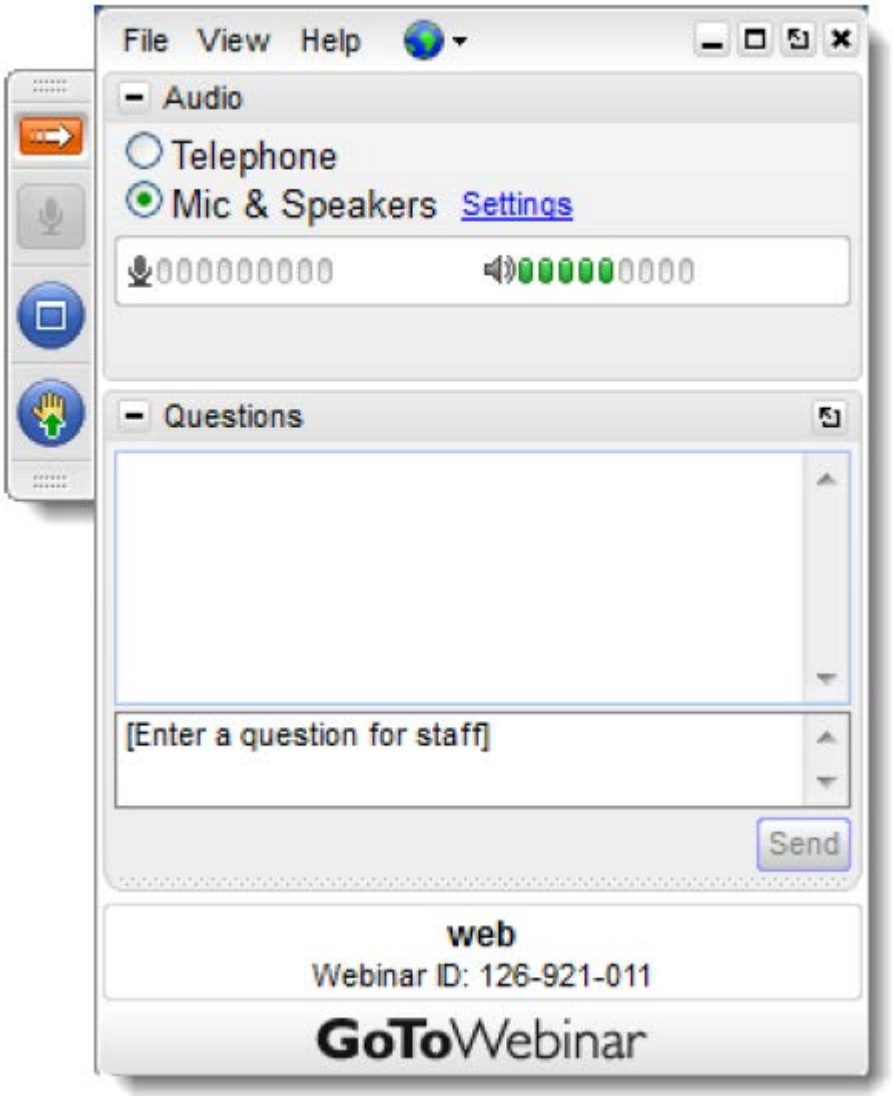
Value-Based Payment: Strategies for Pharmaceuticals

July 2016

VHCIP Webinar Series

Before we get started…



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Before we get started…

- **We've reserved time for Q&A at the end of this event.** Submit questions via Questions pane in webinar control panel.
- **This webinar is being recorded.** Slides and recording will be posted to the VHCIP website following the event: http://healthcareinnovation.vermont.gov/
- **Please complete our brief evaluation survey** at the end of the event. We value your feedback!

