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Optimizing medicine.
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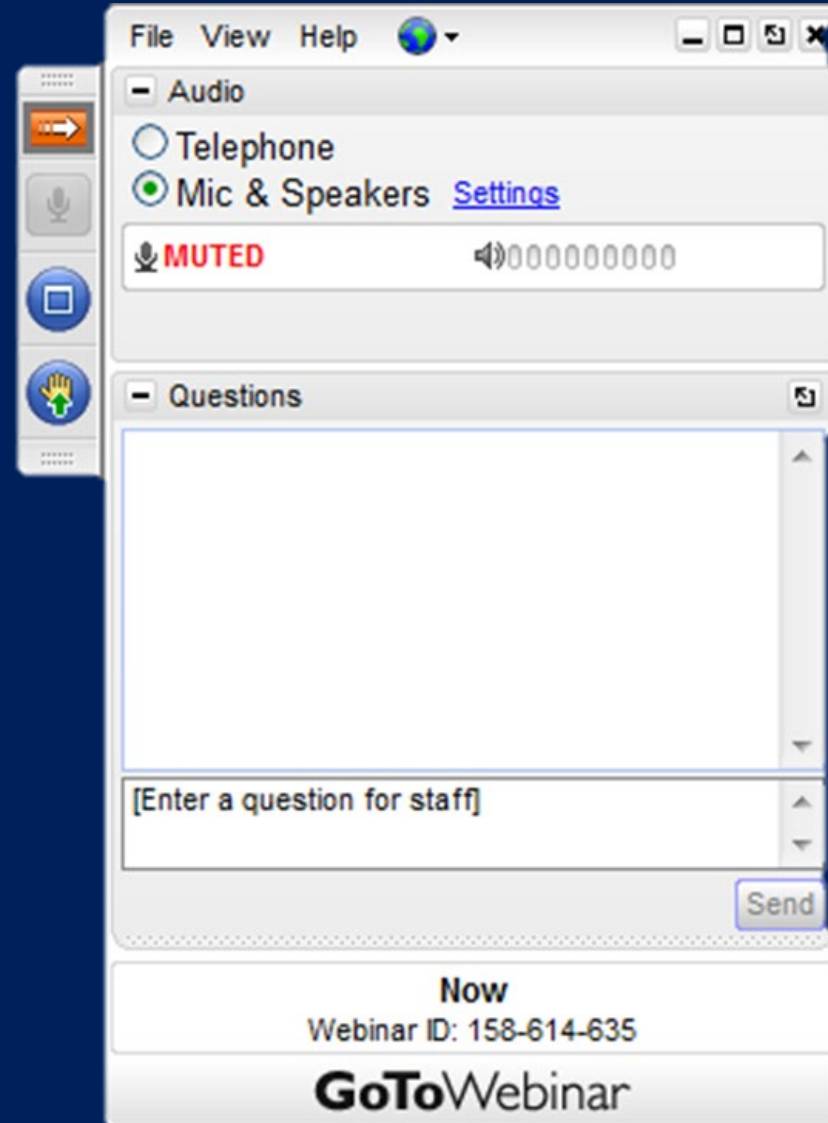
AMCP 2021 Legislative and Regulatory Priority Issues & Strategies

March 4, 2021

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How to Ask a Question



Presenters



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Rising Cost of Medications Platform



AMCP stands against racial injustice



2021 Legislative/GR Priority Setting Process

1. Inputs

- Member Survey
- PPC & LRAC Committees
- AMCP Leadership/Staff
- AMCP Strategic Initiatives
- External – Federal & State Governments
- Leadership/Board

2. Public Policy Committee & LRAC Joint Priority Setting Meeting (Nov. '20)

3. State Advocacy Leaders Program Revamp

2021 Government Relations Priority Issues

- Rising Cost of Pharmaceuticals and Price Transparency
- Shift from Fee-For-Service to Value-Based Care
- Promote Managed Care Pharmacy Strategies



Rising Cost of Pharmaceuticals and Price Transparency





Shift from Fee-For-Service to Value-Based Care





Promote Managed Care Pharmacy Strategies



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AMCP Annual Government Relations Priority Issues



