan's Comments and Recommendations: Magellan believes the proposed requirements are sufficiently protective and provide plans with the flexibility to apply their own additional network rules

and conditions, as they determine necessary, to ensure enrollees receive high-quality care. We also recommend CMS include specific language allowing Medicare beneficiaries to be served by credentialed providers with licensure under different states. And we encourage CMS to ensure providers are given clear guidance on new requirements used to identify providers who offer telehealth services to streamline current processes for ensuring provider directory accuracy.

42 C.F.R. PART 2

A topic not mentioned in the proposed rule that would also improve access to healthcare treatment and services, and care coordination and integration, under the Medicare program is alignment of 42 C.F.R. Part 2 (Part 2) with HIPAA. Part 2 limits the use and disclosure of patients' substance use records from certain substance use treatment programs. This can prohibit payers from sharing substance use disorder (SUD) information with healthcare providers serving individuals living with opioid use disorder and other SUDs. Access to a patient's full medical record (including SUD information) also will be critical for telehealth providers.

Part 2 severely constrains the healthcare community's efforts to coordinate care for individuals living with SUDs and remains one of the most significant barriers to comprehensively addressing the public health challenge of opioid misuse and diversion.

Magellan's Comments and Recommendations: Magellan continues to encourage HHS to issue regulations aligning 42 C.F.R. with HIPAA for the purposes of treatment, payment, and healthcare operations.

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Dual Eligible Special Needs Plans

Magellan thanks CMS for carefully considering and balancing the complex federal, state, and market dynamics comprising the Medicare and Medicaid landscape for Americans served by both programs in the development of these provisions. We support most of the D-SNP provisions of the proposed rule with some questions and recommendations, detailed below.

INTEGRATION REQUIREMENTS FOR D-SNPS (§§422.2, 422.60, 422.102, 422.107, 422.111, AND 422.752)

The BBA of 2018 calls for D-SNPs, for 2021 and subsequent years, to meet one or more of three specified requirements for integration of benefits. CMS delineates the three types of D-SNPs permitted by the statute and their respective responsibilities to coordinate or cover Medicare and Medicaid benefits. The agency also proposes additional performance requirements on all D-SNPs to coordinate the delivery of benefits. States continue to retain authority for determining the state's Medicare-Medicaid integration environment and D-SNP options available to their dual eligible residents.

Magellan thanks CMS for the proposed approach outlined in the NPRM, which closely adheres to the intent of the BBA. We believe the proposals will enhance Medicare-Medicaid integration, while at the same time minimizing disruption by providing different pathways for states. We also support structural changes in the regulatory language (e.g., consolidating statutory and regulatory references; minimum requirements for each type of D-SNP).

Magellan's Comments and Recommendations: Additional clarifications and examples related to the following requirements would be helpful and better advance the agency's goals of integration for Medicare-Medicaid enrollees (MMEs), such as:

- *Clearer parameters for demonstrating coordination*, such as through a combination of guiding principles and additional examples, to inform states and their contracting D-SNPs as they collaborate to identify specific plan activities that might differ by program or type of service;
- *Technical assistance and additional guidance regarding appropriate methods, content and timeframes for notification of admissions for high-risk members,* such as formats for data exchanges and processes for designating contracts who will receive admission information; and,
- *Continue to permit state Medicaid agencies to determine D-SNP enrollment policies regarding partial duals*. To the extent a state determines it is in the interests of its partial dual eligible residents to enroll in D-SNPs, Magellan concurs such individuals can benefit from an enhanced degree of care coordination, even if the extent of their Medicaid benefits is limited.

UNIFIED GRIEVANCE AND APPEALS PROCEDURES FOR D-SNPS AND MEDICAID MANAGED CARE PLANS AT THE PLAN LEVEL (§§422.560–562, 422.566, 422.629–634, 438.210, 438.400, AND 438.402)

Section 1859(f)(8)(B) of the Social Security Act, as amended by the BBA, directs the HHS secretary to establish new procedures that fully integrate, to the extent feasible, Medicare and Medicaid grievance and appeals procedures for D-SNPs. This proposal would apply only to the enrollees of the subset of D-SNPs that are fully integrated D-SNPs (FIDE SNPs) or highly integrated D-SNPs (HIDE SNPs), under the newly proposed definitions, with "exclusively aligned enrollment" and the affiliated Medicaid managed care plans through which such enrollees receive their Medicaid services. CMS also proposes to implement unified grievance and appeals procedures for D-SNP enrollees pursuant to Social Security Act section 1859(f)(8)(C), also added by the BBA.

Magellan supports CMS' overall approach to implement the new requirements in a way balancing the goals of the statute while minimizing administrative complexity and burden, where possible. We believe the proposals appropriately recognize that the Medicare and Medicaid statutes and benefit structures conflict too much in some cases to allow a fully unified appeals process, including post-plan appeals. Furthermore, we agree targeted application of the rules is appropriate given the difficulty of implementing these types of procedures for plans without exclusively aligned enrollment. (There are only 37 plans in eight states with exclusively aligned enrollment.)

Magellan HEALTH

Magellan's Comments and Recommendations: Additional clarifications and other guidance to assist stakeholders in implementing these provisions would be helpful, such as:

- *Additional guidance on enrollee assistance with appeals and grievances,* perhaps as the product of a technical expert panel where participants with backgrounds in Medicaid and Medicare appeals and grievance processes are convened to recommend appropriate practices around enrollee assistance, including guidelines for coaching enrollees on self-advocacy. Such recommendations could inform future guiding principles for enrollee assistance, inclusive of examples and related issues for states and plans to consider;
- *Clarification as to whether the CMS-10003 Integrated Denial Notice meets the proposed integrated notice of adverse determination requirements;* and,
- *Indication as to how these proposed regulatory changes affecting appeals and grievance processes may impact or be implemented in the ongoing Medicare-Medicaid Plan demonstrations,* whether in the final rule or subsequent sub-regulatory guidance.

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Proposal for PDP sponsors' access to Medicare Parts A and B claims data extracts (§423.153)

This provision seeks to implement a provision of the BBA ("Providing Prescription Drug Plans with Parts A and B Claims Data to Promote the Appropriate Use of Medications and Improve Health Outcomes"), which allows PDP sponsors, beginning in CY 2020, to request extracts of Medicare claims data about their enrollees. Below we summarize the elements of the agency's proposal and comment accordingly. In its proposal, CMS would provide PDPs with Medicare claims data no sooner than on a quarterly basis with a three-month lag from the last day of the last month of the prior quarter.

PURPOSES AND LIMITATIONS ON THE USE OF DATA

CMS proposes the "full range of activities for which plan sponsors would need Medicare claims data," for which PDP sponsors would be permitted to use such data, is: to optimize therapeutic outcomes through improved medication use; to improve care coordination to prevent adverse health outcomes; or, to execute certain "health care operations" or "fraud and abuse or compliance activities" under the HIPAA privacy regulations, specifically for the purposes described in the first or second paragraph of "health care operations" under 45 CFR 164.501, or that qualify as "fraud and abuse detection or compliance activities" under 45 CFR 164.506(c)(4).

CMS also proposes to permit disclosures that qualify as a "required by law" disclosure as defined at 45 CFR 164.103. The agency proposes that PDP sponsors would not be permitted to use Medicare claims data to inform coverage determinations under Part D; conduct retroactive reviews of medically accepted indications (MAIs) determinations; facilitate enrollment changes to a different PDP or an MA-PD plan offered by the same parent organizations; and/or, inform marketing of benefits.

As a condition of receiving the requested data, CMS also proposes to require that plan sponsors attest that they will adhere to the permitted uses and limitations on the use of the Medicare claims data and requests comment on the proposed attestation. And CMS proposes to require that the PDP sponsor contractually bind its Contractors that it anticipates giving access to Medicare claims data, and any other potential downstream data recipients, to the terms and conditions imposed on the PDP sponsor. CMS may refuse to make future releases of Medicare claims data to the PDP Sponsor if it decides or has a reasonable belief that unauthorized uses, reuses, or disclosures have taken place.

We note that there are numerous examples where CMS currently allows PDP sponsors to access Parts A and B claims data which would seemingly conflict with the proposed impermissible uses. Therefore, Magellan encourages CMS to clarify the "permissible" and "impermissible" uses under § 423.153 apply only to data obtained under that section and do not preempt any other plan use of such data that is otherwise required and/or obtained through other permissible avenues. We also encourage CMS to ensure implementation of this proposal does not inadvertently restrict PDP sponsors' other, less restricted access to claims data.

In addition, under "permissible uses," as proposed, we are concerned PDP sponsors would not be able to use data extracts to inform coverage determinations to support approvals for beneficiaries. We recommend PDP sponsors be permitted to use these data as an optional, supplemental source of information to support approval of coverage determinations. We request CMS clarify, for purposes of audits and reviews, PDP sponsors will not be penalized for failure to account for Parts A and B claims data that is excluded from permissible uses (e.g., failure to implement MAIs and other restrictions, even if the PDP sponsor has this data on hand, because of the prohibition on conducting retroactive reviews of determinations related to MAIs). We also note, given the definition of permissible use is confined by HIPAA, it does not appear SUD-related information will affectively be excluded under current 42 C.F.R. Part 2 restrictions.

