Economic/Policy: Current Outlook

CBO Scoring 201: What Is the CBO Missing, and How Can You Bridge the Gap?

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a medical knowledge group company

Magnolia Market Access: Today's Speakers

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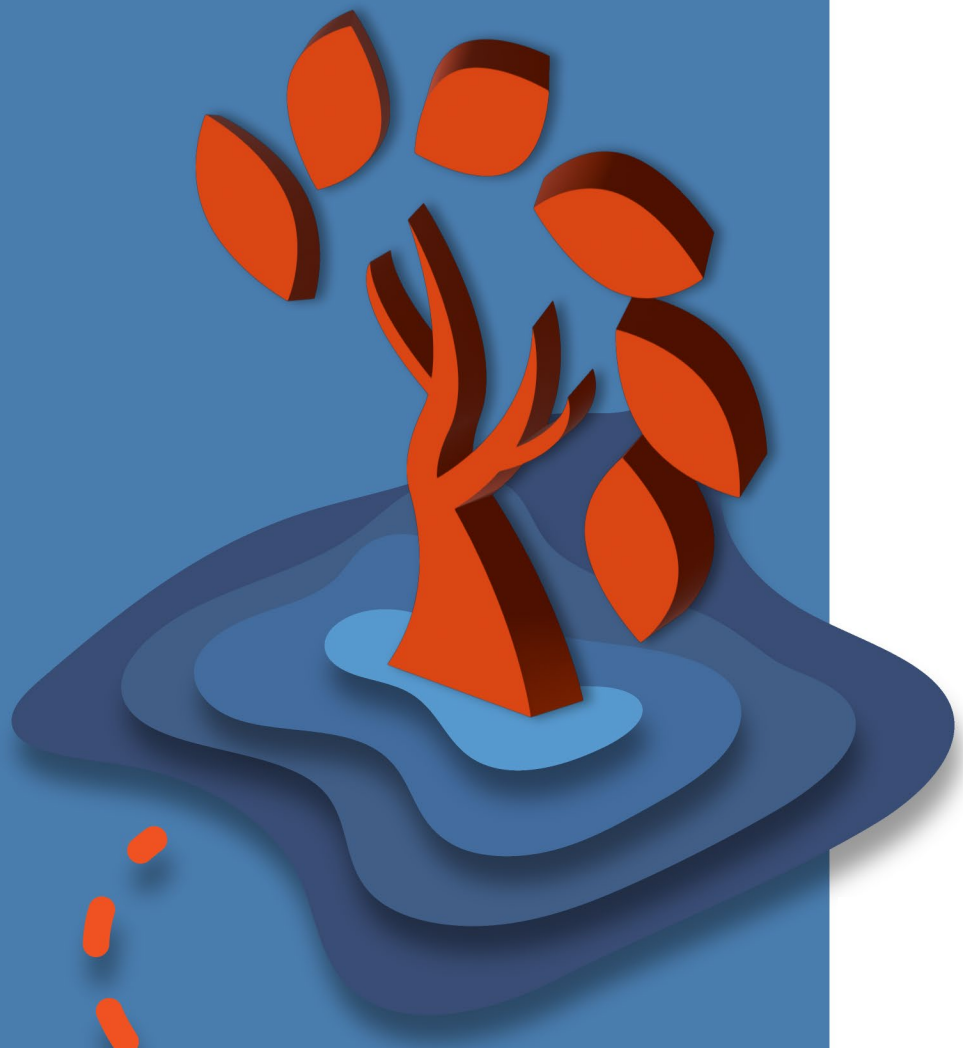

Agenda

1. Introduction
2. Economic/Policy Outlook
3. CBO Budget Scoring
4. Rethinking CBO Budget Scoring
5. CBO Examples

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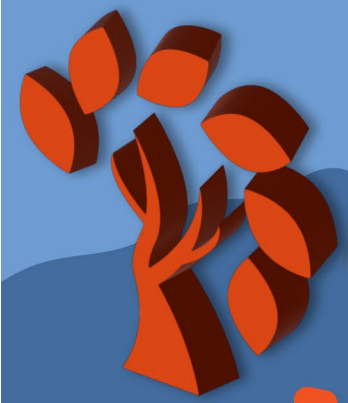
Economic/Policy Outlook