AMCP Annual Government Relations Priority Issues

Each year, AMCP establishes policy and government relations priority issues that become the focus of AMCP's advocacy efforts for that year. The priority issues are developed during a joint meeting of the Public Policy Committee and the Legislative and Regulatory Action Committee (LRAC). At that meeting, Committee members and AMCP staff review the results of an AMCP member survey and discuss relevant federal and state legislative and regulatory actions that impact managed care pharmacy. After careful consideration of AMCP's strategic initiatives, member input, and pertinent legislative and regulatory actions, the committees develop recommendations, which are reviewed by the Board before a final decision is made on the year's priority issues.

AMCP staff and committee members focus on strategies where AMCP can be most effective in these targeted priority issue areas. Participation in response to grassroots alerts is every AMCP member's opportunity to engage in those efforts. Your participation is a key element of AMCP's overall efforts to ensure that the voice of managed care pharmacy is heard by federal and state legislatures and regulators.

- [AMCP 2021 Government Relations Priority Issues](#)

<https://www.amcp.org/policy-advocacy/policy-advocacy-focus-areas>

AMCP 2021 Federal Legislative Agenda

1. Pharmaceutical Information Exchange (PIE) Legislation
2. COVID-19 Relief
3. Drug Pricing
4. Managed Care Tools

* Additional State-level priorities will be discussed later

Pre-approval Information Exchange (PIE)

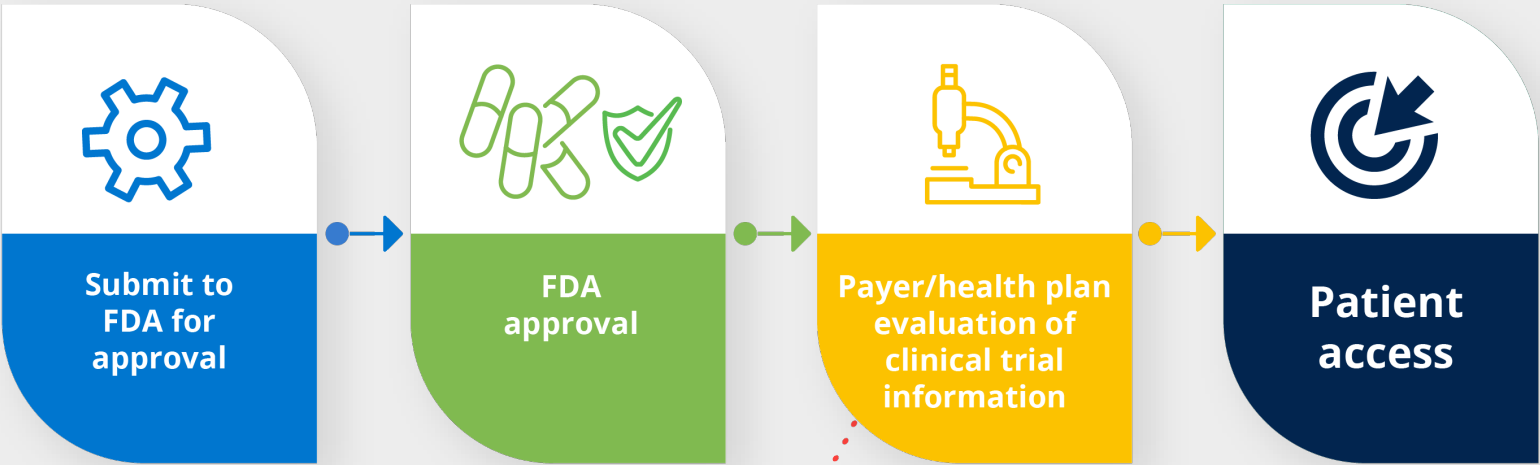
A crucial effort to ensure payers have access to critical information and research-based evidence to provide timely coverage decisions and patient access when new therapies come to market

