BluePeak Advisors' 2019 Call Letter Summary

April, 2018

BluePeak ADVISORS

Table of Contents

Part C and D Updates

VALIDATION AUDITS

Threshold for Requiring an Independent Validation Audit

- Exclude Compliance Program Effectiveness (CPE) conditions from the threshold calculation
- More than 5 non-CPE conditions cited in their final audit report will be required to hire an independent auditor
  - CMS will conduct the validation audits of sponsoring organizations below the proposed threshold
  - CMS estimates that the number of sponsoring organizations that would be required to hire an independent auditing firm would decrease by approximately 11%

Conflict of Interest Limitations on Independent Auditing Firms - *Informational*

- CMS clarifies that sponsoring organizations are not precluded from selecting the same independent auditing firm that is used for their annual external CPE audit, as long as the firm has not provided consulting services or assistance with the correction of audit findings
- CMS clarifies that consultants used by the sponsoring organization to conduct "mock audits", "pre-assessments" or prior independent audits, or those who have never provided consult or assistance with the correction of audit findings for the sponsoring organization are not considered to have a conflict of interest

Required use of CMS Validation Audit Work Plan Template

- CMS intends to create a validation work plan template that sponsoring organizations undergoing independent validation audits in 2019 would be required to submit
- CMS will move forward with including the work plan template in an upcoming proposed information collection via notice in the Federal Register

Timeframe to Complete Validation Audits

- Sponsoring organizations would have 180 days (currently 150) from the date that CMS accepts their program audit CAPs to undergo a validation audit and submit the report to CMS for review
- CMS to make the change effective as of the publication date of the Final 2019 Call Letter so that sponsoring organizations subject to a 2018 program audit will have 180 days for validation audit completion and submission of the independent audit report to CMS

Submitting Independent Audit Report to CMS

- The sponsoring organization would continue to submit its independent auditing firm's validation report to CMS but would also be required to copy the independent auditor on the submission

ADDITIONAL PART C AND D CHANGES

Enforcement Actions for Provider Directories

- All instances of non-compliance, CMPs and other enforcement actions may be imposed against MAOs that have received a compliance notice or notices for violations that have gone uncorrected
- CMS can take enforcement actions when egregious instances of non-compliance are discovered
- If CMPs are imposed for provider directory errors, penalty amounts would initially be calculated on a per determination basis
- CMS to release further guidance and consider CMPs on egregious instances of provider directory non-compliance

Audit of the Sponsoring Organization's CPE

- CMS will allow sponsoring organizations that have undergone a program audit to treat the program audit as meeting the annual compliance program audit for one year from the date of the CMS program audit
- CMS will make updates to Chapter 9 of the PDP Manual and Chapter 21 of the Managed Medicare Care (MMC) Manual

New Medicare Card Project - *Informational*

- Beginning in April 2018, the current Social Security Number based HICN will be replaced with a new Medicare number, the Medicare Beneficiary Identifier (MBI)
- MBIs will be assigned to all Medicare recipients, and new Medicare cards will be mailed to beneficiaries beginning in April 2018
- During the transition period, (April 1, 2018 to December 31, 2019), Medicare plans can use either the HICN or the MBI to exchange data with CMS

PART C UPDATES

SNPs Permanently Reauthorized - *Informational*

- Congress reauthorized SNPs several times and on February 9, 2018, section 50311(a) of the Bipartisan Budget Act of 2018 (Public Law No. 115-123) permanently reauthorized SNPs.
- The legislation also added new requirements for integration of SNPs for dually eligible beneficiaries. We anticipate that additional guidance will be forthcoming as CMS evaluates the changes necessary as result of the statutory changes.

Plans with Low Enrollment

- Plans in existence for three or more years- Non SNP with < 500 and SNP with < 100
- CMS sent letters in March to non-renew these plans unless there are service area needs
- Plans must provide a justification for renewal

Meaningful Difference (Substantially Duplicative Plan Offerings)

- MAOs offering more than one plan in a given service area must ensure the plans are substantially different so that beneficiaries can easily identify the differences between those plans in order to determine which plan provides the highest value at the lowest cost to address their needs
- CMS will provide guidance and instructions in the final rule or a HPMS memorandum regarding the meaningful difference requirement for CY 2019.