Vehicles of Change

Statute

A law passed by Congress and signed by the President

Regulation

A rule issued under the authority of the statute, written by experts employed in federal agencies

Executive Order

A directive from the President to enforce laws or manage government operations; cannot create new laws

Origin

- The authority for executive orders comes from the U.S. Constitution, primarily from the Take Care Clause (Article II, Section 3) and the President's role as head of the Executive branch

Limits

Executive orders **cannot**:

- Violate the Constitution
- Override existing laws passed by Congress
- Infringe on the powers reserved to other branches of government

Challenging or Amending

Executive orders **can** be:

- Challenged in court if unconstitutional/exceed authority
- Overturned by Congress through legislation
- Revoked or modified by a future President

Section 232 Investigation of the Pharmaceutical Industry

Background

- **Tariffs:** US Constitution **grants Congress the sole authority** to levy taxes, including tariffs; however, Congress has passed laws allowing the President to impose tariffs for **national security reasons** unilaterally
- Section 232 is used to investigate and determine the existence of a national security threat, which can then justify tariffs by EO

Impact on Pharma

- Over half of the APIs for prescription medicines in the U.S. originate from India and the European Union, while **only about 4% are produced domestically**
- Transitioning capacity to the US will take time and will likely results in shortages and price increases
- Manufacturers have begun to move significant quantities of final product from ex-US manufacturing sites to US warehouses
- Announcement of Section 232 investigation sent stocks lower for brand manufacturers as well as Indian pharmaceutical exporters

EO 14273: Lowering Drug Prices by Once Again Putting America First

Background	Impact on Pharma
Alignment of timing for small molecule and biologic negotiation; recommendations on Part D premium stabilization	- Will require legislation and regulations to change the IRA and could negatively affect the Part D market - There are still active lawsuits challenging the IRA (e.g., Teva)
Reduce amount charged for 340B drugs by some covered entities	- Could be a positive development for some companies and patients
Improve employer health plan transparency and PBM fiduciary responsibilities	- Sounds positive, but UM will continue
Facilitate state implementation of drug importation	- Negative for industry, unlikely to have a large overall effect on the market
New Medicare drug pricing model to increase value from high-cost drugs	- Puts pressure on drugs not selected for Medicare drug price negotiation to provide data to support price
Research and report on anti-competitive behavior by pharma manufacturers	- Still unclear, but could include patent evergreening, citizen's petitions, pay for delay, scrutiny of M&A - Could include FTC engagement
Accelerate generic and biosimilar drug approvals	- Neutral on its surface - Will require restoration of some FDA funding to implement

EO14293: Regulatory Relief to Promote Domestic Production of Critical Medicines

Background

- Gives HHS 180 days to review/streamline regulations/guidance to accelerate manufacturing facility construction. Also includes the following:
  - Improve inspection processes to ensure they are prompt, efficient, and limited
  - Develop/improve risk-based inspection of overseas manufacturing facilities
  - Regulations governing inspection/approval of new/expanded manufacturing capacity of pharmaceutical products, active pharmaceutical ingredients, key starting materials, and associated raw materials in the US

Impact on Pharma

- Could result in significant de-regulation, but likely not enough to incentivize or increase US product/producing sites

EO 14297: Delivering Most Favored Nation Status to American Patients

Background

- May 12: HHS was to “equalize” prices in US and ex-US
- May 20: MFN pricing was accelerated when Trump statement identified the expected US price from manufacturers to be equal to the lowest price given to any OECD country with a GDP at least 60% of per capita US GDP
- Senate bill “Fair Rx Pricing for Americans” introduced: requires prices to be the ”average of the retail prices” in 6 countries (Canada, France, Germany, Italy, Japan, UK)
- The 2018 Trump MFN proposal could not be implemented without rulemaking
- HHS to facilitate pharma direct to patient purchasing program/processes to pass on discounts