Improves and increases patient access to emerging pharmaceuticals and devices



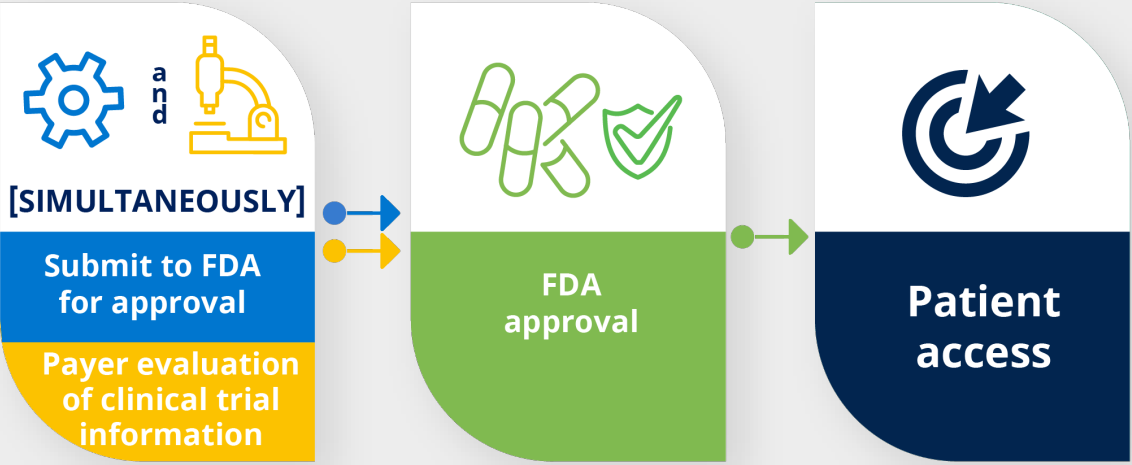
CURRENT SYSTEM

IMPACT: Patient access to medications is delayed because payers and health plans must wait to review the clinical trial information once the medication is approved by the FDA.



PIE –
What?

IMPACT OF MAKING THIS SWITCH:
By distributing clinical trial information to payers and health plans earlier, the review process is able to start earlier so expedited coverage decisions can be made immediately upon FDA approval.

