Medicare Part D Proposed Rule AMCP Comment Areas

Centers for Medicare and Medicaid Services (CMS) Released on January 6, 2014

CMS Proposed Changes to Protected Classes

Establishes objective criteria for whether a medication should be included in a protected class

- Initial administration required in less than 7 days of prescription and the coverage determination and appeals process would not properly provide for independent review and determination within that timeframe, and failure to provide would likely lead to hospitalization, incapacity, disability or death ***and***
- CMS cannot ensure that a formulary containing anything less than all medications would be sufficient to treat diseases or conditions in that class

CMS Proposed Changes to Protected Classes

Pharmacists within CMS reviewed 6 protected classes

- Anticonvulsants, antineoplastics, and antiretrovirals met proposed criteria to remain protected
- Antidepressants, antipsychotics, and immunosuppressants do not meet definition and could be subject to formulary management
  - CMS considering whether antipsychotics require additional review and scrutiny and would not change until 2016
  - Antidepressants and immunosuppressants would change in 2015

CMS Proposed Changes to Protected Classes

- CMS' review finds that pharmacy and therapeutics process combined with CMS discrimination review ensures robust medication selection for formularies
- CMS' review finds that Medicare eligible individuals, particularly dual eligible individuals now have more experience with plan management of medications
- Plans' inability to negotiate for rebates in protected classes potentially increases costs in the Medicare program
  - Cites AMCP's 2008 Milliman study *Potential Cost Impacts Resulting from CMS Guidance on "Special Protections for Six Protected Drug Classifications" and Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275)*

    http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=11197
- CMS estimates savings of $720 million between 2015-2019

AMCP Perspective: Changes to Protected Classes

- AMCP supports the changes that allow plans flexibility to use formulary tools to ensure appropriate coverage of medications in 3 of the six protected classes
  - AMCP supports CMS' analysis that the Medicare Part D program is now well established and that plans have robust processes in place to ensure sufficient access to appropriate medications
  - AMCP supports plan flexibility in making formulary determinations
- AMCP supports changes to allow the competitive formulary process to be implemented for all classes of medications
  - AMCP has consistently opposed requirements in MIPPA and ACA to expand protected classes

AMCP Perspective: Changes to Protected Classes

- Protected class requirement is inconsistent with the competitive structure of Part D
  - Undermines the long-term financial sustainability of the program by impeding the P&T process of formulary development
  - Undermines the ability of plans to negotiate favorable pricing for medications considered to be safe and effective for coverage using an evidence-based process
  - Introduces politics into the competitive market process by cherry-picking certain classes of medications for coverage

AMCP Perspective: Changes to Protected Classes

Opportunity for AMCP comment

- AMCP supports changes in the clinically protected class policy and would like feedback on the proposed requirements
- Should CMS consider other criteria when establishing whether a medication should be included in protected classes?
- Does the new criteria proposed set an unreasonable standard for determining whether a class receives protection? What else should CMS consider?

CMS Proposed Changes for Medication Therapy Management

- Expands number of individuals potentially eligible for medication therapy management (MTM) to approximately 55% of Medicare population
- Reduces number of multiple chronic diseases eligible for coverage from 4 to 2
  - Consolidates core chronic conditions of congestive heart failure and hypertension under a single term "cardiovascular disease"
  - Other core chronic conditions as defined in 2010 and updated in 2013
    - Diabetes
    - Dyslipidemia
    - Respiratory disease
    - Bone disease/arthritis
    - Mental health
    - Alzheimer's disease
    - End stage renal disease
- Reduces number of medications required to meet definition of multiple Part D medications to 2 or more
  - Would apply to any Part D covered drug and may include OTC use
- Reduces targeted spending from $3,144 to $620 per year
- Estimated cost based on comprehensive medication review completion cost is $111 million

AMCP Perspective: MTM

AMCP supports pharmacist provided MTM services for Medicare Part D but opposes imposition of a rigid and specific set of statutory or regulatory requirements that undermine the program, costs more, and does not improve outcomes

- AMCP finds that the existing MTM program does not establish a solid practice model to allow for robust pharmacists' interventions but rather represents a statutory and regulatory mandate that results in additional administrative costs to plans and to the government

AMCP Perspective: MTM

AMCP recommendations

- Link Star Ratings program more closely with MTM to provide more definitive measures and encourage participation by community pharmacies
- Allow for service-based performance-based contracts with pharmacies
- Allocate funding to AHRQ to implement the MTM grant program enacted under Sec. 3503 of ACA