Magellan's Comments and Recommendations: Magellan requests CMS clarify that "permissible" and "impermissible" uses, as defined under § 423.153, apply only to data obtained under that section and do not preempt any other plan use of such data otherwise required and/or obtained through other permissible avenues. We also request CMS clarify, for purposes of audits and reviews, PDP sponsors will not be penalized for failure to account for Parts A and B claims data that is excluded from permissible uses. We encourage CMS include, as a permissible use, use of the data to make favorable coverage determination decisions.

DATA REQUEST

Regarding the process for requesting the Medicare claims data from CMS, the agency proposes to accept data requests on an ongoing basis beginning Jan. 1, 2020. CMS proposes to not allow plan sponsors to request data for subsets of their enrolled beneficiary populations. CMS proposes allowing requests to be submitted without an end date, such that the request, once reviewed for completeness and approved, will remain in effect until one or more of the following occur: the PDP sponsor notifies

CMS that it no longer wants to receive Medicare claims data; CMS cancels access to Medicare claims data when a PDP sponsor leaves the Part D program; or, CMS concludes or has reasonable belief that the PDP sponsor has used, reused, or disclosed the Medicare claims data in an impermissible manner.

Magellan's Comments: Magellan requests clarification as to PDP sponsors' access to the data (e.g., single point person or multiple individuals within the PDP permitted to access the data extract).

DATA EXTRACTION CONTENT

In detailing the content and timeframes, CMS proposes the first standardized data extract would be available to PDP sponsors no earlier than Aug. 15, 2020, which would include, at a minimum, data for the period beginning Jan. 1, 2020 and ending on March 1, 2020. CMS would use a standard format to deliver the resulting data to each PDP sponsor with standard format extracts. These extracts will be available to eligible PDP sponsors at least quarterly, but only on a specified release date that would be applicable to all eligible PDP Sponsors.

Magellan is concerned the proposed timeframe would significantly delay access to and impact the utility of the Medicare Parts A and B claims data and is not consistent with congressional intent for providing actionable information.

Magellan's Comments and Recommendations: Magellan recommends CMS make the claims data available to PDPs more frequently and timely than proposed and as close as possible to real time—preferably monthly vis-à-vis final-action claims with at most a one-month lag and reflecting a 14-month look-back period (as under the Bundled Payment for Care Improvement (BPCI) initiative). Since PDPs do not require final-action claims to use the information for care coordination and other clinical purposes, the timeliness for PDPs could be improved further beyond the BPCI initiative.

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MA and Part D PDP quality rating system (§§422.162(a) and 423.182(a), §§422.166(a) and 423.186(a), §§422.164 and 423.184, and §§422.166(i)(1) and 423.186(i)(1))

CMS proposes changes to the MA and PDP Star Ratings program relating to the cut-point methodology for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures, specifications for several existing measures, and data integrity policy related to appeals measures. The proposed rule also codifies requirements for calculating Star Ratings in cases of extreme and uncontrollable circumstances.

Magellan HEALTH

MEASURE-LEVEL STAR RATINGS

Starting with 2022 Star Ratings, CMS proposes to add mean resampling to reduce the sensitivity of the clustering algorithm to outliers and reduce the random variation that contributes to fluctuation in cut points for non-CAHPS measures. In addition, CMS proposes to implement a 5 percent bi-directional cap that restricts movement both above and below the prior year's cut points. The bi-directional cap would be used for measures that have been in the Part C and D Star Ratings program for more than three years.

Magellan appreciates CMS' willingness to consider changes to increase predictability and stability of the cut points from year to year. Absent access to simulation data and detail regarding the methodology, it is very challenging to assess and comment on the impact of the proposed changes. To support transparency, accountability, and ensure fairness, we recommend CMS provide simulation data related to the proposed changes to the cut point methodology and provide pre-determined cut points in advance of the measurement period. We ask that these be provided in the forthcoming Call Letter or through other guidance.

While we believe such data would be helpful, we would like to offer comment on ways CMS may further refine the methodologies proposed, including an alternative algorithm. An alternative algorithm we believe may address some of the outlier issues the agency has identified is *k*-means clustering with outlier removal, as described by Guojun Gan and Michael Kwok-Po Ng in *Pattern Recognition Letters*. The *k*-means clustering is one of the oldest and most commonly used clustering methodologies; however, it is sensitive to noisy data and outliers. Gan and Ng propose the KMOR (*k*-means clustering with outlier removal) algorithm by extending the *k*-means algorithm for outlier detection. Given a desired number of clusters *k*, the KMOR algorithm partitions the dataset into *k* + 1 groups, which include *k* clusters and a group of outliers that cannot fit into the *k* clusters. Unlike most existing clustering algorithms with outlier detection, the KMOR algorithm assigns all outliers into a group naturally during the clustering process.[2]

We also encourage CMS to consider further refinements to the proposed methodologies beyond the algorithm, including a restricted-range cap and caps for new measures. CMS proposes a 5 percent restricted range cap, defined as (0.05) * (maximum value – minimum value) only for measures not scored on a 1 to 100 scale. Magellan believes this percent-restricted range cap may be more appropriate than the 5-percentage point absolute cap for all measures, including those scored on a 1 to 100 scale. CMS also proposes the cap would apply to non-CAHPS measures that have been in the Part C and D Star Ratings program for more than three years. We are concerned new measures often are where the most fluctuation is seen. MA plans and PDP sponsors need the ability to work with providers to improve performance on new Star Rating measures, and it is challenging to provide appropriate feedback and incentives with such fluctuation. We believe some guardrails should be established for new measures, although we acknowledge that new measures will present different challenges.

2. Guojun Gan and Michael Kwok-Po Ng, "*k*-Means clustering with outlier removal," *Pattern Recognition Letters* 90 (March 8, 2017): 8-14.

Magellan HEALTH

We also are concerned about fundamental underlying limitations of the cut-point approach within Stars that will not be addressed by these proposed modifications. Magellan notes these enhancements do not account for necessary adjustments for socio-economic factors. We are particularly concerned plans with a high proportion of low-income subsidy enrollees, with significant social determinants of health and care complexity factors, may be disadvantaged by the cut-point approach. We know population-level characteristics, including care complexity and social risk factors, greatly affect what plans and providers can do, when, and how. Achieving thresholds on some of these Star measures requires exponentially more effort for people with high social risk factors and care complexities. We encourage careful CMS consideration of these complexities.

We have an additional concern increasing the need for guardrails. While we are supportive of the CMS proposal for policy to adjust the methodology for Star Ratings for affected Medicare Advantage and Part D plans in the event of extreme and uncontrollable circumstances, we recognize the repeated removal of certain contracts has an impact on the overall cut-point thresholds and may lead to incremental volatility. CMS should be mindful of the impact of such excluded contracts. We believe the Extreme and Uncontrollable Circumstances proposal reinforces the need for meaningful and effective guardrails. Finally, our understanding from reading the NPRM is the cut-point methodology changes would be implemented for CY 2020. We encourage CMS to confirm when the change is applicable for; for example, is it for data collected in CY 2020 (used for the 2022 Star Ratings, which are released in 2021), or for the 2021 Star Ratings (released in 2020)? We also encourage CMS to provide a timeline for when additional substantive methodological improvements to the cut-point approach may be expected.

Magellan's Comments and Recommendations: Magellan recommends CMS provide simulation data related to the proposed changes to the cut point methodology and provide pre-determined cut points in advance of the measurement period. We encourage CMS consideration of an alternative algorithm to better address the outlier issues the agency has identified (i.e., *k*-means clustering with outlier removal, as described by Gan and Ng in *Pattern Recognition Letters*). We also encourage CMS to consider further refinements to the proposed methodologies beyond the algorithm, including a restricted-range cap and caps for new measures. We urge CMS to consider how these methodological changes and refinements may impact or necessitate adjustments for socio-economic factors. We also urge CMS to be mindful of the impact of the repeated removal of certain contracts under the Extreme and Uncontrollable Circumstances proposal on the overall cut-point thresholds, which may result in incremental volatility. We also request CMS confirm when the proposed changes would be applicable.

UPDATING MEASURES

CMS proposes measure changes to the Star Ratings program for performance periods beginning on or after Jan. 1, 2020 and performance periods beginning on or after Jan. 1, 2021.

- MPF Price Accuracy (Part D)

CMS indicates the new MPF Price Accuracy measure will be a Display Measure for 2020 and 2021, and then will become a new Star Rating measure in 2022 in place of the current MPF measure. The new

measure will include the Price Accuracy Index (magnitude difference) and Claims Percentage Index (percentage of prescription drug events (PDEs), with total PDE cost higher than total MPF cost). CMS will use $0.01 rather than $0.005 to identify claims to be included in the Claims Percentage Index. The new MPF Star Rating measure will have weight of 1 in 2022 Star Ratings.