Impact on Pharma

- All drugs, all channels are included in the revised interpretation
- Impact on pricing metrics – AMP, WAC, Medicaid best price, MFP – is not known
- Significant renegotiations between industry and ex-US countries could occur
- Enforcement mechanism undefined
- Direct to patient creates a question around claims processing, reimbursement, and PBM role

Department of Government Efficiency/Administration Cuts to Key Health Agencies within Health and Human Services

Background

- Workforce decrease of 20,000 at HHS
  - 3,500 FDA/2,400 CDC/1,200 NIH
  - 50% eliminated/50% left with offered package
  - Inspector General was dismissed
- FDA budget slashed 18.6%
  - Reorganization/changes to ad comms and processes will limit levels of expertise available for NDA reviews

Impact on Pharma

- Longer approval times, missed PDUFA deadlines, larger fees within PDUFA to make up for federal dollars cut
- Different PDUFA priorities and discussions than in the past
- De-regulation (from EO and lack of funds)
- Changing approval standards can be costly, at least initially
- Ex-US requirements on diversity in clinical trials, HTA data, etc. unlikely to change

Outlook

MFN via EO

- This is very difficult to implement in one channel, much less all channels
- Given progress of this initiative, Pharma lobby un-likely to be successful in educating
- PBMs should also be wary of this order, since additional discounts will be unlikely

MFN via statute

- This could be more likely and would have an implementation date to allow preparation time
- Pharma will likely negotiate higher prices ex-US, and some US companies may refuse to sell a product if the ex-US prices are too low
- It is more costly to do business within the US system (PBMs, sales reps, DTC), some withdrawal from the US market will occur

FDA

- PDUFA discussions will result in more fees from industry, but also a reinstatement of some funding
- Changes in approvals, committees, expert panels, and clinical trials will likely be implemented
- Some therapeutic areas – ie. Vaccines – may see major changes
- Resulting delays at least short-term

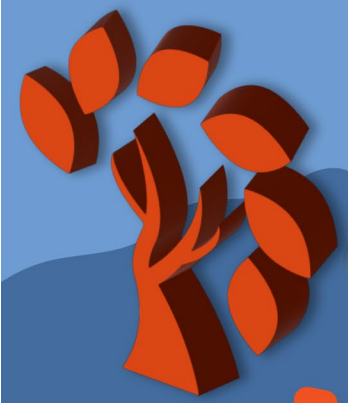
Patients

- Medicaid is likely to be seriously affected by the budget that is currently under discussion, resulting in millions losing coverage
- Without a renewal of the ACA tax credits, millions more will be uninsured
- Estimated loss of coverage in current House proposal is 13.7M

340B

- Slow to evolve, and yet MFP and now MFN will mandate that manufacturers can track pricing at the dispensing level to prevent double or triple dipping
- Recent District Court decision prevented changes to 340B purchase model without HRSA approval

CBO Budget Scoring



Overview of the Congressional Budget Office (CBO)

What is the CBO?

Established in 1974 as an independent, nonpartisan agency.

Provides **objective, impartial analysis** to support budgetary and economic policy decisions.

Role & Importance in Legislative Process

Provide economic forecasts, analyses, & assessments of short- & long-term financial impacts & implications of proposed legislation

Budgetary Projections, Economic Impact Analysis, & Cost Estimations

Impact on Healthcare Policy & Funding

Influences decisions on & assists in information dissemination to public & policy makers on resource allocation, funding priorities, & potential economic outcomes of healthcare reforms

Resource Allocation, Legislative Influence, Transparency & Accountability

Key Contributions to Healthcare Legislation

Pivotal role in shaping major programs (e.g., **Medicare, Medicaid, & the ACA**) by providing essential data & projections

Aid in identifying potential **cost-saving measures & efficient policy implementations** within healthcare sector

Meeting with CBO

Who

- Bill sponsors
- Advocacy organizations
- Trade associations
- Manufacturers

Why

- To provide information to CBO that could affect an upcoming score
- To discuss a previous score and concerns about the assumptions

Remember: The CBO is an accounting office; they do not understand every business and its economics. It is up to industry to educate the CBO and provide transparent, reasonable assumptions to influence more accurate scoring.