Vermont Health Care Innovation Project

Speakers

- Moderator: Georgia Maheras, Director, Vermont Health Care Innovation Project (VHCIP), and Deputy Director of Health Care Reform for Payment and Delivery System Reform, Agency of Administration

- Speaker: Margaret Houy, Senior Consultant, Bailit Health Purchasing

Agenda

- Presentation: Value-Based Payment: Strategies for Pharmaceuticals
- Q&A

Value-Based Payment: Strategies for Pharmaceuticals

VHCIP Webinar Series

Marge Houy

July 13, 2016

bailit health

Presentation Goals

1. Background
2. Summarize value-based payment (VBP) activities with regard to new, expensive pharmaceuticals
   - Effectiveness Pricing
   - Performance Pricing
   - Indication-Specific Pricing
   - Cap on Financial Exposure
3. Discuss applicability to commercial/state-purchaser strategies and to legislature

Changing Pharmaceutical Marketplace

- Pharmaceuticals have traditionally be chemically based
  - Drugs are delivered in pill form, available in local retail pharmacy, easy storage, easy to administer
  - Large manufacturers developed new drugs internally
  - Competitive drugs to treat the same condition often available
  - Drugs are easy to duplicate and numerous generic drug companies ready to create generics when patents ended

Changing Pharmaceutical Marketplace

- Today we are seeing the growth of biologically based pharmaceuticals; expected to be 50% of market by 2018
  - Often requires refrigeration or other special storage and administration; often available only through specialty pharmacies or through doctor's office or clinical facility
  - New drug development is being done by hundreds of small biotech companies getting venture capital money in addition to large drug manufacturing companies
  - Large manufacturers are feeding their drug pipelines most often by purchasing biotech companies, so market is consolidating
  - Biosimilars are harder to create once a drug is off patent

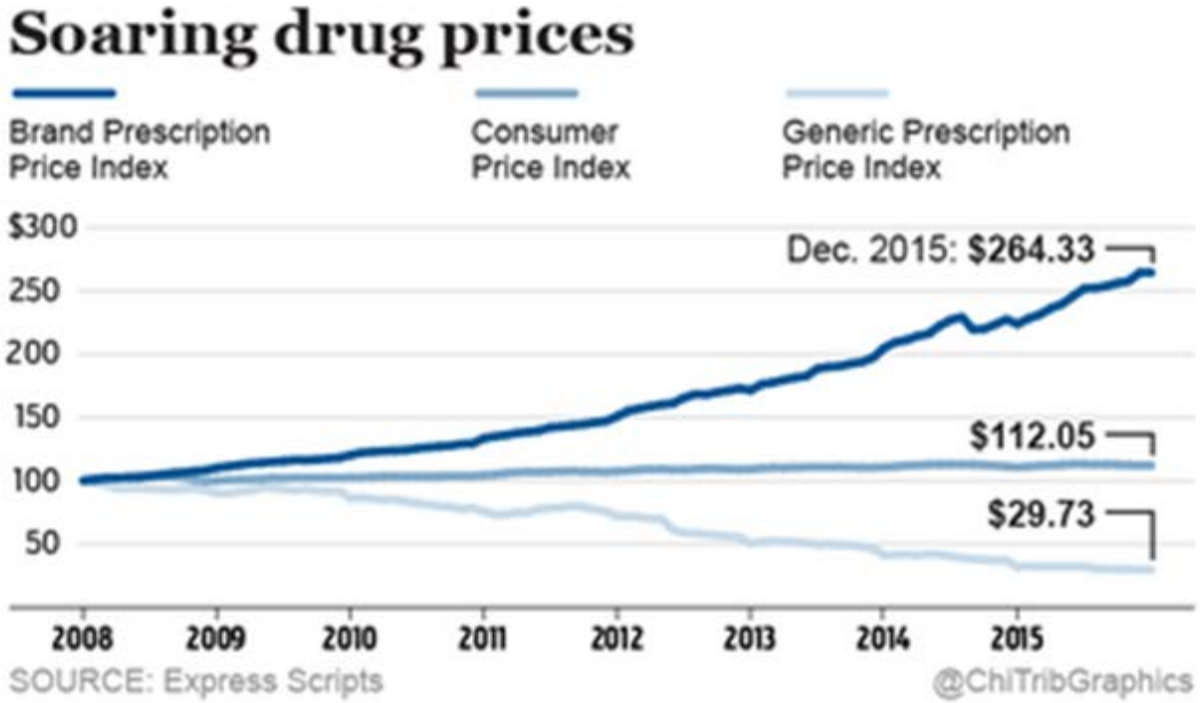
Manufacturer Market Dynamics Leading to Price Increases