While we continue to oppose CMS' addition of a frequency component to the MPF Price Accuracy Measure, we also reserve opinion on the proposed measure change until we can consider simulation data. We do continue, however, to recommend CMS convene a technical expert panel to assess the most appropriate measurement of MPF Price Accuracy to reflect more accurate information on drug pricing that also is meaningful to beneficiaries.

Magellan's Comments and Recommendations: We continue to believe the frequency of price changes is not an appropriate measure of concern to beneficiaries; beneficiaries are impacted when the pricing data available on the MPF (i.e., MPF Price Accuracy (Part D)) is significantly different than the price charged at point-of-sale and reflected in the PDE data. We look forward to future discussions on a more meaningful and accurate tool for beneficiaries to understand this important information.

- Improvement Measures (Parts C and D).

CMS proposes modifying the Improvement measures to exclude from the improvement calculation any measure that receives a measure-level Star Rating reduction for data integrity concerns for either the current or prior year.

Magellan's Comments and Recommendations: Magellan supports the current recommendation on Improvement Measures (Parts C and D), thanks CMS for this important change, and encourages the agency to continue to adapt the Quality Improvement Star Rating methodology to both encourage underperforming contracts to meet CMS standards and reward high-achieving contracts to strive for further excellence.

DATA INTEGRITY

Current CMS policy makes scaled reductions to the Star Ratings for a contract's Part C or Part D appeals measures if the relevant Independent Review Entity (IRE) data are not complete based on the Appeals Timeliness Monitoring Project (TMP) data or audit information. CMS proposes to assign a 1-star rating to the applicable appeals measure(s) if a contract fails to submit TMP data for CMS' review to ensure the completeness of their IRE data.

Magellan's Comments: Magellan supports CMS' efforts to ensure data integrity and we believe the proposal addresses CMS' current challenges of "scoring" in the absence of data. We encourage CMS to consider providing one to two additional weeks for a sponsor to submit their TMP data, due to the time of year the data are being requested. We also request that TMP results be shared with sponsors much sooner than they previously have been (i.e., nine months later).

Magellan HEALTH

REVIEW OF SPONSORS' DATA

CMS proposes requests for CMS or the IRE to review contract data must be received no later than June 30 of the following year. CMS also proposes that any requests for readjustments following CMS' CTM Standard Operating Procedures for the complaints measures be made by June 30 of the following year for the changes to be reflected in a contract's Star Ratings data.

Magellan's Comments and Recommendations: Magellan generally is supportive of the proposal; however, instead of June 30 of the following year, CMS may consider selecting a date aligned with the end of the first plan preview of Star Ratings performance metric (usually occurring in the second or third week of August). This later date would allow plans to fully respond to all appeals and complaints information and still allow CMS time to incorporate this data into the Star Ratings.

EXTREME AND UNCONTROLLABLE CIRCUMSTANCES

CMS proposes a new methodology for adjusting CAHPS and other Star Ratings program measures in the event of an extreme and uncontrollable circumstance (such as hurricanes or other disaster). This proposal reflects similar policy in the 2019 Call Letter for calculation of Star Ratings of certain contracts.

Magellan's Comments and Recommendations: Magellan supports CMS' proposal to codify such rules and its ongoing efforts to address the impact of extreme and uncontrollable circumstances on beneficiaries and Star Rating measures. We encourage transparency around the global list of affected MA plans and plan sponsors, including by providing more information about the impacts of such adjustments (e.g., public information of the identify of affected contracts, reporting on the impact for the Star Ratings program overall, etc.). We also support clarification of the definition's inclusion of "affected contracts" impacted by Public Health Emergency Declarations in addition to section 1135(g) of the Social Security Act. We also recommend CMS consider the implications of applying the methodology year-over-year as some regions unfortunately face consecutive years of disasters. With some regions, we are concerned 2017 data could be continued to be pulled forward each year and be used in the 2022 Star Ratings program. We request CMS consider the implications of ongoing and repeated extreme and uncontrollable circumstances.

FUTURE STAR RATINGS ISSUES

Magellan notes further there are additional, meaningful Star Ratings issues not addressed in the NPRM but anticipated for the 2020 draft Call Letter, including proposed enhancements to the Categorical Adjustment Index (CAI) methodology. We support continued use of the CAI in the Star Ratings program while CMS develops a long-term solution to address disparities in plan performance associated with socio-economic status and other risk factors. We look forward to discussing these and other important Star Ratings issues in our consideration of the draft Call Letter.

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Magellan HEALTH

Preclusion list requirements for prescribers in Part D and individuals and entities in MA, cost plans, and PACE (§§422.222 and 423.120)

The NPRM proposes revisions to the preclusion list policy finalized in the CY 2019 MA and Part D final rule; specifically, it seeks to streamline the appeals process and placement of providers/prescribers on the preclusion list. Under current timeframe standards, a prescriber that is, for example, convicted of a felony, could "delay" their placement on the preclusion list for up to nine months by taking advantage of the various levels of appeals and decision timeframes available to them (e.g., request for reconsideration of revocation, request for reconsideration of inclusion on preclusion list). Through various regulatory changes, CMS proposes to shorten this nine-month timeframe to five months. CMS also proposes to consolidate the (1) revocation and (2) preclusion appeals timeframes so they run concurrently. CMS notes that this requirement, if finalized, would be effective 60 days after the publication of the final rule.

Magellan appreciates CMS' efforts to reduce fraud and abuse in the Medicare program while reducing unnecessary administrative burden. To that end, we remain supportive of CMS' decision in the 2019 final rule to remove the prescriber and provider enrollment requirements and we support CMS' overall approach to implementing the preclusion list, including the agency's decision to not finalize a proposal that would have required provisional fills for prescriptions written by prescribers on the preclusion list. We remain concerned, however; CMS is now proposing changes to its preclusion list policy that would create additional complexity, provide limited value, and work against CMS' stated goal (i.e., "the preclusion list will be operationalized in the same manner as the [Office of Inspector General] OIG exclusion list ….''). In addition to other complexities, we believe the separate required beneficiary notices, and claims denial deadlines triggered by the notices, are inconsistent with this goal.

Consistent with CMS' stated intent, the preclusion list should be operationalized the same way as the OIG exclusion list. Under the exclusion list process, CMS makes the exclusion list public, updates monthly, posts 15 days prior to the exclusion effective date, and expects plans to deny claims as of the effective date. As providers and prescribers are given a chance to appeal before being added to the preclusion list, we believe it would be appropriate for CMS to make the preclusion list public and implement it in the same manner as the exclusion list. Such an approach, we believe, would alleviate a range of existing concerns and inconsistencies identified to date by plans and other stakeholders.

Magellan's Comments and Recommendations: Magellan urges CMS not to implement this proposal. Alternatively, we recommend the effective date be delayed until the preclusion list – as envisioned in the proposed rule and in other related guidance – can be implemented in alignment with agency intent or, at minimum , until Jan. 1, 2020. As a further alternative to delay, CMS may consider committing to exercise enforcement discretion against plans until Jan. 1, 2020 for such plans that make a good faith effort to comply with the rule.

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Improving clarity of the exceptions timeframes for Part D Drugs (§§423.568, 423.570, and 423.572)

CMS proposes a change to Part D adjudication timeframes related to exception requests in cases where a prescribing physician's or other prescriber's supporting statement has not been received by the plan sponsor. The federal agency intends to limit the amount of time an exception request can be held open in a pending status while the Part D plan sponsor attempts to obtain the prescribing physician's or other prescriber's supporting statement. Specifically, CMS proposes to amend existing regulations to clarify that the plan must notify the enrollee (and the prescribing physician or other prescriber involved as appropriate) of its decision no later than 72 hours (or 24 hours in the case of an expedited decision) of receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first.

Magellan supports CMS' proposed changes to the Part D exceptions timeframes and the agency's effort to promote consistency in how receipt of supporting statements is handled across the industry. It provides plans with needed clarity on the exceptions timeframes. We also appreciate the effort to ensure consistency with IRE processes. We would note, however, the proposal appears inconsistent with the "New Appeals Chapter" proposed by CMS in select ways (e.g., effective date (i.e., 2019 or 2020); whether the 14 days is an absolute maximum; and, whether the period to address the exception request (24 or 72 hours) must be concluded in the 14 days or whether it only needs to be triggered in that timeframe ("tolling")).

Magellan's Comments: Magellan asks CMS to issue one set of aligned, consistent guidance (i.e., both a revised New Appeals Chapter and a final rule), potentially as follows:

- *Effective date of 90 days after the "New Appeals Chapter" is released and* allowing plans to phase in the new protocols with compliance effective as of Jan. 1, 2020;
- *Built-in flexibility on whether the 14-day period for additional support can be extended* and, if so, clear rules on his this practically would work; and,
- *Retracting the shortened outside limit to the time frame where the supporting statement is received late in the adjudication,* and replacing it with a clear statement affirming the decision process must begin within the 14 days but no requirement it be completed in that period.

