Where Might CMS Drive the Industry in the Next Few Years?

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How far into the future does your strategic plan need to go? Most organizations have a long-term plan that looks less than 2 years down the road. Having worked in the public sector, my goal was to always look 5 years into the future. The annual CMS Call Letter only addresses next year's Medicare Part D program; however, there other notices that provide a clue as to the direction that CMS is heading and how it could shape the future.

In looking forward to 2018 and the potential impact of governmental regulations and changes to the Affordable Care Act, we should remain cognizant of how governmental actions may affect the healthcare industry. Among the routine events is the annual proposed rules changes to Medicare Part D. This year will also see the release of a request for information by the CMS Innovation Center seeking feedback on a new direction to promote patient-centered care and test market-driven reform. You can read the proposed rules yourself at innovation.cms.gov/initatives/epm or in any of the numerous reviews done by various organizations, such as the Pharmaceutical Care Management Association. All of the reviews will provide a perspective of the proposed rules and what is important based on the individual interest of the authors.

CMS released the proposed rules for the Medicare Part D drug program on November 16, 2017. In the bigger picture, it is important to review the proposal for the concepts that could affect the manner in which pharmacy benefit managers (PBMs) administer the program and could impact the profitability of Part D. One of the more important concepts from the proposed rules appears to be a belief that beneficiaries are not receiving the benefits from contracted rebates to lower drug costs, as direct and indirect remuneration fees go toward plan profits without lowering premium costs. Therefore, the first question to arise is, why is this concept important to the clinical reviewers who perform product evaluations for formulary inclusions?

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Although PBMs have relied on clinical reviews to support their formulary decisions, there appears to be a consensus that cost considerations outweigh clinical efficacy decisions and plan profit has become the ultimate driver of plan design. CMS has stated the opinion that sponsors prefer higher-cost drugs that shift expenses to beneficiaries and the Part D program. It appears that CMS thinks profit is the overriding factor in program design, as it fails to mention clinical efficacy in any of the discussions regarding the proposed rules.

CMS has also proposed changes to an existing policy regarding permissible limitations by proposing to eliminate this provision. Doing so would allow plans to exclude a dedicated generic tier from the exceptions process and establish a framework based on the type of drug (ie, brand name, generic product, biological product) requested and the cost sharing of applicable alternative drugs.

The key here is to consider a larger perspective, instead of just the proposed rules; what is behind the rule proposal; and why does CMS have that opinion. CMS staff have a responsibility to protect both patient and government interests, not the payers or program sponsors.

A second notice from the CMS Innovation Center, "Innovation Center New Direction" was essentially a request for information. This was an interesting document, and I think it helps provide a window into what CMS is thinking moving forward. The guiding principles speak to existing partnerships with healthcare providers, clinicians, states, payers, and stakeholders, which CMS has stated provides important values and lessons. It is the end of the sentence that is insightful as to what CMS is envisioning as the new direction for the Innovation Center. This is illustrated in the following guiding principles the center will use to approach new model designs:

1. **Choice and competition in the market:** Promote competition based on quality, outcomes and cost.
2. **Provider choice and incentives:** Focus on voluntary models, with defined and reasonable control groups or comparison populations, to the extent possible and reduce burdensome requirements and unnecessary regulations to allow physicians and other providers to focus on providing high-quality healthcare to their patients. Give beneficiaries and healthcare providers the tools and information they need to make decisions that work best for them.
3. **Patient-centered care:** Empower beneficiaries, their families, and caregivers to take ownership of their health and ensure they have the flexibility and information to make choices as they seek care across the care continuum.
4. **Benefit design and price transparency:** Use data-driven insights to ensure cost-effective care that also leads to improvement in beneficiary outcomes.
5. **Transparent model design and evaluation:** Draw on partnerships and collaborations with public stakeholders and harness ideas from a broad range of organizations and individuals across the country.
6. **Small-scale testing:** Test smaller models that may be scaled if they meet the requirements for expansion under 115A(a) of the Affordable Care Act.

CMS also lists several potential models that they are interested in exploring at innovation.cms.gov/initiatives/index.html#views=models, all of which it believes will provide additional value and provide better cost controls. The question is, how does the current pharmacy model fit and what, if any, changes will be needed in the future if CMS is successful in its endeavors?

Do you have a plan or is your organization looking at what it could change? For many of you in the formulary and clinical areas, you must consider how you will demonstrate that the functions you perform meet the intended goals of CMS. ajpb

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