- Companies are developing targeted, specialty drugs with limited or no competition. Examples:
  - Hep C drugs offer a new cure and while price came down after second manufacturer introduced a competitive product, price is still very high because of limited competition (now 3 companies)
  - New class of cholesterol drugs priced very high because of drug's promise and very limited competition (2 companies)
- Manufacturer consolidation, so fewer competitors
  - Brand: 10 companies control over 33% of world market
  - Generic: 4 companies control over 50% of the US market

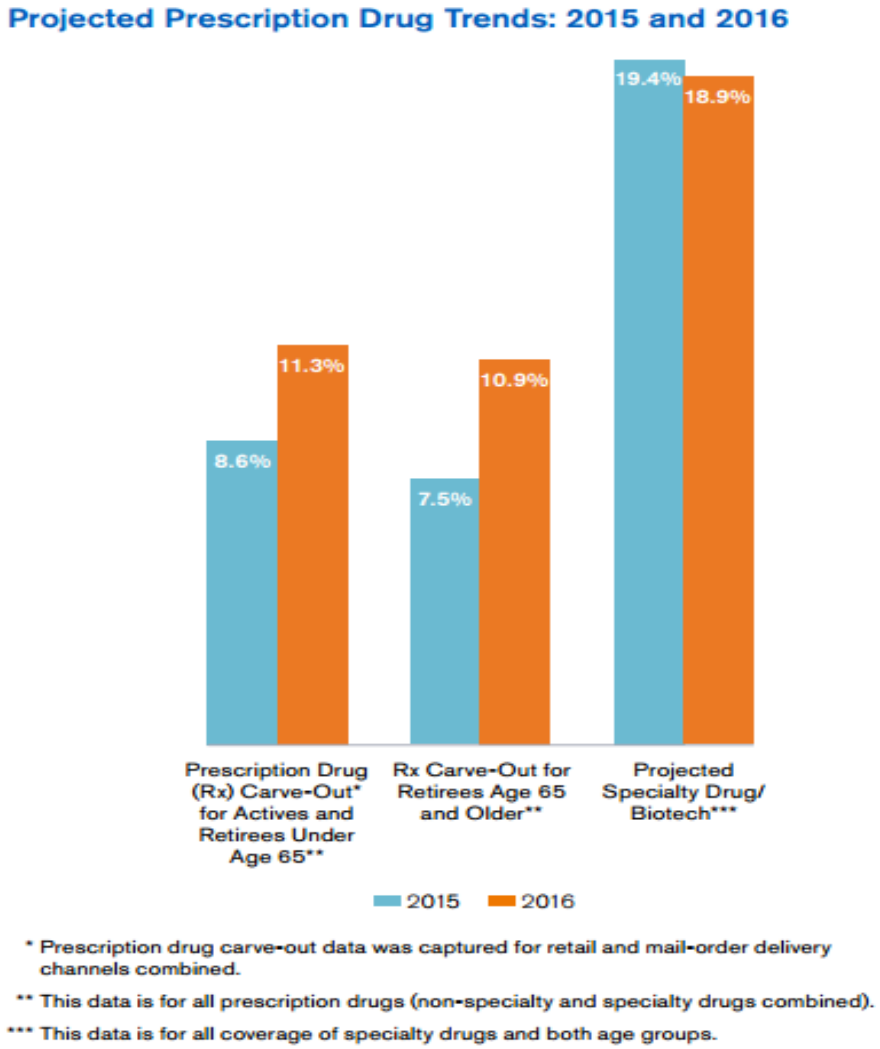
Manufacturer Market Dynamics Leading to Price Increases (cont'd)