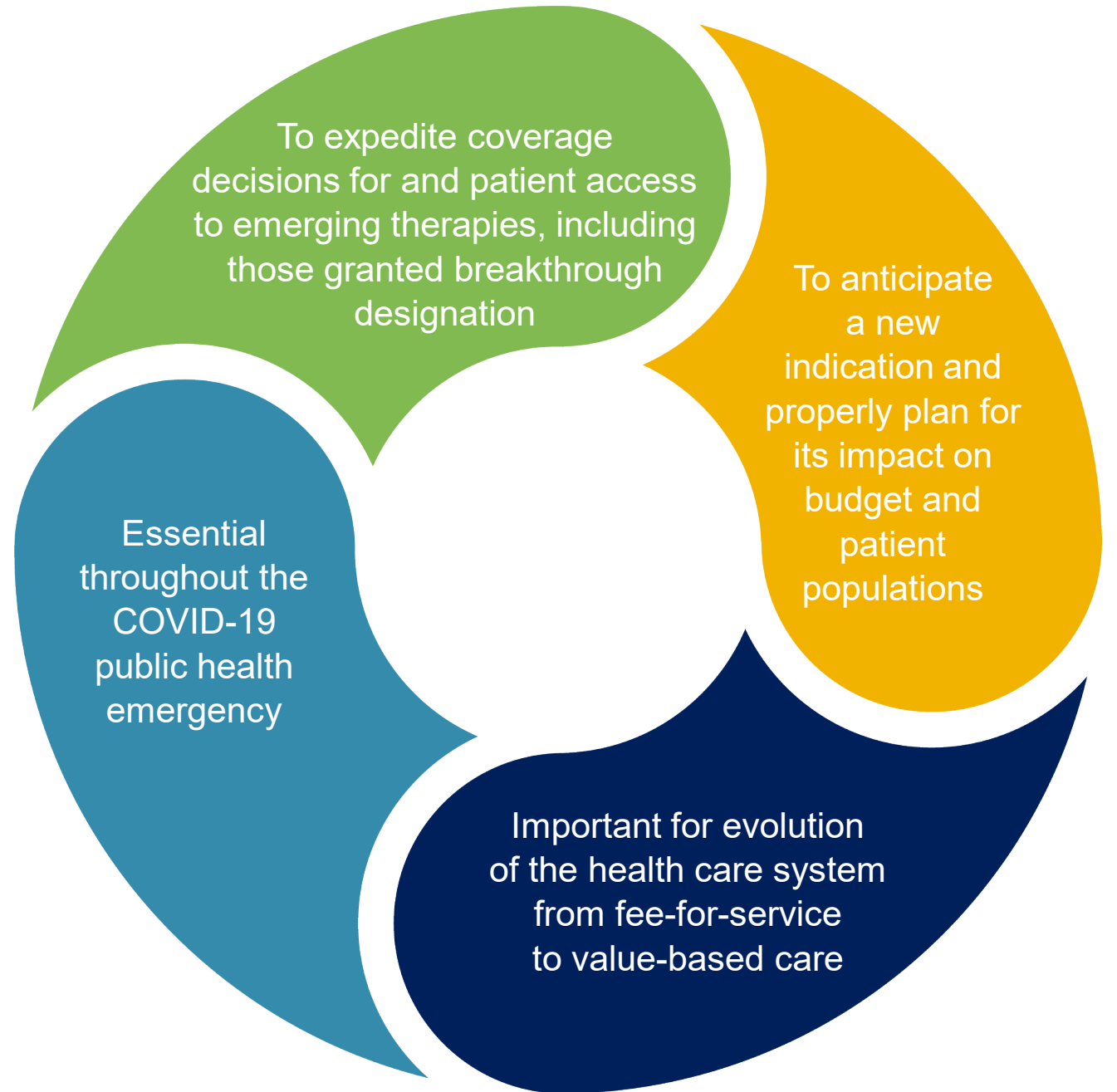


A BETTER SYSTEM

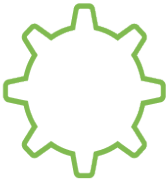
IMPACT: Proactive distribution of clinical trial information to payers and health plans so they can make expedited coverage decisions upon FDA approval.





PIE – Why?




PIE – Next Steps



Urge Congress to introduce and support legislation codifying current regulatory safe harbors that allow for proactive pre-approval information exchange between manufacturers and health care decision-makers



This legislative safe harbor for PIE will confirm that the proactive dissemination of certain information does not violate the prohibitions against preapproval promotion and does not run afoul of the labeling, misbranding, and intended use provisions of the Federal Food, Drug, and Cosmetic Act and its regulations on implementation



Federal Regulatory Issues



- Medicare Part D Rebate Rule
- Most Favored Nation (MFN) Model Interim Final Rule
- FDA Prescription Drug Importation Final Rule
- Medicare Coverage of Innovative Technology (MCIT) Final Rule
- Value-Based Pricing Rules
- COVID-19 Regulatory Update

Medicare Part D Rebate Rule

- Final Rule released Nov. 20, 2020 by HHS OIG
- Eliminates the safe harbor protections for manufacturer price concessions offered to plan sponsors or their contracted PBMs and establishes two new safe harbors.
- In response to their lawsuit, PCMA reached an agreement with the Biden administration, approved by a federal judge, to postpone the effective date of the rebate safe harbor elimination to January 1, 2023.

Most Favored Nation Model

- Released on Nov. 20, 2020 as an Interim Final Rule with Comment Period (IFC)
- Mandatory, nationwide demonstration which includes all Medicare Fee-for-Service beneficiaries
- Initially includes 50 medications that account for the largest percent of Part B spending
 - More drugs added annually as new drugs
- Model was slated to begin Jan. 1, 2021
 - California court granted a preliminary injunction

FDA Prescription Drug Importation

- FDA Issued Final Rule on Sept. 24, 2020
- Provides FDA-authorized programs to import specific drugs from Canada
- Importation plans would be administered by states or Indian tribes after authorization by the FDA and would specify the drugs eligible for importation