Expanding Use of Electronic Health Date for MA Enrollees

- This will enable beneficiaries to connect their data to applications, services, and research programs they trust.

  CMS recommends and encourages plans to adopt data release platforms for their enrollees that meet or exceed the capabilities of CMS's Blue Button 2.0. CMS is contemplating future rulemaking in this area to require the adoption of such platforms by MA plans beginning CY2020.

Part C Cost Sharing Standards

- For CY 2019, CMS will continue the current policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing by adopting a lower, voluntary MOOP limit than is available to plans that adopt the higher, mandatory MOOP limit
- Inpatient and Skilled Nursing Facility (Days 21 through 100) standards have been updated to reflect estimated changes in Original Medicare cost for CY 2019
- The Emergency Care/Post Stabilization Care limit for plans has been increased for CY 2019 to better align cost sharing with actual costs and as an incentive to use primary and specialty care services for routine care and avoid using the emergency room for non-emergent routine services
  - The voluntary MOOP amount increased from $100 to $120, while the mandatory MOOP amount increased from $80 to $90

Tiered Cost Sharing of Medical Benefits - *Informational*

- For CY 2019, instead of submitting a proposal summarizing intent to tier cost sharing of medical benefits prior to bid submissions, MAOs will indicate their intent in the applicable service categories in Section A-6 of the PBP

Coverage of Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) - *Informational*

- For CY 2019, MAOs should include these items and services in their bids as a basic benefit and not as supplemental benefits
- CMS will consider creating a separate PBP data entry field for SET for PAD in CY 2020. For CY 2019, MA plans should include Medicare-covered SET for PAD in the cardiac and pulmonary rehabilitation services section of the PBP.

Health Related Supplemental Benefits - *Informational*

- CMS intends to expand the scope of the primarily health related benefit standard to include a service or item that "must diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization
- CMS will continue to consider the scope of the additional flexibilities authorized by the Bipartisan Budget Act of 2018 and will provide guidance prior to the CY 2020 bid deadline
- Additionally, the forthcoming detailed guidance will further differentiate newly allowable supplemental benefits under our reinterpretation and those new supplemental benefits that will be allowed for the chronically ill beginning CY 2020.

Enhanced Disease Management (EDM) for Dual Eligible Special Needs Plans (D-SNPs) and Institutional Special Needs Plans (I-SNPs) - *Informational*

- Beginning CY 2019, D-SNPs and I-SNPs may offer the EDM supplemental benefit that is currently available to Non-SNP MA plans

Medicare Advantage (MA) Segmented Service Area Options - *Informational*

- CMS is revising plan segments regulations to allow MA plan segments to vary by supplemental benefits, premium and cost sharing

Rewards and Incentives for Completion of a Health Risk Assessment (HRA) - *Informational*

- Beginning CY 2019, MA plans may include the completion of a health risk assessment (HRA) as a permitted health-related activity in a Rewards and Incentives (RI) Program
- CMS clarifies that while an RI Program is not a benefit but it must be included in the bid as a non-benefit expense

Improving Beneficiary Communications and Reducing Burden for Integrated D-SNPs - *Informational*

- CMS has identified the following areas for administrative alignment for integrated D-SNPs:
  - Oversight
  - Integrated model materials
  - D-SNP renewals and Model of Care
- CMS is taking all comments into consideration and noted they also received two additional areas: appeals and grievances and joint CMS-state review of member material

Encounter Data Listening Forums, Monitoring and Compliance Activities - *Informational*

- In order to assist organizations in meeting requirements for submitting complete and accurate data, CMS conducts a range of activities aimed at providing feedback and technical assistance to, and soliciting input from, stakeholders
  - Listening Forums - CMS expects to continue holding listening forums in 2018 and will again be reaching out to plans to participate
- Monitoring and Compliance Activities - CMS continues to take a phased-in approach that targets entities experiencing the most difficulty in submitting encounter data

