

Implementing Drug Price Negotiation

Lessons Learned from Past Large-Scale Provision Implementations

The Centers for Medicare & Medicaid Services (CMS) is facing the implementation of drug price negotiation through the Inflation Reduction Act (IRA) and must implement the provision across CMS. Guidehouse has a history of helping agencies with large-scale provision implementation, including:

- U.S. Treasury Troubled Asset Relief Program (TARP)
- U.S. Treasury Small Business Lending Fund (SBLF)
- U.S. Treasury Community Development Financial Institutions (CDFI) Fund Bond Guarantee (BG) Program
- Coronavirus Aid, Relief, and Economic Security (CARES) Act
- Medicare Access and CHIP Reauthorization Act (MACRA)
- Affordable Care Act (ACA)
- Medicare Prescription Drug, Improvement, and Modernization Act (MMA)

With our extensive experience has also come numerous lessons learned, which we believe could add value as CMS develops strategies for implementing the drug price negotiation provision of the Inflation Reduction Act (IRA).

Use an Enterprise Risk Management Approach and Embed Risk Management throughout the Business Lifecycle

One of the top lessons learned is to ensure risk is managed using an enterprise risk management approach and embedding risk discipline throughout the business lifecycle, which will ensure risks to achieving strategic objectives (Strategic Pillars for CMS) are identified and that a broad, portfolio view of risk is maintained throughout implementation. Some of the specific areas of risk to consider include:

- **Impact to Current Enterprise Risks.** It is important to understand impacts of the new legislation provision on current enterprise risks. The new provision may increase the potential impact and likelihood of an enterprise risk materializing into an issue, or perhaps there is an opportunity to address an enterprise risk using the new provision as a catalyst for change.
- **Resource Optimization.** An enterprise risk management approach will help inform risks an organization is willing to accept in pursuit of its strategic objectives, which will then inform optimal resource allocation. When organizations attempt to over-control risks, resources are often sub-optimized, and risk is increased through the sub-optimal use.

Our Experience with 340B Program

For over 20 years, Guidehouse has partnered and advised a broad spectrum of covered entity types, which include federal grantees and some of the nation's largest health systems.

Guidehouse has provided support around the 340B Program, which enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Manufacturers participating in Medicaid agree to provide outpatient drugs to covered entities at significantly reduced prices.

Guidehouse's approach to 340B advisement is rooted in being patient-centric, delivering high-quality service, and ensuring affordable local drug access to patients.

The Guidehouse 340B team is built of subject matter experts with a broad range of specialized skill sets. The Guidehouse 340B team leverages standardized tool sets, advanced analytics, and methodologies that help assess and implement comprehensive, compliant, and innovative 340B optimization strategies.

Recent Client Examples:

In 2021, Guidehouse partnered with a rural sole community hospital in Montana. Guidehouse developed and implemented thoughtful and compliant 340B program enhancement strategies that resulted in ~\$16M in annual program value, increasing benefit to the local community and improving the financial viability of the safety-net hospital.

In 2022, Guidehouse advised a regional South Carolina health system on acquiring and integrating two local community oncology practices. Through this process, the health system developed an integrated oncology service line and strategically leveraged the 340B program to decrease the cost of care to patients, resulting in ~\$45M annual program value.

- **Risks Associated with Different Implementation Strategies.** There are often multiple strategies that can be selected to implement new provisions, however, the risks associated with each strategy should be identified and assessed to inform the chosen strategy. Once a strategy is chosen, organizations should continue to review and revise the strategy, based on ongoing risk identification and assessment.
- **Looking Around Corners.** When risk management is embedded across the business lifecycle, business leaders can “look around corners” and anticipate impact to their operations and objectives at all levels of the organization.

Strategic Approach: Establish Programs or Modify Existing Programs

A final lesson learned is it is important to consider not only new programs that may need to be established but also modifications to existing programs, which may decrease duplication of work, reduce implementation costs, and optimize use of existing resources (i.e., people, process, technology). There are early steps that are critical to ensuring the near- and long-term success of new legislation provisions, which should be documented in a Concept of Operations:

- **Set and Unite Around a Vision.** Develop and communicate a vision that aligns to legislation and is grounded in the strengths of the organization, while remaining flexible to changing internal and external factors.
- **Set Clear Objectives and Key Milestones.** Define objectives and associated milestones that are SMART (specific, measurable, actionable, relevant, and timely) and define the “what” and “why,” including what is wanted (or needed) in the end state.
- **Set the Tone and Importance.** Set the tone and importance across the programs for the need to move quickly, share openly, work collaboratively, communicate that failure is not an option, and seek out full commitment from involved parties.
- **Clarify Key Roles, Responsibilities, and Authority.** Define a governance model that enables swift and informed decision making. Define an operating model that accounts for the roles of all key stakeholders, including external stakeholders, such as other agencies, private sector stakeholders, and legal counsel.
- **Enable Transparency and Reporting.** The public will demand transparency and oversight for an initiative this important. Additionally, transparency and reporting will be necessary to bolster trust in the efforts. This will require establishing or leveraging existing processes and mechanisms for proactive communication across a range of media including agency website(s) and overall government websites and other channels, as well as responding to Freedom of Information Act, Inspector General (IG), Government Accountability Office (GAO), Congress, and media requests. This will also require strong records management policies and practices.
- **Design Operations.** Design programs and processes in a collaborative manner that enables proactive communication, clear understanding of roles, responsibilities, and hand-offs, and effective management of risk.

MACRA

CMS contracted Guidehouse to provide the QPP and New Medicare Card Project programs with support in the following areas: agile and waterfall project management, risk management, schedule management, stakeholder engagement, communications management, performance management, requirements management, change management, knowledge management, and testing support. These initiatives were critical to move the provider community from a quantity-based payment model to a quality care-based model and removing SSN on Medicare cards to protect beneficiaries against identity theft and provide a randomly generated Medicare Beneficiary Identifier (MBI).





MMA

Guidehouse has supported CMS with performing actuarial bid desk reviews on Medicare Advantage and Prescription Drug Plans since 2006. Guidehouse recently completed over 1700 bid reviews for CY23 on behalf of CMS and in conformance with the requirements under MMA. These bids represent a broad spectrum of MA-PDP product offerings (e.g., PFFS, Regional PPO, SNP, etc.). Guidehouse performs a high-level review of the pricing assumptions contained in each bid form and works with the health plans and their actuaries along with CMS to resolve any potential issues. The results of our bid desk reviews are documented within HPMS.

Guidehouse has experience working with public entities and regulatory agencies and have professionals with significant Medicare, employer, provider, and prescription drug experience.

Another key consideration related to establishing a Concept of Operations is establishing critical success factors. Asking questions such as “What are the implications of success?” and “How can we maximize our chances of success?” will help inform these measures. Within the context of drug price negotiation, CMS might consider the following success measures:

Process, Inputs, & Personnel

-  Clear framework – **defensible and objective approach**
-  Selection criteria given narrow scope of eligible drugs – **seek early wins and avoid combative entities**
-  Defined and defensible inputs – **non-confidential and aligned to framework**
-  Workgroup / panel personnel with requisite skills – **credibility to stakeholders**

Consider Unintended Consequences

Once enterprise risks have been addressed, it is important to consider unintended consequences associated with policy and procedure development, operationalizing policies and procedures, and establishing monitoring and reporting processes. Some specific considerations for drug price negotiation include:

- **Skyrocketing Drug Prices.** Knowing that CMS will be negotiating for a lower price, the cost of drugs could be set at an initial premium for in-scope drugs. Alternatively, pharmaceutical companies could increase the prices of many drugs to account for negotiated decreased prices on in-scope drugs.
- **Misaligned Enforcement Driving Undesired Behaviors.** The enforcement of the prescription drug provisions should support and align with desired behaviors, focusing on root causes rather than symptoms. If enforcement measures are designed to align behavior with desired outcomes, it is important to consider whether the behavior to achieve desired outcomes could have other implications.
- **Research and Development (R&D) Funding Bias.** Pharmaceutical companies may shift their R&D budgets from innovation to more frequently occurring disease types that align with in-scope drugs.

ACA

HHS established the Consumer Operated and Oriented Plan (CO-OP) Program to provide loans to foster the creation of new consumer governed nonprofit health insurance issuers, referred to as CO-OPs, in every State. Guidehouse completed reviews of CO-OPs to ensure the CO-OPs were using government loan funds appropriately, were in compliance with applicable Federal and State statutes, rules, and regulations, and met the terms and conditions of the CO-OP Start-Up and Solvency Loan Agreement and CO-OP Program requirements. These reviews provided direct oversight of CO-OP start-up activities as a new consumer-run, private, nonprofit, qualified health plan offered in the Health Insurance Exchange. Guidehouse also performed data analytics and actuarial analysis on discrepancies in claims and premium data reported by at least 250 health insurance issuers for the Risk Corridors Program managed by CMS CCIIO.

Contact Us



Dennis Chesley
Partner
dchesley@guidehouse.com
202-964-3418



Chance Scott
Partner
cscott@guidehouse.com
312-583-5718



Cindi Bassford
Partner
cbassford@guidehouse.com
443-948-6912



Nadine Lewis
Director
nlewis@guidehouse.com
240-639-8303