*

MA risk adjustment data validation provisions (§§ 422.300, 422.310(e), and 422.311(a))

On Dec. 20, 2018, CMS released a memorandum ("Risk Adjustment Data Validation (RADV) Industry-wide Training and Audits and CMS-4185-P RADV Provision Notice") stating the agency "will extend the public comment period by 120 days, until April 30, 2019, for the RADV provision" included in the

proposed rule. It also published an accompanying notice December 27 in the *Federal Register* sharing CMS' intent to release data underlying the FFS Adjuster study.

While Magellan has concerns with the proposed use of extrapolation in MA RADV contract-level audits and the proposal not to apply a FFS Adjuster to such audit findings, as a result of this announcement we intend to file comments in response to the modified April 30, 2019 deadline. We thank HHS and CMS for affording this additional time to the public to thoughtfully consider the magnitude of the proposal, and we look forward to reviewing the additional data.

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Thank you for the opportunity to comment on the proposed rule. We look forward to engagement with CMS on these and other issues to help advance the agency's goals with respect to implementing certain provisions of the Bipartisan Budget Act of 2018, promoting affordability and meaningful competition in these programs, and reducing unnecessary regulatory complexity to ensure the MA and Prescription Drug programs meet the healthcare needs of its diverse beneficiaries.

As CMS considers our comments, Magellan would be glad to answer questions. Please contact Brian Coyne, vice president of federal affairs, at (804) 548-0248 or bcoyne@magellanhealth.com; or, Claire Wulf Winiarek, vice president of public policy, at (860) 507-1918 or cwulfwiniarek@magellanhealth.com.

Sincerely,

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83 Fed. Reg. 16440, 16520, 16521 (Apr. 16, 2018)

codifying the rules that govern the Star Ratings system, we are demonstrating a commitment to transparency and predictability for the rules in the system so as to foster investment.

b. Background

We originally acted upon our authority to disseminate information to beneficiaries as the basis for developing and publicly posting the 5-star ratings system (sections 1851(d) and 1852(e) of the Act). The MA statute explicitly requires that information about plan quality and performance indicators be provided to beneficiaries to help them make informed plan choices. These data are to include disenrollment rates, enrollee satisfaction, health outcomes, and plan compliance with requirements.

The Part D statute (at section 1860D–1(c)) imposes a parallel information dissemination requirement with respect to Part D plans, and refers specifically to comparative information on consumer satisfaction survey results as well as quality and plan performance indicators. Part D plans are also required by regulation (§ 423.156) to make Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey data available to CMS and are required to submit pricing and prescription drug event data under statutes and regulations specific to those data. Regulations require plans to report on quality improvement and quality assurance and to provide data which CMS can use to help beneficiaries compare plans (§§ 422.152 (b)(3) and 423.153(c)(5)). In addition we may require plans to report statistics and other information in specific categories (§§ 422.516 and 423.514).

Currently, for similar reasons of providing information to beneficiaries to assist them in plan enrollment decisions, we also review and rate section 1876 cost plans on many of the same measures and publish the results. We also proposed to continue to include 1876 cost contracts in the MA and Part D Star Rating system to provide comparative information to Medicare beneficiaries making plan choices. We proposed specific text, to be codified at § 417.472(k), requiring that 1876 cost contracts to agree to be rated under the quality rating system specified at subpart D of part 422. Cost contracts are also required by regulation (§ 417.472(j)) to make CAHPS survey data available to CMS. As is the case today, no Quality Bonus Payments (QBP) will be associated with the ratings for 1876 cost contracts.

In line with §§ 422.152 and 423.153, CMS uses the Healthcare Effectiveness Data and Information Set (HEDIS), Health Outcomes Survey (HOS), CAHPS data, Part C and D Reporting requirements and administrative data, and data from CMS contractors and oversight activities to measure quality and performance of contracts. We have been displaying plan quality information based on that and other data since 1998.

Since 2007, we have published annual performance ratings for stand-alone Medicare PDPs. In 2008, we introduced and displayed the Star Ratings for Medicare Advantage Organizations (MAOs) for both Part C only contracts (MA-only contracts) and Part C and D contracts (MA–PDs). Each year since 2008, we have released the MA Star Ratings. An overall rating combining health and drug plan measures was added in 2011, and differential weighting of measures (for example, outcomes being weighted 3 times the value of process measures) began in 2012. The measurement of year to year improvement began in 2013, and an adjustment (Categorical Adjustment Index) was introduced in 2017 to address the within-contract disparity in performance revealed in our research among beneficiaries that are dual eligible, receive a low income subsidy, and/or are disabled.

The MA and Part D Star Ratings measure the quality of care and experiences of beneficiaries enrolled in MA and Part D contracts, with 5 stars as the highest rating and 1 star as the lowest rating. The Star Ratings provide ratings at various levels of a hierarchical structure based on contract type, and all ratings are determined using the measure-level Star Ratings. Contingent on the contract type, ratings may be provided and include overall, summary (Part C and D), and domain Star Ratings. Information about the measures, the hierarchical structure of the ratings, and the methodology to generate the Star Ratings is detailed in the annually updated Medicare Part C and D Star Ratings Technical Notes, referred to as Technical Notes, available at *http://go.cms.gov/partcanddstarratings.*

The MA and Part D Star Ratings system is designed to provide information to the beneficiary that is a true reflection of the plan's quality and encompasses multiple dimensions of high quality care. The information included in the ratings is selected based on its relevance and importance such that the ratings can meet the needs of beneficiaries using them to inform plan choice. While encouraging improved health outcomes of beneficiaries in an efficient, person centered, equitable, and high quality manner is one of the primary goals of the ratings, they also provide feedback on specific aspects of care and performance that directly impact outcomes, such as process measures and the beneficiary's perspective. The ratings focus on aspects of care and performance that are within the control of the health plan and can spur quality improvement. The data used in the ratings must be complete, accurate, reliable, and valid. A delicate balance exists between measuring numerous aspects of quality and the need for a small data set that minimizes reporting burden for the industry. Also, the beneficiary (or his or her representative) must have enough information to make an informed decision without feeling overwhelmed by the volume of data.

The Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Healthcare and Education Reconciliation Act (Pub. L. 111–152), provides for quality ratings, based on a 5-star rating system and the information collected under section 1852(e) of the Act, to be used in calculating payment to MA organizations beginning in 2012. Specifically, sections 1853(o) and 1854(b)(1)(C) of the Act were added and amended to provide, respectively, for an increase in the benchmark against which MA organizations bid and in the portion of the savings between the bid and benchmark available to the MA organization to use as a rebate. Under the Act, Part D plan sponsors are not eligible for quality based payments or rebates. We finalized a rule on April 15, 2011 to implement these provisions and to use the existing Star Ratings system that had been in place since 2007 and 2008. (76 FR 21485–21490).[32] In addition, the Star Ratings measures are tied in many ways to responsibilities and obligations of MA organizations and Part D sponsors under their contracts with CMS. We believe that continued poor performance on the measures and overall and summary ratings indicates systemic and wide-spread problems in an MA plan or Part D plan. In April 2012, we finalized regulations to use consistently low summary Star Ratings—meaning 3 years of summary Star Ratings below 3 stars—as the basis for a contract termination for Part C and Part D plans. (§§ 422.510(a)(14) and 423.509(a)(13)). Those regulations further reflect the role the Star Ratings have had in CMS' oversight, evaluation, and monitoring of MA and Part D plans to ensure compliance with the

[32] The ratings were first used as part of the QBP Demonstration for 2012 through 2014 and then used for payment purposes as specified in sections 1853(o) and 1854(b)(1)(C) of the Act and the regulation at 42 CFR 422.258(d)(7).

respective program requirements and the provision of quality care and health coverage to Medicare beneficiaries.

The true potential of the use of the MA and Part D Star Ratings system to reach our goals and to serve as a catalyst for change can only be realized by working in tandem with our many stakeholders, including beneficiaries, plans, and advocates. The following guiding principles have been used historically in making enhancements and updates to the MA and Part D Star Ratings:

- Ratings align with the current CMS Quality Strategy.
- Measures developed by consensus-based organizations are used as much as possible.
- Ratings are a true reflection of plan quality and enrollee experience; the methodology minimizes risk of misclassification.
- Ratings are stable over time.
- Ratings treat contracts fairly and equally.
- Measures are selected to reflect the prevalence of conditions and the importance of health outcomes in the Medicare population.
- Data are complete, accurate, and reliable.
- Improvement on measures is under the control of the health or drug plan.
- Utility of ratings is considered for a wide range of purposes and goals.
  - ++ Accountability to the public.
  - ++ Enrollment choice for beneficiaries.
  - ++ Driving quality improvement for plans and providers.
- Ratings minimize unintended consequences.
- Process of developing methodology is transparent and allows for multi-stakeholder input.

We used these goals to guide our proposal and intend to use them to guide how we interpret and apply the final regulations. For each provision we proposed, we solicited comment on whether our specific proposed regulation text best serves these guiding principles. We also solicited comment on whether additional or other principles are better suited for these roles in measuring and communicating quality in the MA and Part D programs in a comparative manner.