STAR RATINGS

New Measures

- Statin Use in Persons with Diabetes (SUPD) (Part D)
  - Added to the 2019 Star Ratings (based on 2017 data) with a weight of 1 for the first year
  - The measure will have a weight of 3 starting with the 2020 Ratings
- Statin Therapy for Patients with Cardiovascular Disease (Part D)
  - Added to the 2019 Star Ratings as a process measure with a weight of 1, since it is based on one fill

Improvement Measures

- One change: The measure Reducing the Risk of Falling will be included in the improvement measure calculations for the 2019 Star Ratings
- Medication Adherence (ADH) for Hypertension (RAS Antagonists Medication Adherence for Diabetes) (Part D) will expand exclusion sources for ESRD to be broader
- Medication Adherence (ADH) for Hypertension (RAS Antagonists) Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D) days covered is adjusted for IP and SNF stays and hospice enrollment
- MPF Price Accuracy (Part D) moved to 2020
- Members Choosing to Leave the Plan (Part C & D) expanding exclusions to include PBP SAR

Removal of Measures from Star Ratings

- Beneficiary Access and Performance Problems (BAPP) retiring and moving to display as a modified metric including only CAM data

Data Integrity - *Informational*

- CMS proposes to define a contract as being non-compliant if it either receives a "No" or a 1, 2, or 3 on the 5-point Likert scale in the specific data element's data validation
- CMS is proposing statistical criteria to reduce a contract's Star Rating for data that are not complete or lack integrity using TMP data or audit

Additional Adjustment to Address Lack of an LIS Indicator for Enrollees in Puerto Rico

- CMS proposes to continue to reduce the weights for the adherence measures to zero (0) for the summary and overall rating calculations and maintain the weight of three (3) for the adherence measures for the improvement measure calculations for contracts that solely serve the population of beneficiaries in Puerto Rico

Disaster Implications

- Due to the effects of extreme and uncontrollable circumstances that occurred during the performance period, CMS proposes a policy to identify which contracts were impacted as well as rules to adjust the following 2019 and 2020 Star Ratings measures:
  - Identification of Affected Contracts
  - CAHPS/HOS/HEDIS Adjustments
  - Other Star Ratings Measure Adjustments
  - Cut Points for Non-CAHPS Measures
- With slight additions to the proposed policy, CMS will adjust the 2019 and 2020 Star Ratings to take into account the effects of extreme and uncontrollable circumstances that occurred during the performance period, such as the disasters that occurred during the 2017 performance period

STAR RATINGS CATEGORICAL ADJUSTMENT INDEX

CMS will consider how to implement Pharmacy Quality Alliance (PQA) recommendations on the Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, and Medication Adherence for Cholesterol

The measures selected for adjustment for the 2019 Star Ratings include six Part C measures and two Part D measures

Part C Measures

- Annual Flu Vaccine
- Breast Cancer Screening
- Diabetes Care – Blood Sugar Controlled
- Medication Reconciliation Post-Discharge
- Osteoporosis Mgmt. in Women who had a Fracture
- Plan All-Cause Readmissions

Part D Measures

- Part D Medication Adherence for Hypertension
- MTM Program Completion Rate for CMR

DISPLAY MEASURE UPDATES

New 2019 Display Measure

- Plan Makes Timely Decisions about Appeals (Part C)

Changes to Existing Display Measures

- Hospitalizations for Potentially Preventable Complications (Part C)
- High Risk Medication (Part D)
- Drug-Drug Interactions (DDI) (Part D)
- Antipsychotic Use in Persons with Dementia (APD) (Part D)
- Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D)
- Transition Monitoring (Part D)
- Formulary Administration Analysis measure (Part D)
- Timely Effectuation of Appeals (Part D)

Display measures on CMS.gov are not part of the Star Ratings' calculation

Display Measures Being Retired - *Informational*

- Enrollment Timeliness (Part C and D)
- Appropriate Monitoring of Patients Taking Long-term Medications and Asthma Medication Ratio (Part C)