- Change in culture: Merck vs Turing Pharmaceuticals
  - Ex-Merck CEO said company took the long-term view to focus on patient welfare
  - Turing CEO charged with criminal activities re: drug pricing
- Temporary or permanent exit from specific drug market: Production problems; strategic decision
- Generic drug returning to brand status (e.g., asthma inhaler)
- Use of captured mail-order pharmacies
  - Controls access to drug
  - Ability to more tightly control price

Background: Impact on Prices



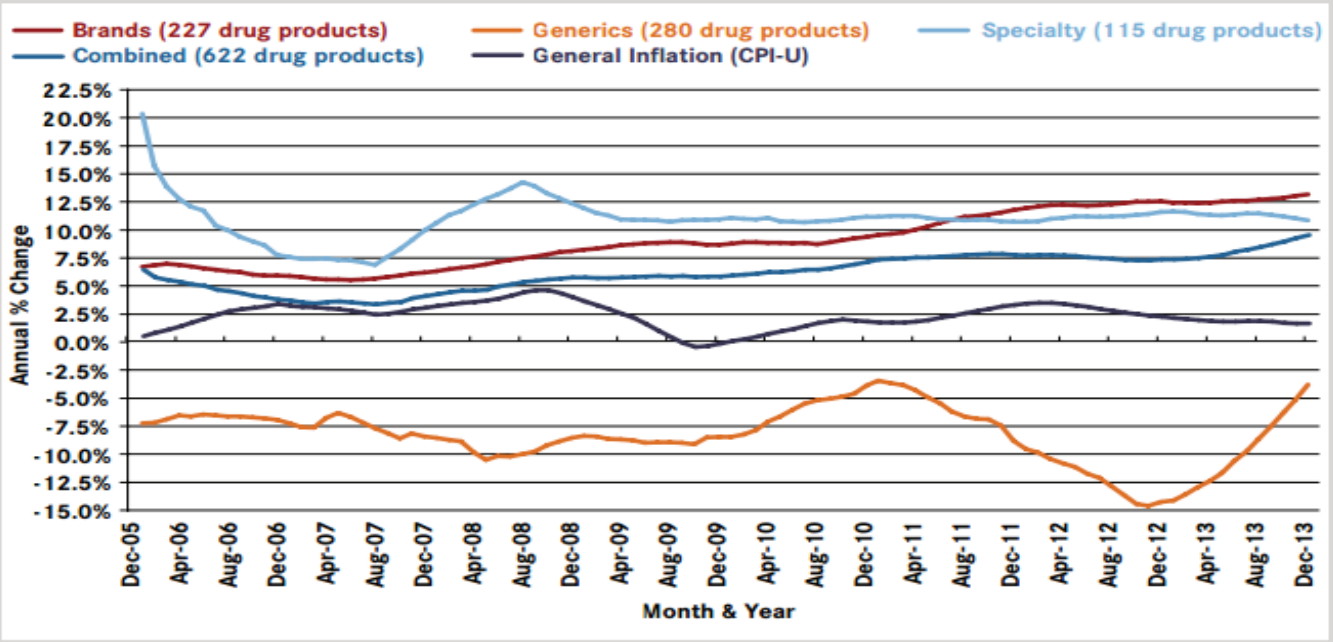
Background: Specialty Drug Trends



Background: Rx Increases Compared to CPI-U

Figure 3

Components of Annual Percentage Change in Retail Prices in AARP Combined Market Basket of Most Widely Used Prescription Drugs, 2006 to 2013



Note: Calculations of the average annual prescription drug price change include the 622 drug products most widely used by older Americans (see Appendix A).

Source: Prepared by the AARP Public Policy Institute and the PRIME *Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.*

TRENDS IN RETAIL PRICES OF PRESCRIPTION DRUGS WIDELY USED BY OLDER AMERICANS, 2006 TO 2013 5

State Government Responses to Rising Prices

- States are considering…
  - Drug cost transparency requirements (CA, OR, MA, NC, PA, NY, VA, VT)
    - Require submission of cost information, which would be made publicly available
    - Fierce opposition from PhRMA
  - Limits on co-pays (DE, LA, MD, ME, VT, NY)
    - Some specify dollar caps on co-pays for specialty drugs
    - Others limit rate of annual increases on co-pay amounts