How Does the CBO Generally Think?

Baseline Scoring

Use of Public vs Private Data

How to Make Assumptions

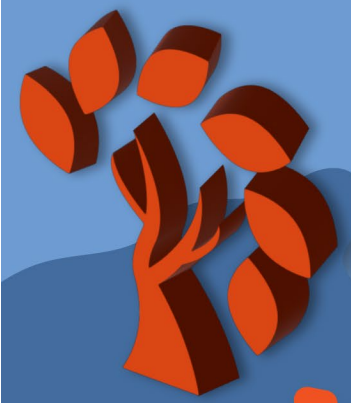
Static vs Dynamic Scoring

Growth Rates

CBO's General Equation:

Federal Spending = Cost x Volume – offsets (maybe)

Rethinking CBO Budget Scoring



How Should CBO Think Differently?

- Baseline Scoring
- Scenario and Sensitivity Analyses
- Static vs Dynamic Scoring
- Potential Impact on Outcomes
- Use of Public vs Private Data
- Potential Impact on HCRU
- How to Make Assumptions
- Methodological Transparency
- Growth Rates
- Potential Impact on Industry

Evolving the CBO Equation:

Federal Spending = Cost x Volume – Offsets

How Should You Score Policy?

Team and Sponsor Engagement

- Engage with your team to define a policy that can be discussed with a “straight face”
- Communicate with legislation sponsors throughout the process
- Identify effective communication plan for education throughout the process

Think Like CBO

- Understand the principles, methodologies, and assumptions CBO has used in previous scoring
- Build a “CBO-esque” score and use conservative assumptions for best- and worst- case estimates

Create an Interactive Score

- Develop a complete score with multiple assumptions based on public and private data (when available)
- Provide transparent information and adjustable assumptions for sensitivity analysis

Prepare Educational Materials

- Develop Hill briefings and technical memos to raise awareness and provide transparency to the process
- Decide what you want to share pre/post-CBO meeting with the public

Meeting with CBO

Meeting Rules

- Approach CBO in a conversational, non-aggressive way
- Prepare a script and have the technical team share the model and discuss assumptions
- Listen to their feedback and respond to easy questions. For “gotcha” questions, plan to follow-up
- Remember: An interactive approach enhances your credibility and working relationship with CBO

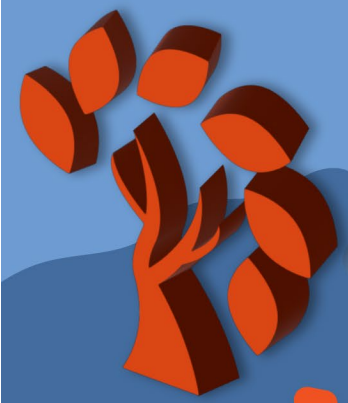
Accept Feedback

- The CBO will provide some nuggets of knowledge while they question your model. This will help you understand how they are thinking and how that may or may not align with how the industry operates
- If reasonable, leverage this information to adjust your scores. If not, follow-up with more detailed information on why you believe your assumptions are more appropriate

Develop Supplemental Materials

- Following the meeting, identify which materials are crucial for translating complex budget analyses into accessible content for varied audiences (e.g., Hill staff, response to CBO)
- Maximize impact through effective and strategic dissemination

CBO Examples



Where has CBO Gotten it Wrong or "Kinda" Right?