As we continue to consider making changes to the MA and Part D programs in order to increase plan participation and improve benefit offerings to enrollees, we also solicited feedback from stakeholders on how well the existing stars measures create meaningful quality improvement incentives and differentiate plans based on quality. We solicited comments on those topics, and have considered them in adopting this final rule, as noted in the responses below, and will consider them for future rulemaking. We specifically asked for feedback on the following topics:

- Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans.
- Whether CMS' current process for establishing the cut points for Star Rating can be simplified, and if the relative performance as reflected by the existing methodology to establish cut points accurately reflects plan quality.
- How CMS should measure overall improvement across the Star Ratings measures. In the proposed rule, we specifically requested input on additional improvement adjustments that could be implemented, and the effect that these adjustment could have on new entrants (here meaning new MA organizations and/or new plans offered by existing MA organizations).
- Additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance (for example, rural geographies or monopolistic provider geographies), and the operational difficulties that plans could experience if such adjustments were adopted.
- In order to further encourage plan participation and new market entrants, whether CMS should consider implementing a demonstration to test alternative approaches for putting new entrants (that is, new MA organizations) on a level playing field with renewing plans from a Star Ratings perspective for a pre-determined period of time.
- Adding measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or increasing implementation of the use of telemedicine) or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.
- Including survey measures of physicians' experiences. (Currently, we measure beneficiaries' experiences with their health and drug plans through the CAHPS survey.) Physicians also interact with health and drug plans on a daily basis on behalf of their patients. We noted in the proposed rule that we are considering developing a survey tool for collecting standardized information on physicians' experiences with health and drug plans and their services.

CMS appreciates the feedback we received on our proposals and on the solicitations for comment on the various topics. In the sections that follow, which are arranged by topic area, we summarize the comments we received on the background section and policies, proposals and solicitations summarized there and provide our responses to the comments. (In each section in II.B.11.c through w, we summarize the proposals from the corresponding section of the proposed rule, the applicable comments, and our responses.)

Comment: Most commenters supported both the principles and the decision to codify the methodology for the Part C and D Star Ratings. Of the commenters who supported those aspects of our overall proposal, a few suggested adding principles, such as the measure data should be timely and that distinctions between measure-level Star Ratings (cut points) should be meaningful.

Response: CMS appreciates the support to codify the methodology for the Part C and D Star Ratings. We will codify the methodology in this final rule as outlined in this preamble, and will consider the additional principles raised by the commenters for adoption in the future as we continue to refine the principles in consultation with experts and stakeholders through the regulatory process.

Comment: Several commenters requested CMS to continue updating the methodology though the Call Letter instead though regulation. Commenters were concerned that the regulatory process would lead to CMS not being able to act quickly when there are public health or patient safety concerns or when treatment guidelines are changed. Commenters also cited other concerns, including introducing a burdensome regulatory process that delays the implementation of essential measures which can improve the quality of care for patients with chronic illness, as reasons to not to finalize this proposal but to continue using the Call Letter process to modify the Star Ratings methodology. They also noted that there are already multiple opportunities for comment on new measures; thus, the regulatory process does not create additional transparency. A few commenters supported the general effort to put the Star Ratings principles and process into regulation, but encouraged CMS to adopt a few exceptions (such as allowing new measures (but not measures with substantive changes) to enter Star Ratings through the Call Letter process).

Response: CMS understands the commenters' concerns about how the regulatory process may, in some cases, prevent CMS from quickly changing or adopting measures. However, given the

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84 Fed. Reg. 15680, 15770-74 (Apr. 19, 2019)

Response: Although there are enough data provided on the MAXIMUS website for contracts to determine if a case is late, CMS has worked with MAXIMUS, the IRE, to add a late indicator on the website for Part C Appeals data to make it easier for plans to monitor the timeliness of their cases. This update will further allow plans to request adjustments to their Part C appeals, if necessary, in a timely manner before Star Ratings calculations.

Comment: A commenter supported the proposal, but requested a clarification of the application of the deadline related to CTM data, because CMS often changes the CTM case status so that cases are no longer visible and cannot be monitored for accuracy.

Response: We appreciate the support and the opportunity to clarify which CTM data are used for Star Ratings purposes. For CTM, the quarterly reports only contain CTM complaints that are used to calculate the Star Rating CTM measure. If a CTM is not in the report, the complaint is not considered a plan issue and it would not be included in the Star Ratings measure. Therefore, sponsoring organizations may wish to focus their requests for CMS review of CTM data on the data that are part of the quarterly reports.

Comment: A few commenters supported the proposal but noted that CMS should publish a schedule of the timing of all related reports, while a commenter did not support the proposal and requested similarly a schedule of reports. Additionally, a commenter stated the Part C MAXIMUS IRE reports are not published and are only made available upon request to the CMS account manager each quarter.

Response: We appreciate the support and the opportunity to clarify the timing and availability of the reports which contain data used for the Star Ratings. Part D appeals and CTM reports are posted in HPMS quarterly; approximately 2 months following the close of the quarter. Information regarding the Part C reconsideration process is available to Medicare Advantage (MA) organizations on the *www.medicareappeal.com* website. The data available on this website are updated daily; therefore, MA organizations that notice discrepancies or have questions about the data should bring these issues to the attention of the IRE as they arise. On the website, MA organizations are able to see all the cases related to a particular plan for the date range they chose and they are also able to search by case number. MAXIMUS has added a late indicator to their website to help in the review; therefore, plans should be able to fully monitor their data throughout the year.

Comment: A commenter supported the codification of deadlines for requests by an MA organization or Part D plan sponsor to review contract appeals or Complaints Tracking Module data.

Response: CMS appreciates the support.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to related comments summarized earlier, we are finalizing the provisions at §§ 422.164(h)(1) and 423.184(h)(1) related to the policy regarding the deadlines for an MA organization or Part D plan sponsor to request CMS or the IRE to review its' appeals data or CMS to review its' Complaints Tracking Module (CTM) data with a substantive modification. We are not finalizing the June 30th deadline in regulation. To provide more flexibility to set the deadline contingent on the timing of the availability of data for plans to review, we are finalizing in this regulation that an MA organization or Part D plan sponsor may request that CMS or the IRE review its' data, provided that the request is received by the annual deadline set forth by CMS for the applicable Star Ratings year. We intend to use the annual Call Letter or an HPMS memo to set the annual deadline.

e. Extreme and Uncontrollable Circumstances (§§ 422.166(i), 423.186(i))

We proposed a policy to address how extreme and uncontrollable circumstances may have a negative impact on the Quality Star Ratings of an MA or Part D plan. Extreme and uncontrollable circumstances such as natural disasters can directly affect Medicare beneficiaries and providers, as well as the Parts C and D organizations that provide them with important medical care and prescription drug coverage. These circumstances may negatively affect the underlying operational and clinical systems that CMS relies on for accurate performance measurement in the Star Ratings program, all without fault on the part of the MA organization or Part D plan sponsor. We proposed to adjust the Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance or measurement period in a manner that would generally hold the affected contract harmless from reductions in Star Ratings. We proposed to codify a series of special rules for calculation of the Star Ratings of certain contracts in certain extreme and uncontrollable circumstances in paragraph (i) of §§ 422.166 and 423.186.

We proposed that the adjustments be tailored to the specific areas experiencing the extreme and uncontrollable circumstance in order to avoid over-adjustment or adjustments that are unnecessary. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. To ensure that the Star Ratings adjustments focus on the specific geographic areas that experienced the greatest adverse effects from the extreme and uncontrollable circumstance and are not applied to areas sustaining little or no adverse effects, our proposal targeted the adjustments to specific contracts and further specified and limited the adjustments.

Below we summarize the comments we received on the disaster adjustments in general.

Comment: Most commenters supported our proposals to adjust Star Ratings in the event of an extreme and uncontrollable circumstance.

Response: We thank the commenters for their support of the proposal, which we are finalizing with some substantive modifications in this final rule as described below.

Comment: A few commenters requested that CMS delay codifying the extreme and uncontrollable circumstances policy and continue to assess and develop the methodology in case additional modifications are needed. A commenter requested that CMS implement the policy for measurement year 2018 in order to avoid a temporary lapse in the application of the proposed policy.

Response: The policy being adopted in this final rule will apply to the 2022 Star Ratings and beyond, for extreme and uncontrollable circumstances that begin on or after January 1, 2020. If adjustments are needed to the policy, CMS will propose them through a future rulemaking or sub regulatory guidance. The 2020 Call Letter includes CMS's policy for the 2020 Star Ratings for extreme and uncontrollable circumstances that occurred in 2018. We decline to delay adoption of this policy for a future period, because similar procedures were successfully applied to the 2019 Star Ratings as a result of the multiple 2017 disasters.