Potential Changes to Existing Measures - *Informational*

- Controlling High Blood Pressure (Part C)
- Plan All-Cause Readmissions (Part C)
- Initiation and Engagement in Alcohol or Drug Dependence (AOD) Treatment (Part C)
- Telehealth and Remote Access Technologies (Part C)
- Cross-Cutting Exclusions for Advanced Illness (Part C)
- Medication Adherence (ADH) for Cholesterol (Statins) (Part D)
- Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D)

NEW 2020 STAR RATINGS MEASURES

Potential New Measures - *Informational*

- Transitions of Care (Part C)
- Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions (Part C)
- Care Coordination Measures (Part C)
- Opioid Overuse (Part C)
- Assessment of Care for People with Multiple High-Risk Chronic Conditions (Part C)
- Depression Screening and Follow-Up for Adolescents and Adults (Part C)
- Unhealthy Alcohol Use Screening and Follow-Up (Part C)
- Readmissions from Post-Acute Care (Part C)
- Adult Immunization Measure (Part C)
- Anxiety (Part C)
- Polypharmacy Measures (Part D)
- Additional PQA Medication Adherence Measures (Part D)

Part D Updates

2019 FORMULARY UPDATES

CY 2019 Formulary Submission Window - *Informational*

- The CY 2019 HPMS formulary submission window will open this year on May 14, 2018 and close at 11:59 PM PDT on June 4, 2018

CY 2019 Formulary Reference File (FRF)

- CMS is analyzing the Part D utilization of current FRF drugs and will be removing drugs from the FRF based on low utilization
- CMS released a draft CY 2019 FRF reflecting these changes on February 28, 2018 and a subsequent CY 2019 FRF on March 27, 2018.
- CMS will maintain a late-July or early-August window in order to provide Part D sponsors with enough time to finalize formulary documents for printing.
- CMS will add two (2) optional formulary submission windows: Late Fall and January

Changes for CY 2019 Formulary Submissions

- For MMP Plans, CMS will make an Additional Demonstration Drug (ADD) Validation File available via HPMS in advance of the File submission deadline
- The Non-Extended Day Supply (NDS) supplemental file will be eliminated for 2019
- CMS will provide plans with an OTC reference file for CY 2019 that uses a proxy code (e.g., RXCUI) to represent each unique drug ingredient, strength, route, and dosage form

IMPROVING DRUG UTILIZATION REVIEW CONTROLS IN MEDICARE PART D

High Risk Opioid Use and the Overutilization Monitoring System (OMS)

- Beginning with the 2018 Overutilization Monitoring System (OMS) reports, CMS has changed the Opioid Daily Dose measurement period from 12 months to 6 months
- Beginning in April 2018, Plans will report:
  - 90 Morphine Milligram Equivalent (MME) Opioid Daily Dose rate
  - 120 MME Opioid Daily Dose rate with the latter being discontinued in 2019
- CMS is adding the following to the criteria for other non-opioid potentiator drugs that may pose safety risks when misused with opioids
  - Beneficiaries with a high dose of gabapentin (> 2400mg) will be added

Part D Opioid Overutilization Policy

- All Part D sponsors are expected to have a documented, written strategy for addressing overutilization of prescription opioids given the public health crisis
- CMS is suggesting the maintenance of a soft reject for a morphine milligram equivalent (or MME) dose of 90 per day and a hard reject when a daily dose exceeds 200 MME dose. CMS is requiring that an opioid care coordination safety edit should be implemented whereby the Plan Sponsor should instruct the pharmacist through messaging to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that indicates the prescriber has been consulted.