Vermont's Pharmaceutical Cost Transparency Act (enacted 6/2/16)

- Requires the GMCB, working with DVHA, to identify up to 15 prescription drugs annually and provide list to AG for which
  - The state spends significant health care dollars
  - The wholesale acquisition cost has increased by 50%+ over past 5 years, or by 15%+ over 12 months
- AG to require manufacturer to provide justification for price increases
  - AG may impose sizable civil penalties for failing to report
- AG to submit report to legislature and DVHA annually
- Information provided to AG may not be disclosed in any manner that allows for manufacturer identification

State Government Responses to Rising Prices (cont'd)

- MA:
  - State senator has introduced price transparency legislation requiring drug makers to report costs of:
    - Manufacturing, advertising, research
    - Federal research outlays
    - Prices charged in the US, compared to other countries

    And
    - Provide price relief to publicly funded health programs
  - AG has notified Gilead (Hep C) that it may face unfair trade practices if it doesn't lower its prices

- CA: Ballot initiative to limit state drug prices to what the VA pays: controversial within pharmaceutical, medial and advocacy communities

Purchaser Market Dynamics to Gain More Leverage

- National insurers merging to increase negotiating leverage: Aetna/Humana, Anthem/Cigna, Centene/HealthNet
- National insurers buying or aligning with independent pharmacy benefit managers (PBMs):
  - Anthem aligned with Express Scripts
  - Aetna aligned with CVS/Caremark
  - UnitedHealth Group owns Optum Rx and Catamaran
- PBMs expanding scope of services
  - Vertical integration: CVS/Caremark, Walgreens/Walgreens PBM
  - New service areas: Medco acquired genotyping company

Increasing Interest in Value-based Pricing Models

- Avelere Health queried 42 plans, representing 161 million insured people, about responses to increased Rx costs
  - Most interest centered on expensive specialty drugs:
    - Hep C treatments
    - Oncology drugs
    - Rheumatoid arthritis drugs
    - Multiple sclerosis treatments
  - Outcomes contracts of interest because of increased availability of both clinical and pharmaceutical claims data
  - More public availability of effectiveness research results

VBP Activities

- PBMs/national plans beginning to implement VBP models; manufacturers receptive
  - Effectiveness Pricing
  - Performance Pricing
  - Indication-specific Pricing
  - Cap on Financial Exposure
- Directly applicable to new, very expensive drugs

1. Effectiveness Pricing

- Aim: Convert evidence about the improvement a drug provides in patient clinical outcomes into a benchmark price for that drug compared with other treatment options

- Only a few organizations are currently doing this work to create a benchmark price other than manufacturers, including
  - Institute for Clinical and Economic Review (ICER)
  - DrugAbacus
  - American Society of Clinical Oncology
  - Some national PBMs

1. Effectiveness Pricing: How Benchmark Price is Created

- General Description of ICER Methodology:
  - Estimates total dollars available for new drug coverage annually and number of new drugs to be approved by FDA to get average $s available
  - Reviews clinical trials for drug's effectiveness and adoption rates
  - Calculates budget impact at market price
  - Calculates cost per quality-adjusted life year gained compared with other treatments
  - Creates a value-based price benchmark that reflect magnitude of estimated improvements in LT patient outcomes and available $
  - Vets with several review panels of experts

1. Effectiveness Pricing: Effectiveness Pricing Example

- Example: "Effectiveness Price" for new class of cholesterol drugs (PCSL9 inhibitors) calculated by ICER

Market Price = $14,350 average annual list price

Effectiveness Price calculated to be 45% to 65% lower

1. Effectiveness Pricing: Challenges

- No single clearinghouse for Effective Pricing analyses
- PhRMA challenges methodology, so achieving benchmark pricing in price negotiations requires significant negotiation leverage
- Applicable to a small number of drugs: those new to the market and expensive
- Value-based price could be higher than market price