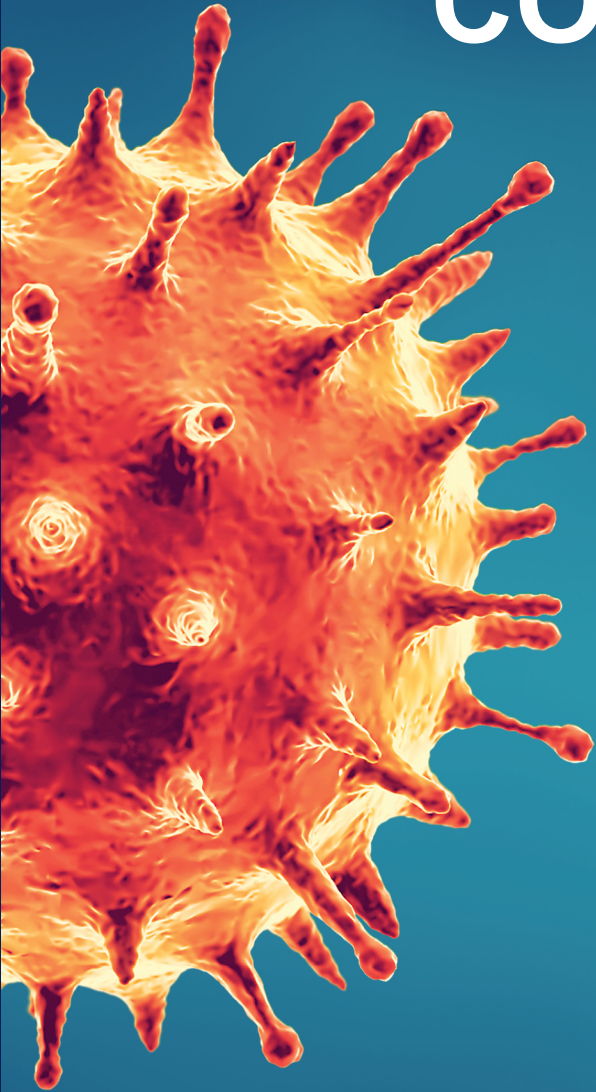
Medicare Coverage of Innovative Technology (MCIT)

- Final Rule released Jan. 12, 2021, effective March 15, 2021
- CMS details the establishment of a coverage pathway for new, innovative medical devices approved by the FDA
 - Allows Medicare beneficiaries faster access to these breakthrough technologies
 - Applies to devices that receive market authorization by the FDA through the agency's Breakthrough Devices Program, including digital therapeutics

Value-Based Pricing Rules

- Medicaid Best Price Final Rule
- Physician Self-Referral Rule Exceptions for Value-Based Arrangements Final Rule
- Anti-Kickback Statute Value-Based Arrangements Safe Harbors Final Rule
- HIPAA Privacy Rule Modifications

COVID Specific Rules & Regulations



- September 9th rule permits pharmacists to:
 - “Order vaccine”
 - Administer vaccine
 - Restricts authority to those aged 3 years old and older
 - Preempts state laws that would effectively prohibit this
- Previous rule broadened access to Medicare telehealth services

State Policy Priorities and Strategies



State Priorities

- Promote meaningful transparency on drug pricing and patient cost-sharing
- Advocate for the development of clear metrics to shift pharmaceutical payments to value-based care
- Encourage data sharing and interoperability of electronic health records
- Promote AMCP's position on formulary requirements, tier restrictions, and coverage mandates
- Support the use of managed care tools

Other State Issues Being Monitored

- Pharmacy benefit managers
- Importation
- Provider status
- Regulatory issues



State Strategies

- Perform 50-state needs assessment
- Grassroots and grasstops advocacy
 - Create grassroots campaigns on relevant state bills
 - Engage State Advocacy Leaders to connect with their state legislators
 - Track activity through report form on AMCP's website



State Advocacy Leader

- Develop “grasstops” relationship with state legislators
- Participate in grassroots advocacy campaigns and report actions
- Encourage other AMCP members to engage in grassroots campaigns and report actions
- Campaigns may take several different forms
Examples: Email, social media, phone calls
- Occasionally present on AMCP advocacy issues
Affiliate meetings/days of education
Student chapters if/when possible
- Help coordinate state legislative days if/when possible



State Advocacy Leader

- amcp.org/state-advocacy-leaders
- <https://www.amcp.org/policy-advocacy/grassroots-advocacy/report>

NEW VOLUNTEER OPPORTUNITY - Get involved in the State Advocacy Leaders program!