(1) Identification of Affected Contracts

In paragraph (i)(1) of §§ 422.166 and 423.186, we proposed to identify MA

and Part D contracts affected by extreme and uncontrollable circumstances during the performance or measurement period that may have affected their performance on Star Ratings measures or their ability to collect the necessary measure-level data. Under our proposal, these ''affected contracts'' are the contracts eligible for the specified adjustments that take into account the effects of the extreme and uncontrollable circumstances. For an MA or Part D contract to be considered an affected contract under our proposal, the contract would need to meet all of the following criteria:

- The contract's service area is within an ''emergency area'' during an ''emergency period'' as defined in section 1135(g) of the Act.
- The contract's service area is within a county, parish, U.S. territory or tribal area designated in a major disaster declaration under the Stafford Act and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s).
- A certain minimum percentage (25 percent for measure star adjustments or 60 percent for exclusion from cut point and Reward Factor calculations) of the enrollees under the contract must reside in a Federal Emergency Management Agency (FEMA)-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance.

We proposed to identify an area as having experienced extreme and uncontrollable circumstances if it is within an ''emergency area'' and ''emergency period'' as defined in section 1135(g) of the Act, and also is within a county, parish, U.S. territory or tribal government designated in a major disaster declaration under the Stafford Act, and the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s) (*https://www.phe.gov/emergency/news/healthactions/section1135/Pages/default.aspx*). Major disaster areas are identified and can be located on FEMA's website at *https://www.fema.gov/disasters.* To ensure the policy is applied to those contracts most likely to have experienced the greatest adverse effects, we proposed to narrow it to apply to contracts with a certain minimum percentage of enrollees residing in an area declared as an Individual Assistance area because of the disaster declaration. Individual Assistance includes assistance to individuals and households, crisis counseling, disaster case management, disaster unemployment assistance, disaster legal services, and the disaster Supplemental Nutrition Assistance Program. We explained that our focus on enrollees residing in counties eligible for Individual Assistance because of a major disaster was because most Star Ratings measures are based on services provided directly to beneficiaries in their local area. Health and drug plans can serve enrollees across large geographic areas, and thus they may not be impacted in the same manner as healthcare providers such as hospitals or medical centers in specific physical locations. Therefore, we proposed to target the adjustments based on extreme and uncontrollable circumstances to contracts serving beneficiaries who were eligible for individual and household assistance because of the disaster declaration.

We further proposed that at least 25 percent or 60 percent of the enrollees under the contract must reside in Individual Assistance areas identified because of the extreme and uncontrollable circumstances in order for the contract to be an affected contract eligible for adjustments. We explained that this limitation would ensure that the adjustments are limited to contracts that we believe may have experienced a real impact from the extreme and uncontrollable circumstance in terms of operations or ability to serve enrollees. In calculations for the 2019 Star Ratings, we observed that contracts tend to have either very few enrollees impacted or most of their enrollees impacted due to the nature of contracts either covering a broad region or a localized area; if 1 out of 4 enrollees were impacted during the period of the year when the disaster hit, we stated our belief that there would be a small chance that scores may have been impacted. We proposed to exclude the numeric measure scores from contracts with 60 percent or more enrollees impacted by the extreme and uncontrollable circumstances from the determination of the cut points and explained it as a conservative rule that would apply only in cases where a clear majority or all of the enrollees are impacted. We also explained that using the Individual Assistance major disaster declaration as a requirement to identify contracts that would be eligible for adjustments ensures that the policy applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings.

We proposed that contracts that do not meet the definition of an ''affected contract'' would not be eligible for any adjustments based on the occurrence of the extreme and uncontrollable circumstances but also noted that the criteria to be an affected contract would not be sufficient to receive all the adjustments we proposed.

Below we summarize the comments we received on the identification of affected contracts and provide our responses and final decisions.

Comment: Several commenters suggested that CMS commit to being transparent in how it has applied the regulations, such as which contracts received adjustments and the impact on the Star Ratings program. A few stated this would allow sponsors a better understanding of marketplace performance and reduce inquiries to CMS. A commenter recommended that CMS announce areas designated as disasters for the purposes of Star Ratings on a quarterly basis, and another requested greater specificity on how a plan within a given county would qualify for the exemption rules. Another commenter requested that data and analysis on affected contracts be shared with state Medicaid agencies as this information is relevant to the states, and data sharing reduces burden on the plans.

Response: Information about which areas are designated in a major disaster declaration under the Stafford Act and when the Secretary exercised authority under section 1135 of the Act based on the same triggering event(s) are all public information we are extracting from the relevant websites. CMS published the list of relevant 2017 disasters and affected counties in the 2019 Call Letter, and state, county, and contract enrollment data are publicly available, so information about affected contracts is already available. We agree that providing additional information when the adjustments authorized under §§ 422.166(i) and 423.186(i) may be possible. To that end, CMS plans to provide information identifying contracts that meet the definition of affected contracts in §§ 422.166(i)(1) and 423.186(i)(1). We note that the definition of ''affected contract'' in these regulations is substantially similar to the definition and standards CMS used to make similar adjustments in the 2019 Star Ratings based on disasters that occurred in 2017. For the 2019 Star Ratings, which were adjusted for the disasters (Hurricanes Harvey, Irma, and Maria, and the wildfires in California) that occurred during the 2017 performance period, 77 contracts met the 25 percent threshold of beneficiaries in FEMA-designated Individual Assistance areas at the time of the disaster. Based on a similar policy to that we are now codifying in §§ 422.166(i) and 423.186(i), affected contracts reverted to the prior year's rating an average of five times for Part

C measures and three times for Part D measures. For the 2019 Star Ratings, 57 contracts met the 60 percent threshold of beneficiaries in FEMA-designated Individual Assistance areas and had their numeric values excluded from the clustering algorithm so they did not influence cut points. CMS will continue to release the list of relevant disasters and FEMA-designated Individual Assistance counties in the Call Letter each year after the performance period so contracts know in advance of the Star Ratings preview periods whether they might be considered an affected contract based on their service area.[38]

Comment: A commenter questioned whether requiring affected contracts to meet all three criteria in §§ 422.166(i)(1) and 423.186(i)(1) was too restrictive if it requires a state-level declaration of emergency and suggested that the third criteria (that is, §§ 422.166(i)(1)(iii) and 423.186(i)(1)(iii)) was most applicable.

Response: Stafford Act disaster declarations are made by state but designate specific counties that are affected. Our policy addresses contracts with service areas in FEMA-designated Individual Assistance counties. We proposed that for a contract to be considered an affected contract it would need to meet all three criteria in §§ 422.166(i)(1) and 423.186(i)(1). This ensures the extreme and uncontrollable circumstances policy is limited to contracts that may have experienced a real impact from the disaster in terms of operations or ability to serve enrollees. It also ensures that it applies only when the event is extreme, meriting the use of special adjustments to the Star Ratings.

Comment: A commenter was concerned that contracts may deliberately combine contracts with enrollment from a non-disaster area with enrollment in a disaster area in order to meet the 25 percent threshold for Star Ratings adjustments and encouraged CMS to implement safeguards to prevent abuse of the extreme and uncontrollable circumstances policy.

Response: CMS appreciates this comment and notes that the April 2018 final rule addresses contract consolidations. In particular, for consolidations approved on or after January 1, 2019 we assign Star Ratings based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) so that the ratings reflect the performance of all contracts (surviving and consumed) involved in the consolidation. Further, the scenario described by the commenter is unlikely to occur as contract consolidations are generally approved in advance; a sponsoring organization would not be able to take advantage of an extreme and uncontrollable circumstance by subsequently consolidating contracts.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the definition of an affected contract in paragraph (i)(1) of §§ 422.166 and 423.186. We are also finalizing the introductory sentence in paragraph (i) substantially as proposed to establish a rule that in the event of certain extreme and uncontrollable circumstances, CMS calculates Star Ratings for affected contracts using the rules specified in paragraphs (i)(2) through (i)(10). Those specific rules and the text in paragraphs (i)(2) through (i)(10) are addressed in sections II.B.1.e.(2) through (10). In finalizing the first sentence of paragraph (i), we are making a grammatical change to use ''calculates'' in place of ''will calculate.'' We address additional text we are also finalizing as a new last sentence in the introductory text of paragraph (i) in section II.B.1.e.(6).

(2) CAHPS Adjustments

For CAHPS, we proposed two different types of special rules for affected contracts: Exemption from having to administer the CAHPS survey or adjustments to the Star Ratings on the CAHPS measures if the affected contract must administer the CAHPS survey. CAHPS measures are based on a survey conducted early in the year in which the Star Ratings are released, that is, the year before the year to which the Star Ratings are applicable. For example, the CAHPS survey in early 2019 will be used for the 2020 Star Ratings, which are released in late 2019, before the annual coordinated election period for 2020.

We proposed at §§ 422.166(i)(2)(i) and 423.186(i)(2)(i), that an MA and Prescription Drug Plan contract, even if it is an affected contract, must administer the CAHPS survey unless the contract demonstrates to CMS that the required sample for the CAHPS survey cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster in the prior calendar year and requests and receives a CMS approved exemption. We explained in the proposed rule our belief that displacement of a substantial number of the contract's enrollees would make it practically impossible to contact the required sample for the CAHPS survey. For an affected contract that receives the exemption from administering the CAHPS survey, we proposed at §§ 422.166(i)(2)(iii) and 423.186(i)(2)(iii) that the affected contract would receive the prior year's CAHPS measure stars (and corresponding measure scores).