MTM Supporting Information

- AMCP members find an inconsistent community pharmacy response to provision of services
- Agency for Health Research and Quality (AHRQ) MTM literature review in 2013 found insufficient evidence to address the effectiveness on most outcomes
  - Review excluded research submitted by AMCP that related to transitions of care and other MTM services outside of the scope of the Part D benefit but acknowledged these programs can improve outcomes

MTM Supporting Information

- CMS' MTM report conducted by Acumen found varying results in MTM intervention
  - Generally Part D MTM improved outcomes and lowered hospitalization rates for some, but not all chronic diseases and used a small sample size
  - Concluded that more research is necessary for a longer period of time to really consider impact on quality

AMCP Perspective: MTM

Opportunity for Comment

- What examples and data can AMCP members provide on the current MTM program and the need for improvements?
- Many Star Ratings measures are directly lined to or impact pharmacists' medication management. Should AMCP consider suggesting to CMS a more direct link between MTM and Stars Ratings? What should AMCP consider in this approach?
- How do AMCP members provide outreach to CMS targeted populations, including minority and other special populations, to improve medication management?

CMS Interpretation of the Non-Interference Clause

- CMS will not interfere with negotiations related to medication contracting or medication pricing or formulary selection or management
- CMS finds the following consistent with Congressional intent for CMS involvement for general oversight of the Medicare Part D program
  - Interpretation of the definition of access to negotiated prices
  - Any willing pharmacy standard terms and conditions
  - Prohibition on any requirement to accept insurance risk
  - Prompt payment
  - Payment standard update requirements
  - Disclosure of drug costs in the marketplace
  - Projected Part D bid amounts that are publicly available
- CMS will not be a direct party to contracts or arbiter of contract meaning

AMCP: Interpretation of the Non-Interference Clause

- AMCP recommends that CMS rescind its interpretation of the non-interference clause
- CMS' interpretation is inconsistent with the plain meaning of the MMA that prohibits interference of negotiations between drug manufacturers **and** pharmacies **and** PDP sponsors
  - CMS has made statements in regulations since the beginning of the program that contradicts its current interpretation
  - CMS' rationale that only negotiations between plans or pharmacies and drug manufacturers is inconsistent with the plain meaning of the statute
  - Statements in the *Congressional Record* involving the MMA legislative history and floor discussions contradict CMS' interpretation
  - CMS' analysis inappropriately interprets Congress' original intent in an impermissible retrospective manner

CMS Proposal: Preferred Networks

- Proposed replacement preferred networks with preferred cost sharing
  - Would apply to any willing pharmacy that accepts terms
  - May apply to all or some medications
- CMS' goal is to lower costs for the government and beneficiaries
  - Negotiated prices must be substantially lower than others in the market
  - CMS might seek a minimum level of savings, such as 10-15% on preferred cost sharing compared to others in the network
  - Contract terms must set a ceiling price and preferred networks must be below that level
  - Preferred rates may not result in increase in overall costs to the government or beneficiaries
- Proposal prohibits performance based preferred networks for medications or services

AMCP Perspective: Preferred Networks

- AMCP supports the use of preferred pharmacy networks as a tool that prescription drug plans (PDPs) and MA-PDs utilize in Medicare Part D plan offerings
- In 2013, nearly 75% of Medicare beneficiaries enrolled in cost-saving preferred network plans
  - *Consumer Reports Magazine* recommends enrollment in preferred pharmacy networks as a way to reduce costs on prescription drug spending

AMCP Perspective: Preferred Networks

AMCP does not agree with findings reported by CMS that preferred networks increase overall program costs

- In 2013, 7 of the top 10 plans with the lowest monthly premiums include pharmacy preferred networks
- 2013 research from Avalere Health suggests that preferred pharmacy networks have contributed to year-to-year premium reductions since first introduced in 2011
  - Study also suggests that preferred networks may lower premiums to beneficiaries and for the government, particularly in payments for low-income subsidies

AMCP Perspective: Preferred Networks

AMCP supports the use of performance-based preferred networks to help improve outcomes and quality measures

- CMS' proposed prohibition on any performance-based contracting for Part D pharmacy networks undermines the goals of the Medicare program to promote value-based purchasing as a means to reduce costs and used performance metrics to improve outcomes
- Risk-sharing arrangements with pharmacy networks may use incentives to improve generic utilization rates and medication adherence
- Performance-based preferred pharmacy networks may incorporate pharmacists' patient care services into accountable care arrangements and other integrated care delivery models to achieve better health outcomes at lower costs

