

Government Relations Division 2017 Annual Report



Our Vision

To create a government relations division that provides exceptional representation for ASHP members, and is forward thinking, professional, credible, and highly valued by policy-makers.

Our Mission

To represent ASHP and its membership before policy-makers at both the state and federal levels. To ensure that the voice of health system pharmacists is expressed throughout all levels of government, other healthcare stakeholders, and the public at large. To position ASHP and its members as a credible, trusted source of information and serve as a resource for policy-makers.

From the Director:

2017 was a year of unprecedented change and challenge. We experienced a new Administration, a new Congress, and a new agenda. Combined, this resulted in a workload that was higher and more intense than I can ever remember in my time in Washington. All of our top issues (provider status, compounding, drug pricing, the 340B Drug Pricing Program, drug shortages, and opioid abuse) were being discussed in Congress, the agencies, or the states.

Overall, ASHP's Government Relations Division met the challenge of representing our members on these issues as well as others, through direct in-person advocacy, by both staff and members, statements for the record submitted to Congress, formal letters and comments to Congress, federal and state agencies, and our presence at Congressional campaign events.

In addition to ASHP's individual advocacy efforts, ASHP remains a lead member in a number of coalitions such as the [Patient Access to Pharmacist Care Coalition](#) and the [Campaign for Sustainable Rx Pricing](#). ASHP continues to work with partners on drug shortages, convening a meeting in early November at ASHP Headquarters with other healthcare stakeholders, including the Food and Drug Administration (FDA) and the Department of Health and Human Services. The meeting resulted in a [number of recommendations](#) that will serve as the basis for renewed advocacy on this issue in 2018.

This report serves as a summary of the year's activities. While our challenges will continue in 2018, ASHP remains steadfast in our commitment to advocating on behalf of our members on issues impacting pharmacy practice.

A handwritten signature in blue ink, appearing to read "Joseph M. Hill".

Joseph M. Hill
Director, Government Relations

ASHP's Top Advocacy Issues

Provider Status

ASHP, as a lead member of the [Patient Access to Pharmacist Care Coalition](#), has been working to pass legislation to include pharmacists as providers in the Medicare program. As of December 31, 2017, our legislation, the [Pharmacy and Medically Underserved Areas Enhancement Act](#), (H.R. 592/S. 109), has 242 cosponsors in the House and 51 cosponsors in the Senate. We will continue pushing for passage of these bills in 2018. [Learn More](#)

Drug Pricing

ASHP has been proactively addressing and tackling challenges related to [drug pricing](#) on several fronts. We have worked with like-minded stakeholders as a lead member of the [Campaign for Sustainable Rx Pricing](#), a broad-based coalition of consumers, clinicians, hospitals, payers, and retailers. We are also educating members of Congress about the unsustainable financial burdens faced by patients, our members, and the entire healthcare system. [Learn More](#)

340B Drug Pricing Program

ASHP supports the 340B Drug Pricing Program, recognizing that it is essential to many hospitals' ability to provide care to uninsured and underinsured patients. ASHP is working with Congress on legislation that would roll back cuts finalized in November 2017 by the Centers for Medicare and Medicaid Services (CMS) and will continue supporting the program in 2018. [Learn More](#)

Compounding

ASHP supports the [Drug Quality and Security Act](#) and continues working with the FDA to ensure that hospitals may compound medications for use in their own systems. Further, ASHP supports a robust 503B category of compounding outsourcer. [Learn More](#)

Drug Shortages

ASHP recognizes that the ramifications of Hurricane Maria and the ongoing challenge of obtaining critical, life-sustaining medications remains an ongoing issue for members. Along with other healthcare organizations, ASHP expects to revisit this issue with Congress in 2018 with the goal of seeing new public policy enacted to help prevent and mitigate the impact of shortages. [Learn More](#)

Opioids

ASHP continues to work with key stakeholders to address the opioid crisis. In particular, ASHP has been supportive of efforts to [promote prescriber education](#) on addiction risk, outlining the [key role pharmacists play in pain management](#), and advocating for additional Congressional funding for the Comprehensive Addiction and Recovery Act, enacted in July 2016. [Learn More](#)