2. Performance Pricing

- Aim: Set the final price of drug based on whether the drug performs “in the field” as expected, based on clinical trials
  - Price is lower if the drug does not perform
  - Structure of P4P arrangements is based on nature of drug and how effectiveness is measured
- Performance is based on actual patient experience

2. Performance Pricing: Performance Pricing Examples

- Cigna's negotiated deal with a manufacturer

If patients taking new class of cholesterol drugs do not lower LDL as expected based on clinical trials,

The manufacturer further discounts the cost of the drugs for all patients taking it

If patients taking the new cholesterol drug have LDL levels that meet expectations

The originally negotiated price stays in place

2. Performance Pricing: Performance Pricing Examples (cont'd)

Manufacturers' Pricing Strategies

- Manufacturer of Bortezomib for myeloma pays for drug costs for any patient who fails to respond after four cycles of the drug
  - Effectiveness will be known within that timeframe
- Manufacturer provides the first two months of Ampyra (MS drug) free
  - It works on only 40% of patients, which becomes evident in a few weeks

2. Performance Pricing: Challenges

- Significant and sustained purchasing power is needed to negotiate these types of deals with manufacturers
  - National plans and top PBMs are starting to move negotiations in this direction
  - Possible Cigna/Anthem merger will expand these two insurers' negotiating power
- Both pharmacy and clinical data must be tracked to evaluate effectiveness, which is challenging on a large-scale basis
  - Example: Patient's LDL levels before and during Rx use

2. Performance Pricing: Challenges (cont'd)

- Details on how to evaluate patient outcomes will need to be decided in advance of implementation.
  - Unanticipated methodological issues are likely to arise
- Outcomes need to be measurable in a relatively short period of time with a clear biomarker
- Need physician engagement
  - Additional reimbursement for additional assessment/reporting
- Applicable to a small number of drugs that are new to the market and expensive

3. Indication-Specific Pricing

- Aim: Set different prices for different indications or for distinct patient subpopulations eligible to use medication
  - Prices vary based on relative clinical benefit
- Express Scripts seeks differential pricing from manufacturers based how cancer drug will be used
  - Tarceva performs betters against lung cancer, compared to pancreatic cancer
  - Price when used for pancreatic cancer (less effective) would be lower than when used for lung cancer (more effective)

3. Indication-Specific Pricing: Challenges

- Potentially a significant administrative burden
  - Current systems are designed to pay same unit price regardless of use
  - Difficult linking to differential patient cost-sharing or placing same drug on different tiers based on use
- Insufficient analytic capabilities
- Could be difficult to explain to patients and stakeholders and may raise concerns if not tied to lower out-of-pocket costs for patients.

4. Set Cap on Total Financial Exposure

- Aim: Limit financial exposure related to use of drugs in a specific drug class based on appropriate usage by covered population
  - Incentivize effective use of targeted drug
- Express Scripts "Trial Balloon"
  - Limit account's financial costs associated with new class of cholesterol drugs
  - Enrollees must use Express Scripts' specialty pharmacy
  - If customer spends more than the pre-set amount, Express Scripts absorbs the overage

4. Set Cap on Total Financial Exposure: Challenges

- Challenges
  - This is in the conceptual stage
  - Payer would need to carefully analyze their data in order to evaluate reasonableness of proposed cap offered by PBM
    - Hard to do with a new drug and no experience
    - Would need to seek data from PBM

Opportunities for Commercial Plans & Purchasers

- Become highly knowledgeable about market pricing developments and new drug launches
- Support and track drug effectiveness research of ICER
  - Reports available on line: Example – Treatments for Multiple Myeloma: https://icer-review.org/wp-content/uploads/2016/06/icer_multiple_myeloma_v4.pdf
  - Opportunities to submit public comments
- Use in performance discussions with PBM
- Use in setting member contribution levels
- Use in educating provider network

Opportunities for Commercial Plans/Purchasers (cont'd)

- Commercial plans: Actively manage PBM contract
  - Meet regularly to understand
    - Current cost drivers
    - New drug pricing trends
    - PBMs cost savings strategies, including performance-based pricing
  - Collaborate on pharmacoeconomic studies to value outcomes and financial benefits
  - Include requirement to do effectiveness-based pricing analyses and to share results with plan
  - Require implementation of value-based payment models where savings from value-based contracting are returned to the plan/purchaser