We proposed that affected contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or the current year's Star Rating (and corresponding measure score) for each CAHPS measure (including the annual flu vaccine measure). For example, for the 2022 Star Ratings for affected contracts, we would take the higher of the 2021 Star Ratings or the 2022 Star Ratings for each CAHPS measure. The affected contract would receive the CAHPS measure score for the corresponding Star Rating year chosen. We proposed the 25 percent threshold to avoid including contracts with very few enrollees impacted and explained our belief that the measure-level scores should not be adjusted for contracts with very few enrollees impacted by the extreme and uncontrollable circumstances. We stated that if a small percentage of enrollees were impacted by an extreme and uncontrollable circumstance, there should not be a significant impact on measure scores. Comments received on this specific proposal in §§ 422.166(i)(2) and 423.186(i)(2) are discussed in section II.B.1.e.(6) of this final rule.

(3) HOS Adjustments

For the HOS survey, we proposed to follow similar procedures as CAHPS but due to the follow-up component of HOS, we proposed that the adjustment be to the Star Ratings for the year after the completion of the follow-up HOS survey (that is administered 2 years after the baseline HOS survey). For example, the 2022 Star Ratings are based on data collected from April through June 2020 and reflect experiences over the past 12 months. The data collected in 2021 will be used for the 2023 Star Ratings, so responses may reflect the impact of 2020 extreme and uncontrollable circumstances and thus, those circumstances may have an impact on the 2023 Star Ratings.

We proposed at § 422.166(i)(3)(i) that an MA contract, even if it is an affected contract, must administer the HOS surveys the year after the extreme and

[38] Tables 14 and 15 in the 2020 Call Letter contain a list of the section 1135 waivers that could affect the 2020 Star Ratings and Individual Assistance counties from all of the 2018 FEMA major disaster declarations. *https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/announcements-and-documents.html.*

uncontrollable circumstance unless the contract demonstrates to CMS that the required sample cannot be contacted because a substantial number of the contract's enrollees are displaced due to a FEMA-designated disaster during the measurement period and requests and receives a CMS approved exemption. For an affected contract that receives the exemption from administering the HOS survey, we proposed at paragraph (i)(3)(iii) that the affected contract would receive the prior year's HOS and HEDIS–HOS measure stars (and corresponding measure scores).

We proposed at § 422.166(i)(3)(iv) that affected contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas at the time of the extreme and uncontrollable circumstance would receive the higher of the previous year's Star Rating or current year's Star Rating for each HOS and HEDIS–HOS measure (and corresponding measure score) for the Star Ratings 3 years after the eligible extreme and uncontrollable circumstance. As an example, we explained that for the 2023 Star Ratings for contracts affected by an extreme and uncontrollable circumstance in 2020, we would take the higher of the 2022 or 2023 Star Rating (and corresponding measure score) for each HOS and HEDIS–HOS measure in applying the proposal. Comments received on this specific proposal in § 422.166(i)(3) are discussed in section II.B.1.e.(6).

(4) HEDIS Adjustments

For HEDIS, we proposed that an MA contract, even if an affected contract, would be required to report HEDIS data to CMS unless the contract demonstrates to CMS an inability to obtain both administrative and medical record data required for HEDIS measures due to a FEMA-designated disaster in the prior calendar year and requests and receives a CMS approved exemption. We stated in the preamble of the proposed rule that all contracts in FEMA-designated disaster areas can work with NCQA to request modifications to the samples for measures that require medical record review; however, in our proposed regulation text codifying this ability, we proposed only that ''affected contracts'' without an exemption from reporting HEDIS data would be able to seek that kind of modification from NCQA. For affected contracts that have service areas with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, we proposed to take the higher of the previous year's Star Rating or current year's Star Rating (and corresponding measure score) for each HEDIS measure. For example, for the 2022 Star Ratings for affected contracts we would take the higher of the 2021 or 2022 Star Ratings for each HEDIS measure. Comments received on this specific proposal in § 422.166(i)(4) are discussed in section II.B.1.e.(6). of this final rule.

(5) New Measure Adjustments

At proposed §§ 422.166(i)(5) and 423.186(i)(3), we proposed to implement a hold harmless provision for *new* Star Ratings measures if the inclusion of all applicable new measure(s) brings down the summary and/or overall rating. That is, for affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance, all the new measures would be excluded from the calculation of the summary and/or overall rating if their inclusion brings a contract's summary (or in the case of MA–PD contracts, the overall) rating down. Comments received on this specific proposal in §§ 422.166(i)(5) and 423.186(i)(3) are discussed in section II.B.1.e.(6). of this final rule.

(6) Other Star Ratings Measure Adjustments

For all other measures for affected contracts with at least 25 percent of enrollees in a FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance (that occurs during the measurement or performance period), we proposed to take the higher of the previous or current year's measure Star Rating (and then use the corresponding measure score), as described at proposed §§ 422.166(i)(6)(i) and 423.186(i)(4)(i). For example, for the 2022 Star Ratings for affected contracts, we would take the higher of the 2021 or 2022 Star Ratings. We also proposed to exclude from this adjustment policy the Part C Call Center—Foreign Language Interpreter and TTY Availability and Part D Call Center—Foreign Language Interpreter and TTY Availability measures, except for extreme and uncontrollable circumstances where there are continuing communications issues related to loss of electricity and damage to infrastructure during the call center study. We explained the proposed exclusion by noting that these measures and the underlying performance are completely in the plan's control and we believed therefore that there should generally be no impact from the declaration of an extreme and uncontrollable circumstance on plan performance in these areas.

Below we summarize the comments we received on the proposed rules at §§ 422.166(i)(2) through (6) and 423.186(i)(2) through (4) for adjustments to CAHPS, HOS, HEDIS, new, and other measures and provide our responses and final decisions.

Comment: A few commenters requested that we clarify whether our extreme and uncontrollable circumstances policy is ''best of'' the Star Rating or measure score. A commenter proposed that we take the higher of the previous and current year's measure score if the Star Rating is the same in both years to ensure the higher score is used in the improvement calculation.

Response: We proposed, for affected contracts as described specifically in the applicable regulation text, to select the higher of the current or previous year's measure-level Star Rating and then use the measure score that corresponds with the year selected with the higher rating. We proposed this use of the ''higher Star Rating'' rule for CAHPS, new, and other measures for MA and Part D ratings, and for HOS and HEDIS measures for MA ratings. We use the Star Rating for the measure-level comparison because the measure stars are used to calculate the overall Star Rating and the measure-level cut points can change each year. We use the corresponding measure scores for improvement calculations in order to maintain consistency in the years being compared. Where the higher score does not correspond to the higher rating, we use the score from the year with the higher Star Rating for the measure nonetheless. If the Star Rating for a measure is the same in both years we use the current year's data (that is, Star Rating and score). We only revert to the previous year's measure Star Rating if it is higher. The regulation text reflects this rule by referring to the higher of the previous or current year's Star Rating (and corresponding measure score) in §§ 422.166(i)(2)(iv), 422.166(i)(3)(iv), 422.166(i)(4)(v), 422.166(i)(6)(i), 423.186(i)(2)(iv), and 423.186(i)(4)(i).

Comment: A few commenters were concerned that the 25 percent cutoff for measure-level adjustments may be inadequate, or that the policy is biased against larger contracts serving populations spread across multiple regions.

Response: CMS chose the 25 percent cutoff for measure-level adjustments because this cutoff avoids including contracts with very few enrollees impacted by extreme and uncontrollable circumstances. As explained in the

proposed rule, we do not believe it would be appropriate to provide an adjustment to the ratings when fewer than a quarter of the enrollees covered under the contract are affected by the extreme and uncontrollable circumstance. If only a small percentage of enrollees is impacted by a disaster, there should not be a significant impact on measure scores (and therefore not on Ratings). We disagree that the policy is biased against larger contracts, since it is applied the same to all contracts. Further, for contracts with smaller service areas, the declaration of an emergency and designation of a FEMA-designated Individual Assistance area in one county might be sufficient to result in 25 percent or more of the contract's enrollees being in the FEMA-designated Individual Assistance area whereas a larger contract covering the same county might only have a small portion of its overall enrollment in the FEMA-designated Individual Assistance area.

Comment: A few commenters suggested that we instead remove beneficiaries who live within impacted geographic areas from measurement calculations. Commenters stated this would ensure that all affected contracts receive an adjustment that is proportionate with the level of impact to plan performance, be consistent with other exclusion criteria used in Star Ratings measures, and ensure that Star Ratings performance is representative of performance during the measurement period.