Actions on Advocacy Issues

340B Drug Pricing Program

- Submitted [comments](#) to CMS on the Hospital Outpatient Prospective Payment System (OPPS) proposed rule opposing reimbursement cuts under Medicare Part B
- Produced an [Issue Brief](#) on Hospital Outpatient Payment System Rule 340B changes
- Submitted [letter of support](#) for 340B bill: H.R 2889, the Closing Loopholes for Orphan Drugs Act
- Produced member alert on the House Energy and Commerce Oversight and Investigation Subcommittee: Hearing Examining Health Resources and Services Administration (HRSA) Oversight of the 340B Drug Pricing Program
- Submitted [letter of support](#) for H.R 4392, which would prevent cuts to Medicare Part B OPPS program for drugs purchased through the 340B program

Biosimilars

- Reviewed proposed legislation for the South Dakota Society of Health-System Pharmacists on biosimilars
- Submitted [comments](#) to the Office of Management and Budget urging them to stay implementation of the final FDA guidance regarding biosimilar naming
- Secured FDA commitment that there will be biologics guidances specific to hospitals and health systems in 2018
- Attended an FDA meeting on biosimilars

Compounding

- Provided written assistance to the Kentucky Society of Health-System Pharmacists for remarks to the Kentucky Board of Pharmacy regarding USP Chapter 797
- Secured FDA commitment that there will be repackaging guidances specific to hospitals and health systems in 2018
- Attended a listening session at the FDA

Diabetes Prevention Program

- Attended a meeting at the CDC to highlight pharmacists' role in the Diabetes Prevention Program (DPP)
- Submitted [comments](#) to CMS on Physician Fee Schedule in support of DPP payment model
- Produced an [Issue Brief](#) on the CMS Physician Fee Schedule proposed rule, which included reimbursement information on DPP

Drug Pricing

- Produced an [Issue Brief](#) on Part D Proposed Rule for CY 2018, focusing on direct and indirect remuneration (DIR) fees
- Produced [Drug Pricing Legislation Tracker](#), which supplies summaries and information on both the cosponsors and the status of legislation related to drug pricing
- Submitted letter of support to the House and Senate cosponsors of [S. 413/H.R. 1038](#), the Improving Transparency and Accuracy in Medicare Part D Drug Spending Act, a bill that would eliminate DIR fees
- Submitted [Statement for the Record](#) to Senate HELP Committee hearing: The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay, Part I
- Submitted [Statement for the Record](#) to Senate Health, Education, Labor, and Pensions (HELP) Committee hearing: The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay, Part II
- Submitted [Statement for the Record](#) to House Judiciary Committee hearing: Antitrust Concerns and the FDA Approval Process
- As part of CSRxP, ASHP submitted letter of support to original cosponsors of S.974, the Creating and Restoring Equal Access to Equivalent Samples Act of 2017 (CREATES)
- Submitted [Statement for the Record](#) to Senate HELP Committee hearing: The Cost of Prescription Drugs: An Examination of The National Academies of Sciences, Engineering, and Medicine Report “Making Medicines Affordable: A National Imperative”

Drug Safety

- Submitted [Statement for the Record](#) to the House Energy and Commerce Committee Health Subcommittee hearing: Examining FDA’s Prescription Drug User Fee Program
- Submitted [Statement for the Record](#) to the House Energy and Commerce Committee Health Subcommittee hearing: Examining Medical Product Manufacturer Communications
- Submitted [comments](#) to FDA on Risk Warning Information

Drug Shortages

- Submitted [statement to leaders](#) of the Energy and Commerce Oversight and Investigation Subcommittee regarding the hearing “Examining HHS’s Public Health Preparedness for and Response to the 2017 Hurricane Season” on impact to drug shortages
- Met with Federal Trade Commission and FDA to discuss ongoing drug shortages crisis
- Led [sign-on letter](#) urging Congressional action on drug shortages
- Launched a lobbying effort of multidisciplinary stakeholders to advocate for long-term solutions for drug shortages
- Developed a [grassroots letter](#) for members to send to their Congressional delegation about the impact drug shortages have on patient care

Healthcare Reform

- Developed [Principles on Health Care Reform](#) detailing ASHP policy priorities
- Submitted [letter to Senate Leadership](#) on H.R. 1628, The Better Care Reconciliation Act of 2017 (BCRA)
- Submitted [letter of support](#) to Senators Alexander and Murray for their bipartisan efforts to stabilize exchanges and shore up the Affordable Care Act

Opioids

- Submitted [comments](#) to FDA on Prescriber Education
- Attended meetings at FDA concerning opioid education and REMS
- Produced [summary](#) of 21st Century Cures Act