[Learn More](#)



[AMCP.org](#) > [Policy & Advocacy](#) > [Grassroots Advocacy](#) > [State Advocacy Leaders](#)

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State Advocacy Leaders

Thank you for your interest in being a leader in AMCP's grassroots state advocacy efforts.

You can use the form linked below to apply to be the State Advocacy Leader in your home state. If the position is open, AMCP staff will follow up to schedule a brief conversation. Please note that application is not a guarantee of selection and that participation is limited to active non-student AMCP members.

[Read more about the role and its responsibilities.](#)

[APPLY NOW](#)



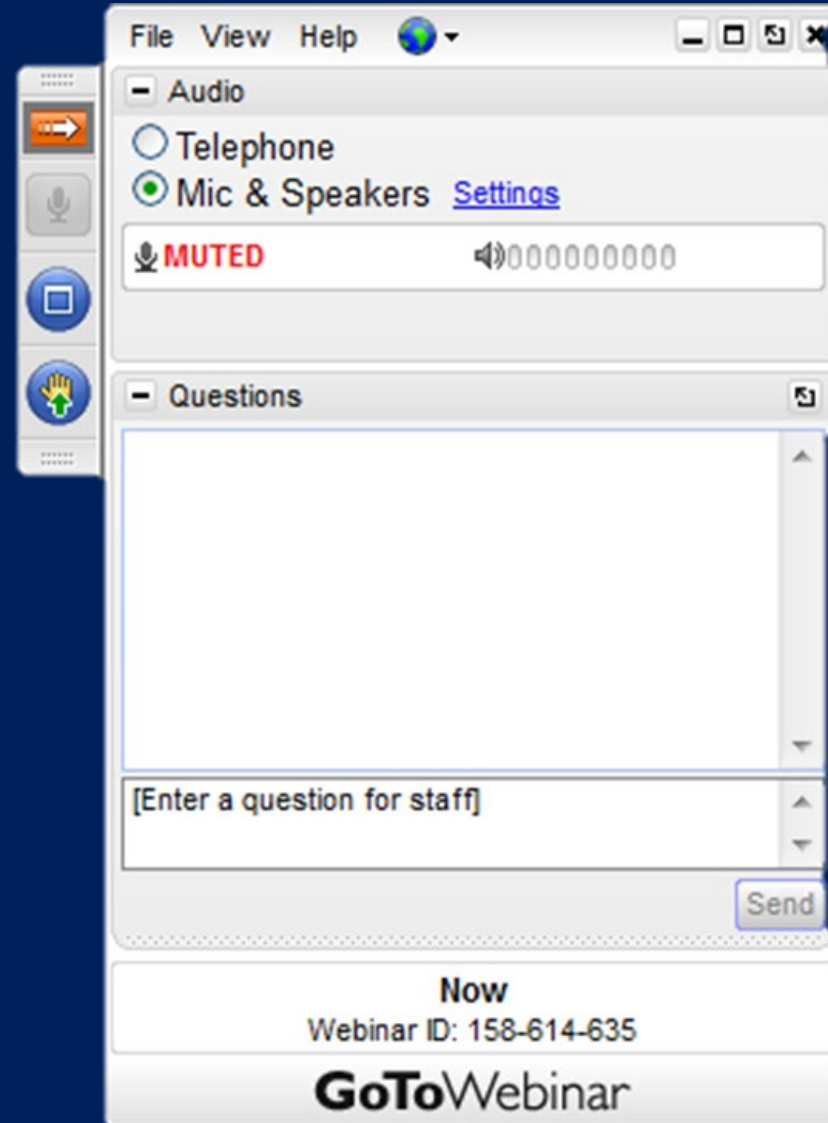
AMCP Resources

- AMCP Grassroots Advocacy Center
- AMCP Policy Digest
- Monthly Legislative and Regulatory Briefing
- Policy Statements
- Website Resources

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How to Ask a Question



Question and Answers with our Presenters



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