Response: We decline to revise our policy to include this type of adjustment, either instead or in addition to the adjustments we proposed and are finalizing in §§ 422.166(i)(2) through (6) and 423.186(i)(2) through (4). For many measures, this is not operationally feasible. For example, this would require modifications to CAHPS and HOS sampling, as well as to HEDIS reporting requirements. Other measures do not have beneficiary-level data that could be adjusted.

Comment: Several commenters questioned how CMS will apply the policy for contracts impacted by disasters in consecutive years. A few suggested that CMS use the ''higher of'' the current year's Star Rating and prior year's adjusted Star Rating, or link back to the most recent year's data not affected by disasters. Another suggested using best of ratings from periods or sources: Current measurement year performance, prior year performance, parent organization average performance, or industry average performance. Other commenters were concerned about old data being pulled forward each year. A commenter stated a ''higher of'' policy would be inappropriate for consecutive disasters, and that CMS should treat multiple year-disaster contracts as new contracts, rate them on a very small set of measures, or base their rating on a small portion of their service area. A commenter suggested that that CMS drop the threshold for relief below 25 percent and 60 percent for contracts that have had two consecutive years of disaster impact. Several commenters requested that CMS extend the disaster adjustment multiple years for select regions continuing to recover from a disaster (for example, Puerto Rico that is still recovering from 2017 hurricanes).

Response: CMS appreciates these comments and acknowledges that our proposal did not address year-over-year disasters. Given the number of comments on this topic, we believe it is appropriate to address by adopting additional provisions specific to this topic. We agree with commenters that are concerned about looking back too many years for contracts affected by disasters multiple years in a row, as well as about including too many measurement periods in 1 year of Star Ratings. We also must consider operational feasibility, and using different thresholds for contracts affected by disasters in different ways would be very complicated for administration and for providing the necessary transparency to MA organizations, Part D plan sponsors, and beneficiaries who use and rely on the Star Ratings.

We must balance these concerns about using older data with concerns about using data based on performance that has been impacted by consecutive disasters. In striking a balance of these concerns, we are finalizing a policy for setting the Star Ratings for contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas that were affected by disasters that began in one year that were also affected by disasters that began in the previous year. Under the regulations we are adopting in this final rule, such multiple year-affected contracts receive the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure. For example, if a multiple year-affected contract reverted back to the 2021 Star Rating on a given measure in the 2022 Star Ratings, the 2021 Star Rating is *not* used in determining the 2023 Star Rating; rather, the 2023 Star Rating is compared to what the 2022 Star Rating would have been absent any disaster adjustments. The rule for treatment of multiple year-affected contracts then does not carry very old data forward into the Star Ratings for many years. Under this final rule, we will use the measure score associated with the year with the higher measure Star Rating regardless of whether the score is higher or lower that year. We are finalizing this policy to address when contracts are affected by separate extreme and uncontrollable circumstances that occur in successive years for the adjustments to CAHPS, HOS, HEDIS, and other measures. This rule would apply for CAHPS, HOS, HEDIS, new, and other measures. Therefore, we are adopting new provisions at §§ 422.166(i)(2)(v), 422.166(i)(3)(v), 422.166(i)(4)(vi), 422.166(i)(6)(iv), 423.186(i)(2)(v), and 423.186(i)(4)(iv) to include this rule for how ratings for these measures will be adjusted in these circumstances.

The issue about whether and how to take into account extreme and uncontrollable circumstances that occur in successive years also raises the question of how to address a specific extreme and uncontrollable circumstance that spans two years. For example, we note that while Hurricane Maria happened in 2017 and the associated declarations of emergency under section 1135 of the Act initially happened in 2017, those declarations extended for some areas into 2018. We did not propose a specific policy for addressing such situations. We are finalizing new text at the end of the introductory language of paragraph (i) of both §§ 422.166 and 423.186 to clarify that the incident start date will be used to determine which year of Star Ratings could be affected. We believe this clarification is necessary because, in some cases, the incident period end date may change, which would make it difficult operationally to determine which Star Ratings year is impacted. For example, the major disaster declaration (DR–4353) for the California wildfires was declared January 2, 2018. The incident period was originally only in December 2017, but it was subsequently extended by FEMA through January 2018. Limiting adjustments for a single extreme and uncontrollable circumstance to one year is appropriate to avoid adversely impacting operational timelines, to limit impacts on contracts not impacted by disasters, and to preserve transparency of the Star Ratings for consumers by not using data from many different measurement years. Further, as we finalized several years ago, at §§ 422.504(o) and 423.505(p), MA organizations and Part D sponsors must develop, maintain, and implement

TAB 24

84 Fed. Reg. at 15821

TABLE 14—COST PER PDP SPONSOR PER QUARTER FOR TRANSMITTING CLAIMS DATA—Continued

PDP size in enrollees	Number of sponsors	Cost per quarter per sponsor for transmission of claims data
Under 100,000	45	10,500

To complete the annual impact analysis we needed an estimate of proportions for each plan size that would request data. For example, we are certain that the 1 PDP sponsor with over 5 million enrollees will request data. Thus the annual burden for that plan size is 1 * 4 quarters × $26,500 per quarter = $106,000. Similarly, if we assume that all six PDP sponsors with enrollments between 1 and 5 million would request data then the annual burden is 6 sponsors * 4 quarters * $17,500 per quarter per sponsor = $420,000. If we assume that only three-quarters of these six sponsors request data then the annual burden would be 0.75 * $420,000 = $315,000. In the absence of any other basis for the decision, it is reasonable to assume that the proportion goes down as the size goes down. In the absence of data, we could use a descent of simple fractions (1, three-fourths, one-half, one-fourth). Note, that 50 percent of plans with under 100,000 enrollees have under 10,000 enrollees. It is very unlikely that such plans would have the resources to use the data. Thus an assumption that only 50 percent of plans under 100,000 request data is reasonable. However, we considered multiple scenarios. Table 15 presents for a variety of scenarios of proportions and their total impact. The average of the five scenarios is $1.5 million while the median is $1.3 million. The range of impacts is $0.8 million to $2.9 million. For purposes of Executive Order 13771 accounting we listed the impact as $1.5 million annually, with a $0.2 million one-time cost in the first year. We did not trend this estimate by year since the number of PDP sponsors has remained at 63 since 2015.

TABLE 15—ANNUAL BURDEN OF PROVIDING CLAIMS DATA TO PDP SPONSORS

Scenario label	Proportion of sponsors with over 5 million enrollees requesting data (%)	Proportion of sponsors with 1–5 million enrollees requesting data (%)	Proportion of sponsors with 100,000 to 1 million enrollees requesting data (%)	Proportion of sponsors with less than 100,000 enrollees requesting data (%)	Aggregate annual burden based on costs provided in Table 14 ($ in millions)
A	100	75	50	33	1.3
B	100	100	75	50	1.8
C	100	50	33	25	0.9
D	100	100	100	100	2.9
E	100	100	50	0	0.8

We did not anticipate any further burden. It is most likely that the PDP sponsor would exclusively use the data. In the event that downstream entities are shared any data they are already bound in their contracts by all Medicare regulations including the regulations of this provision.

We received no comments on this proposal and therefore are finalizing this provision without modification.

5. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§ 422.162(a) and 423.182(a), §§ 422.166(a) and 423.186(a), §§ 422.164 and 423.184, and §§ 422.166(i)(1) and 423.186(i)(1))

We proposed some measure specification updates. These type of changes are routine and do not have an impact on the highest ratings of contracts (that is, overall rating for MA–PDs, Part C summary rating for MA-only contracts, and Part D summary rating for stand-alone prescription drug plans). Hence, there will be no, or negligible, impact on the Medicare Trust Fund.

We also proposed some adjustments to MA and Part D Star Ratings for extreme and uncontrollable circumstances. The proposed policy will make adjustments to take into account the potential impact on contracts when there are extreme and uncontrollable circumstances affecting them. This policy is in response to the multiple disasters in 2017 and 2018, including several hurricanes and wildfires. We proposed a policy to permit an adjustment to Star Ratings when extreme and uncontrollable circumstances occur during the performance period or measurement period for MA and Part D plans.

We also proposed enhancements to the current methodology to set Star Ratings cut points. The intent of the changes is to increase the stability and predictability of cut points from year to year. This proposal is consistent with the CMS goal to increase transparency. We believe this provision would also have minimal impact on the highest ratings of contracts. Specifically, simulations of the proposed changes to the Star Ratings methodology using the 2018 Star Ratings data show that the impact on the MA Quality Bonus Payment (QBP) ratings is minimal with the QBP ratings overall increasing for less than 1 percent of MA enrollees.

We received no comments on our proposed RIA statement and, therefore, are finalizing this provision without modification.

6. Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§ 423.568, 423.570, and 423.572)

We proposed to limit the amount of time an exceptions request can be held open to 14 calendar days, meaning that there will be an outside limit to how long the request is in a pending status while the Part D plan sponsor attempts to obtain the prescribing physician's or other prescriber's supporting statement. Under current manual guidance, plan sponsors are instructed that an exceptions request should only be held open for a reasonable period of time if a supporting statement is needed. We believe that no more than 14 calendar