Inflation Reduction Act (IRA)

Annual Projections

- CBO releases annual spending baselines
  - Between 2020 and 2022, CBO projections for federal Medicare spending were mostly accurate
- In 2023, CBO projected that 2023 Medicare net federal subsidies would be $130B[1]; however, the 2024 baseline showed actual 2023 Medicare federal subsidies were $825B[2]

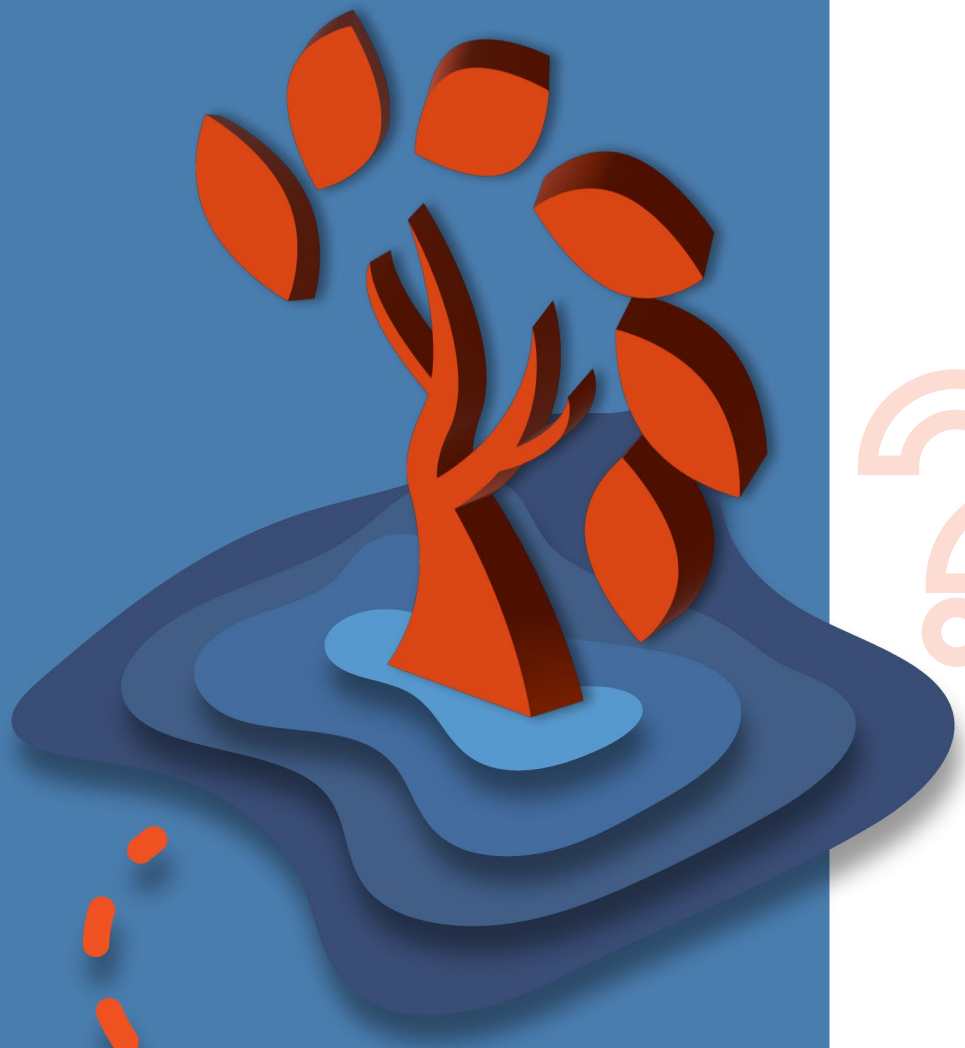
Part D Premiums

- CBO initially estimated that premiums would not increase due to the IRA, resulting in substantial cost savings
- Plan bids have been significantly higher than estimated causing approximately 26% higher federal costs than CBO's forecast[3]
- This resulted in the Part D Premium Stabilization Demonstration[4]

TBD: Pipeline Estimates

- CBO projected that the IRA will result in 13 fewer drugs entering the market over the next 30 years[5]
  - Some critics believe CBO is underestimating the impact on R&D strategies, estimating 135 fewer drugs approved through 2039[6]
  - Others believe the IRA will have little to no impact on the number of drug approvals[7,8]