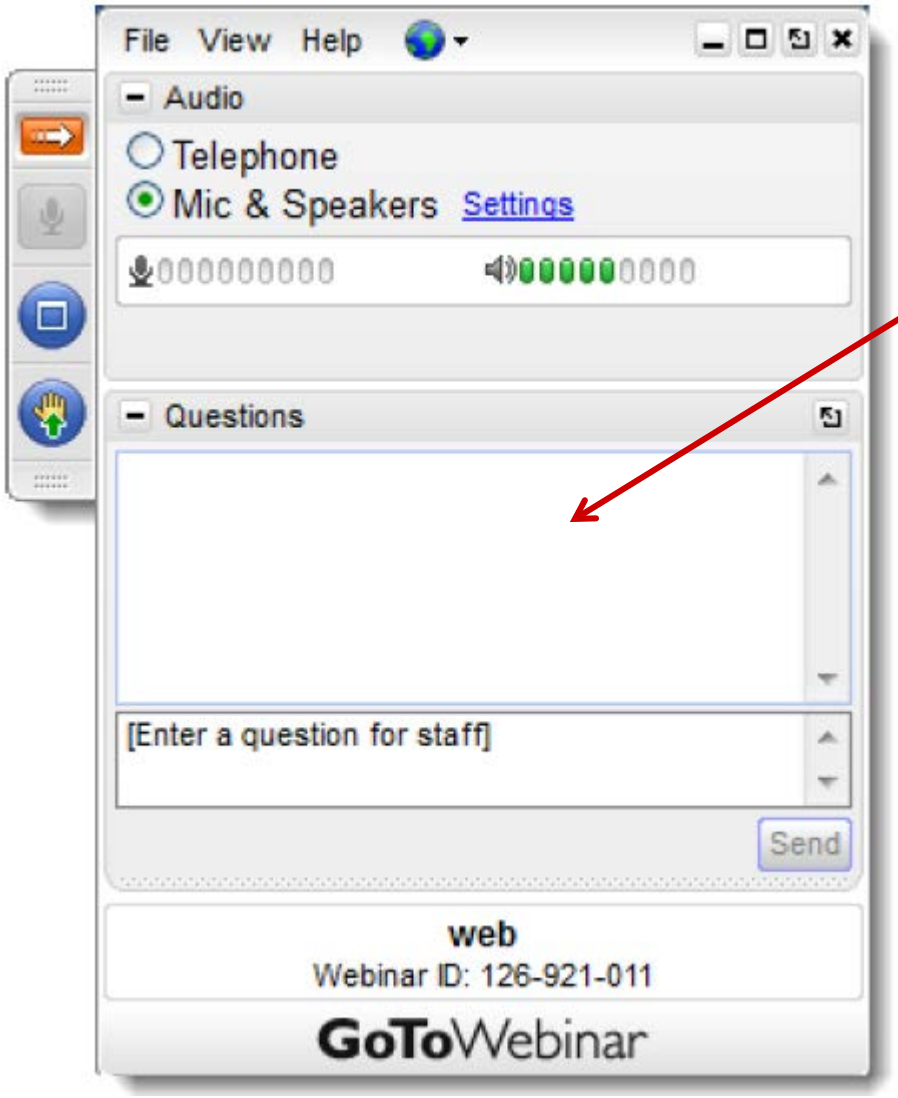
Opportunities for DVHA

- DVHA: Work with Sovereign States Drug Consortium and Goold Health Systems to negotiate VBP arrangements
  - Ask your pharmacy staff to ID new drugs that would be candidates for performance-based purchasing arrangements and then include them in discussions with the Consortium

Opportunities for Legislature to Address Market Failings

- Legislature: Strengthen unfair trade practice legislation to cover drug pricing at levels not supported by ICER or other effectiveness analyses

Questions?



- Enter questions in Questions pane of GoToWebinar control panel.

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Thank you!