Patient Safety

- Submitted nomination to CMS for a Quality Measures Technical Expert panel
- Attended meeting at FDA on patient engagement in clinical trials

Pharmacy Technician

- Led Texas Pharmacy Technician Stakeholder Group
- Wrote a letter of support for California Senate bill 716 on adding a pharmacy technician to the state board of pharmacy
- Provided the Missouri Society of Health-System Pharmacists with strategies for pushing pharmacy technician issues related to education, certification and registration, board of pharmacy regulations, and scope of practice

Provider Status

- Submitted [letter of support](#) to Senate Leadership on the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017
- Submitted [Statement for the Record](#) to the House Energy and Commerce Committee Health Subcommittee hearing: Examining Bipartisan Legislation to Improve the Medicare Program
- Submitted [comments](#) to CMS on Center for Medicare & Medicaid Innovation (CMMI) Request for Information

Reimbursement

- Submitted [comments](#) to CMS on Health Insurance Prospective Payment System
- Submitted [comments](#) to CMS on Physician Fee Schedule in support of TCM/CCM codes
- Developed language for the Kentucky Society of Health-System Pharmacists for the state's Medicaid Managed Care legislation

State Practice Acts

- Provided the Arkansas Association of Health-System Pharmacists with materials to assist in making changes to their state practice act
- Reviewed and recommended changes to the South Dakota Society of Health-System Pharmacists to their state practice act
- Provided opinion and materials to the Missouri Society of Health-System Pharmacists on their telehealth law
- Proposed changes to the Alabama Society of Health-System Pharmacists on collaborative practice legislation and offered strategies on how to process

Track and Trace

- Submitted [comments](#) to FDA on Trading Partners Guidance
- Attended two public meetings on the Drug Supply Chain Security Act (DSCSA) at the FDA

Introduction Letters

- Sent letter to Secretary of Health and Human Services, Tom Price
- Sent letter to FDA Commissioner, Scott Gottlieb
- Sent letter to CMS Administrator, Seema Verna

Legislative Day

Each year, ASHP holds two legislative days for members. The first of 2017 occurred as part of the Student Advocate Training and Legislative Day, and the second took place during ASHP's Policy Week. Sixty-four student members attended Student Advocate Training and Legislative Day. Over the course of a day, students were trained on their role in advocacy and the issues impacting pharmacists. The students met with sixteen Congressional offices and discussed how their education prepares them for patient care, specifically advocating for support of [Pharmacy and Medically Underserved Areas Enhancement Act](#) (H.R. 592 and S. 109).

ASHP's Annual Legislative Day occurred during ASHP Policy Week. The 97 participants visited 122 Congressional offices, discussing ASHP's stance on provider status, drug pricing, DIR fees, preserving the 340B program, and funding to stem the opioid epidemic. Members drew on their experiences with patients and their knowledge to explain the importance of these issues to members of Congress and their staffers.

In total, ASHP members helped secure more than 10 new cosponsors in both the House and Senate through their legislative day meetings and follow-up communications to H.R. 592 and S. 109.

Meetings with Government Officials

A new president means an all-new cabinet, new administrators, and new policy staff at the agencies. In 2017, ASHP met with several high-level agency officials to discuss issues such as provider status, drug pricing, and the importance of the 340B Drug Pricing Program. As agencies consider administrative action on our issues, it is critical that ASHP convey our public policy goals and interests to these groups, who oversee the healthcare environment. Our work with the agencies is ongoing; meetings such as these are critical elements of our advocacy platform.

In May, ASHP met with CMS Administrator Seema Verma to discuss provider status, drug pricing, and DIR fees. CMS later released a proposed rule that limits DIR fees.

In April, ASHP participated in a Government Accountability Office (GAO) interview on opioid takeback bins. We were asked to participate as a result of our members' work in hospitals that are eligible to have the bins installed. The [report](#) was published in October 2017 and describes participation rates among entities eligible to collect unused prescription drugs and factors that affect participation.

In August, ASHP met with Health Resources & Services Administration (HRSA) Administrator George Sigounas to discuss provider status and to express support for the 340B program.

In September, ASHP met with HHS Policy Director Jonathan Brooks to discuss provider status and how it will help Medicare beneficiaries to gain access to care.

In October, ASHP participated in a GAO interview on the Department of Veterans Affairs (VA) inventory management to understand best practices in inventory management. The GAO is examining how the VA practices compare to other institutions.