Discussion



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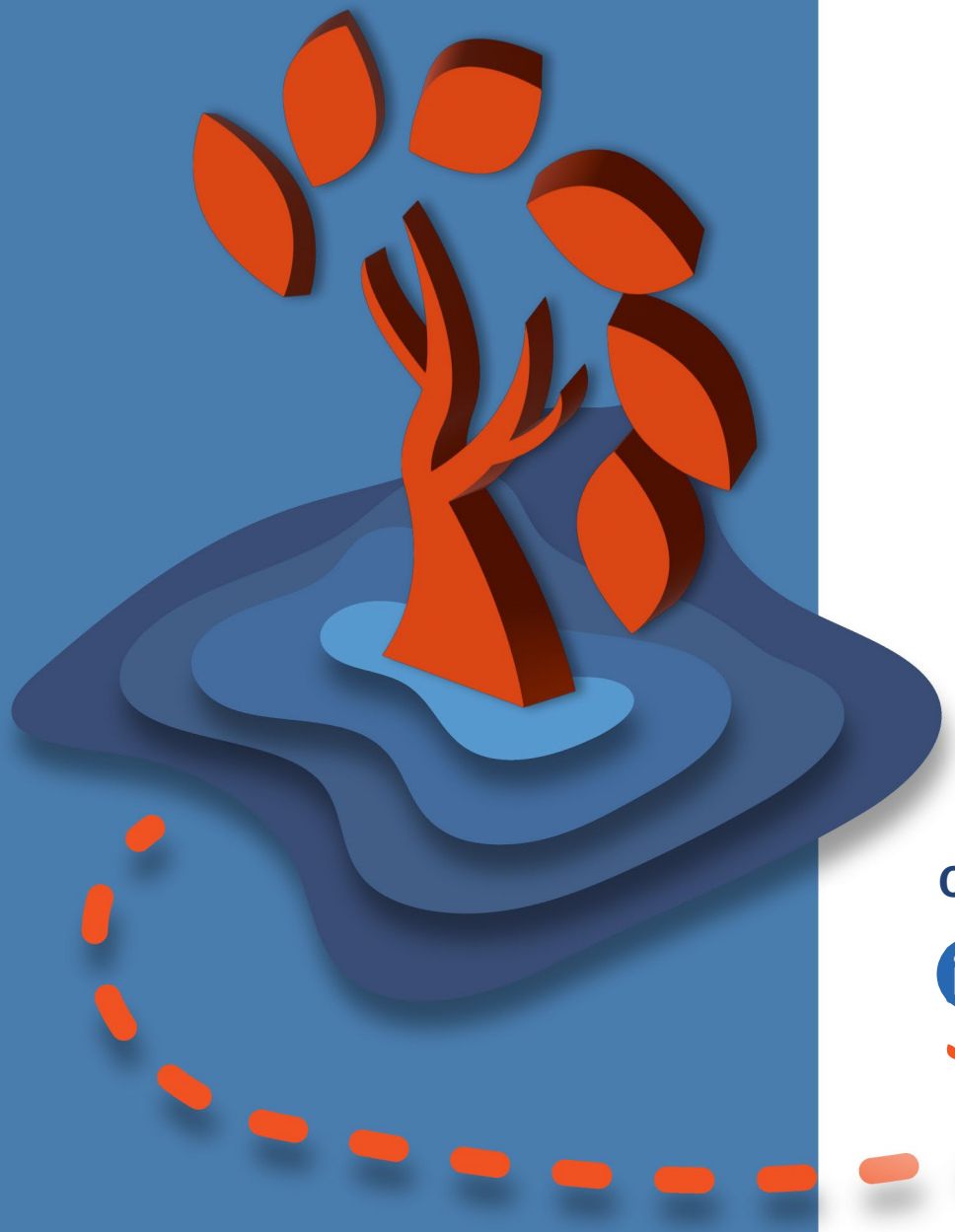

Join us for our next

Navigating Market Access with Magnolia

What To Expect in 2025 and Beyond with Tariffs and Pricing Policies

Thursday, June 26th, 2025
12:00 PM to 1:00 PM Eastern

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