Days Supply Limits for Opioid Naïve Patients

- CMS expects all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7-days supply
- Opioid naïve patient be defined as a patient with an opioid prescription who has not received an opioid fill over the past 60 days or longer
- Include both short-acting and long-acting opioids, except buprenorphine for MAT
- Sponsors must allow pharmacists to communicate this information through the plan's help desk or through override codes for plan authorization

New Opioid Care Coordination Safety Edit for 2019

- CMS aims to implement a policy that will strike a better balance between addressing opioid overuse without a negative impact on the patient-doctor relationship
- Sponsors are required to implement a real-time opioid care coordination safety edit at the time of dispensing which is triggered when a beneficiary's cumulative MME per day reaches or exceeds 90 MME
    - Sponsors should instruct the pharmacist (e.g., through messaging) to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that indicates the prescriber has been consulted
    - CMS recommends excluding beneficiaries who are residents of a long-term care facility, in hospice care or receiving palliative or end-of-life care, or being treated for active cancer-related pain from the opioid care coordination edit or other hard edits
    - CMS expects coverage determination requests seeking exceptions to the MME edit to meet the criteria for expedited review

Concurrent Use of Opioids and Benzodiazepines

- Sponsors are required to implement a concurrent opioid and benzodiazepine soft POS safety edit (which can be overridden by the pharmacist) to prompt additional safety review at the time of dispensing beginning in 2019
    - Sponsors have the flexibility to factor different prescribers, dose or days supply in the edit specifications.

Opioid Duplicative Therapy Safety Edits

- CMS expects all Part D plan sponsors to implement a soft POS edit (can be overwritten by pharmacy) for duplicative Long Acting (LA) opioid therapy beginning in 2019, with or without a multiple prescriber criterion

Access to Medication-Assisted Treatment

- CMS expects Part D sponsors to include products in preferred formulary tiers, and to avoid placing generic drugs indicated for Medication-Assisted Treatment (MAT)
- When a sponsor has authorized MAT for a beneficiary in the prior plan year, CMS expects that the sponsor would carry that authorization through to the next plan year

USING THE BEST AVAILABLE INFORMATION WHEN MAKING B VS D COVERAGE DETERMINATIONS FOR IMMUNOSUPPRESSANTS AND INHALATION DURABLE MEDICAL EQUIPMENT (DME) SUPPLY DRUGS

Immunosuppressants Used to Prevent Transplant Rejection

- Based on audits, CMS has learned that information obtained directly from prescribers often times is not reliable or conflicts with CMS information that is provided
- CMS will launch a new web portal that will provide additional enrollee information to plans.
  - Additional Beneficiary Information Initiatives (ABII), will be part of the group of Acumen web portals to which all Part D contracts already have access.
- The following guidance establishes CMS' expectations for how Part D plans should perform due diligence to ensure that Part D does not pay for drugs that should be paid under Part B:

1. No Prior Part D Claims History for Immunosuppressants
   - Plan has received information from CMS (MARx or ABII) indicating that Medicare covered the enrollee's transplant regardless of previously received information from a prescriber
     - Plans are expected to rely on this information and cannot cover immunosuppressants under Part D
   - Plan has NOT received information from CMS (MARx or ABII) indicating that Medicare covered the transplant
     - CMS expects plans to default to covering the immunosuppressants under Part D
     - CMS no longer expects plans to reach out to prescribers to inquire about Medicare coverage of the transplant
2. Prior Part D Claims History AND the MARx nor ABII indicates Medicare covered the transplant
   - Sponsors must now rely on the MARx or ABII information going forward and notify the enrollee that the plan can no longer cover the immunosuppressant(s) because it is covered under Medicare Part B
     - No changes need to be made to prior Part D claims
3. Prior Part D Claims History, no MARx indicator or MA plan medical claims history of a covered transplant BUT CMS indicates the transplant was covered by Medicare (e.g. Part D sponsor receives the information from CMS as part of a CMS Program Integrity audit or through ABII)
   - Sponsor must now rely on the CMS information going forward and provide notice to the enrollee that the plan will no longer cover the immunosuppressant(s) under Part D because it is covered under Medicare Part B
   - No changes need to be made to prior Part D claims

Inhalation Durable Medical Equipment (DME) Supply Drugs Informational

- Previous guidance documents indicate that inhalation drugs administered in a long-term care setting where the stay is not covered under Medicare Part A can be covered under Part D
- CMS has clarified how Part D plans can determine that a beneficiary is residing in a long-term care facility
  - CMS permits Part D sponsors to rely on a patient residence code of "3" or "9" on a pharmacy claim for determining when such inhalation drugs may be covered under Part D