In December, ASHP spoke with FDA Commissioner Scott Gotlieb to reiterate our commitment to work with the agency on issues such as compounding and drug shortages.

Presentations

Over the course of the year, the Government Relations staff presents to numerous audiences on ASHP's top policy issues and lobbying techniques.

Continuing Education

Each year, the Government Relations Division presents at ASHP's Summer Meetings and ASHP Midyear Clinical Meeting. The presentation is a continuing education session on the year's top issues at both the state and federal level, touching on what has occurred at the state and federal level and what to look for in the coming months.



Presentations to the FDA

ASHP has presented to the FDA and arranged for members to present on compounding and the DSCSA.

Presentations to Students and New Practitioners

- The Government Relations Division began 2017 with a webinar and training sessions for students attending the Student Advocate Training and Legislative Day. Students were educated on ASHP's provider status efforts and lobbying techniques.
- Chris Topoleski presented overviews of the work of the division to Texas A&M Student Society and NEOMED Pharmacy Law class.
- During the ASHP Resident Visits, the division presented an overview of the issues during each of the three sessions to residents.
- On behalf of the division, Nick Gentile presented to the residents from Johns Hopkins during their visit to ASHP Headquarters.
- Chris Topoleski presented on provider status as keynote speaker at the Eastern States Resident and Preceptor Conference.

State-Based Presentations

- Chris Topoleski presented an overview of the year's issues as keynote speaker at the Academy of Health-System Pharmacists of the Montana Pharmacy Association meeting.
- Joe Hill presented an issue update to the West Virginia Society of Health-System Pharmacists.
- At the joint meeting of the California Society of Health-System Pharmacists and Nevada Society of Health-System Pharmacists, Joe Hill presented on provider status.
- ASHP arranged for ASHP member Barbara Lacher to speak at the National Boards of Pharmacy District 5 meeting on pharmacy technician issues.
- Nick Gentile presented an overview of the work of the division during the Affiliated State Society Executives Meeting.

Legislative Day Training

In preparation for ASHP's annual Legislative Day, Chris Topoleski conducted a webinar and in-person training for participating members on the issues they will be lobbying on and what to expect from the experience.

Webinars

- In January, the division held the State of Pharmacy webinar on the state of pharmacy, discussing what we could anticipate at the state and federal level for 2017.
- In August, Jillanne Schulte and Nick Gentile held a webinar updating members on the compounding guidances issued by the FDA.

Coalitions

ASHP is an active participant in several coalitions aimed at influencing public policy. These coalitions help amplify the voice of our members and ensure that they are heard across a variety of professions and at all levels of government.

Patient Access to Pharmacist Care Coalition (PAPCC)

ASHP is a member of the PAPCC Steering Committee. PAPCC was formed to draft and pass legislation to include pharmacists as providers in the Medicare Program.

Campaign for Sustainable Rx Pricing (CSRxP)

ASHP is a lead member of this coalition made up of consumers, clinicians, hospitals, payers, and retailers. The goal of this coalition is to seek market-based changes that would help spur drug company competition to combat the problem of skyrocketing drug prices.

Alliance for Safe Online Pharmacies (ASOP)

ASHP is an active member of ASOP, whose goal is to educate policymakers and the public on the use of registered online pharmacies and the potential dangers of purchasing from rogue internet sites.

National Consumers League (NCL)

ASHP participates in NCL's Health Advisory Council, a group made up of organizations from all parts of healthcare. As a member of NCL, members of the division provide routine updates for their quarterly newsletter on provider status, and other issues impacting public health.

Alliance for a Stronger FDA

ASHP is a lead member of the Alliance for a Stronger FDA, a coalition committed to ensuring that the FDA has the necessary resources to protect patients and consumers while maintain public confidence and trust in the FDA.

Professional Development

To enhance their advocacy skills, the division maintains membership in other groups that provide technical support and professional growth for government relations professionals.

American Society for Association Executives (ASAE)

ASHP maintains membership in this group for professional growth. In addition to individual growth, the division utilizes it for suggestions on growing our grassroots work and fundraising.

National Association of Business PACs (NABPAC)

NABPAC focuses on helping companies and associations build their political action committees, comply with reporting requirements, and provide networking opportunities for government relations professionals. NABPAC has offered tips for improving ASHP-PAC fundraising efforts.