AMCP Perspective: Any Willing Provider

AMCP opposes any willing provider/pharmacy (AWP) provisions

- Managed care health systems build networks of health care providers who demonstrate the ability to deliver high-quality, affordable health services to patients enrolled in plans
  - Any willing provider provisions lower overall plan and health care costs by engaging providers in a competitive manner to achieve the best pricing for consumers
    - Recent studies suggest that states with any willing provider requirements often result in an increase in per-patient health expenditures and per-patient price increases

AMCP Perspective: Any Willing Provider

- Preferred pharmacy networks also positively influence patient care by ensuring that pharmacies that participate can meet the requirements for utilization management and other quality interventions to ensure positive outcomes
- Any willing provider terms and conditions may increase the likelihood of prescription drug fraud and abuse because plans would not have the ability to exclude pharmacies

AMCP Perspective: Preferred Networks & AWP

Opportunity for Comment

- Define the "pros" and "cons" of preferred cost sharing versus preferred networks. How would the proposed changes impact the ability to offer competitive and reduced costs for medications in the market place?
- How could the use of preferred cost sharing rather than preferred networks impact future networks that could be based on performance metrics rather than solely on dispensing services?

CMS Proposal: MAC Pricing

- Proposed updated definition of prescription drug pricing standard for purposes of Medicare Part D reporting
  - Includes maximum allowable price (MAC) reporting and other formulary that rely on varying prices, not a fixed, published price
  - CMS has received complaints about MAC pricing inconsistency and uncertainty
- CMS supports plan reporting to allow pharmacies to have current data on reimbursement expected based and lack of reporting presents a number of risks including
  - Inaccuracies in submitting claims to CMS on prescription drug event files (PDE) without having to make later adjustments disruptive to Medicare Part D operations
  - Information in the Medicare Plan Finder tool is questionable and does not allow beneficiaries to make good drug purchasing choices
- Plans contracts with CMS would be required to disclose all individual drug prices and provide updates to applicable pharmacies in advance of reimbursement of claims

AMCP Perspective: MAC Pricing

AMCP opposes the stringent reporting requirements in the proposed rule for MAC pricing because

- MAC prices are driven by existing market factors and the availability of generics in the marketplace which may change on a regular basis
- Public disclosure of MAC prices would have anticompetitive effects on health plans, Medicare Part D, and beneficiaries by driving up prices
- No other laws exist where a private company must disclose proprietary pricing methodologies to a purchaser and in fact this process would result in inappropriate government intervention in price negotiations between pharmacies and plans
- MAC pricing methodologies serve to encourage reasoned purchasing decisions to reduce overall costs

AMCP Perspective: MAC Pricing

AMCP supports best practices that payers provide a fair and timely MAC appeals process related to a contracted pharmacy's MAC pricing inquiries or disputes

- This provision would be a better alternative than required upfront contract reporting pursuant to the provisions in the proposed rule that could result in interruption of contracts and delayed access to beneficiaries
- Rather than CMS dictating a 7-day reporting period for updates in contracts, network specific contracts should include this information

Mail Order

CMS' proposed rule includes changes to mail order operations including requirements for shipping in 3-days for orders without issues and 5 days for prescriptions with issues

- CMS also seeks input on whether it should create additional beneficiary materials for mail order including process and delivery, customer support, complaints, options for accessing medications when a delivery is lost or delayed; and resolving inappropriate or inapplicable edits, such as refill too soon

Mail Order

CMS would allow differential cost sharing for extended days supply at mail order

- Plans should use a maximum of two cost sharing distinctions based on days' supply
  - One month supply not to exceed 34 days or an extended days' supply of more than 34 days
- Plans may offer retail pharmacies an extended days' supply terms addendum
  - May be at same cost sharing if the terms and conditions are met or
  - May be offered at a higher cost sharing but not higher than 3 times the amount the enrollee would pay at the same retail pharmacy for a 1-month supply

CMS does not support mail order fulfillment for initial fills or routine 30-day supplies

Mail Order

AMCP's mail order position

- Managed care must have flexibility to use mail order delivery of prescription drugs
- Mail order is a valuable tool to increase patient safety and offer patient convenience and maintain affordability
- Mail order can improve patient safety by reducing dispensing errors
- Patients using mail order generally have higher adherence rates than patients using retail
- High-volume purchasing allows mail order pharmacies to secure lower prices for prescriptions that are passed onto beneficiaries and payers
  - CMS' research that suggests that prescription prices in mail order pharmacies are higher than at retail is the result of plans using mail order for higher cost brand name prescriptions