Public Affairs Council (PAC)

PAC provides professional growth and development for government relations professionals. The division utilizes PAC to continuously improve our fly-in events and compliance for our quarterly lobbying disclosure reports.

ASHP-PAC

ASHP-PAC supports friends of health-system pharmacy running for the United States Congress by providing contributions to their campaigns and political or leadership committees. ASHP-PAC evaluates contribution requests based on the following considerations.

Primary Considerations

- The candidate's position on issues affecting health-system pharmacists or pharmacy.
- The candidate's membership on key healthcare committees or likelihood to hold such a position in the future. Top committees for consideration include:
 - House Ways and Means
 - House Energy and Commerce
 - Senate Finance
 - Senate Health, Education, Labor, and Pensions
- The candidate's experience and leadership position or the likelihood that the candidate is likely to hold such a position in the future.
- The nature and strength of the candidate's viability in a given election.
- The candidate's relationship and history with ASHP member(s) or ASHP state affiliates within the candidate's district.

Additional Considerations

- Open-seat candidates with a history of support for or direct connection to health-system pharmacy.
- Contributions to Leadership PACs may be considered when a member of Congress is part of the leadership of a party or on a relevant committee.
- Contributions to national party committees may be given.

In 2017, ASHP-PAC contributed to the following members of Congress:

Sen. Tammy Baldwin (D-WI)
Rep. Marsha Blackburn (R-TN)
Rep. Gus Bilirakis (R-FL)
Rep. Michael Burgess (R-TX)
Rep. G. K. Butterfield (D-NC)
Rep. Earl "Buddy" Carter (R-GA)
Sen. Ben Cardin (D-MD)
Sen. Bob Casey (D-PA)
Sen. Susan Collins (R-ME)

Rep. Diana DeGette (D-CO)
Rep. Brett Guthrie (R-KY)
Rep. Trey Hollingsworth (R-IN)
Rep. Steny Hoyer (D-MD)
Rep. Ron Kind (D-WI)
Rep. Bob Latta (R-OH)
Rep. Dave Loebsack (D-IA)
Rep. Kevin McCarthy (R-CA)
Sen. Claire McCaskill (D-MO)



Rep. Cathy McMorris Rodgers (R-WA)
Sen. Debbie Stabenow (D-MI)

Rep. Greg Walden (R-OR)

Additionally, ASHP-PAC contributed to the Democratic Congressional Campaign Committee and the National Republican Congressional Committee.

Professional Profiles

Joseph M. Hill is the Director of the Government Relations Division. He advocates ASHP's positions on critical issues before members of Congress and their staff. Before coming to ASHP, Mr. Hill was Government Affairs Manager for the American Society of Consultant Pharmacists (ASCP), where he represented ASCP before state and federal legislators. Mr. Hill holds a Master of Arts degree in political science from the University of Tennessee and a Bachelor of Arts in political science from Indiana University of Pennsylvania.

Nicholas J. Gentile is the Director of State Grassroots Advocacy and Political Action. In this position, he works with state affiliates on state-level legislation and promotes ASHP's grassroots mobilization efforts and its political action committee, ASHP-PAC. He received his bachelor's degree from The American University, where he majored in political science and law in society. Prior to joining ASHP, Mr. Gentile spent ten years at the National Association of Home Builders (NAHB), working in various positions in the Government Affairs Department. He worked on state and local government affairs issues, federal relations, grassroots mobilization and BUILD-PAC (NAHB's political action committee).

Naomi Michaelis is the Senior Manager for the Government Relations Division. Ms. Michaelis coordinates with Congressional offices in arranging Legislative Day appointments for ASHP members and produces the legislative tracker on drug pricing, in addition to other tasks. Before starting at ASHP, she worked as the student coordinator and field organizer on four political campaigns in the state of New Jersey. Ms. Michaelis holds a Masters of Public Administration from the Trachtenberg School of Public Policy and Public Administration at the George Washington University and a Bachelors of Arts in political science from Rutgers University.

Jillanne Schulte Wall is ASHP's Director of Federal Regulatory Affairs. Ms. Schulte Wall serves as the association's primary liaison to federal regulatory agencies and, as an integral member of the government relations team, communicates ASHP's position on issues impacting the profession of pharmacy to federal policy-makers. She also works closely with other stakeholders in pharmacy, medicine, manufacturing, and patient advocacy on legislative and regulatory issues of importance to ASHP's members. Prior to joining ASHP, Ms. Schulte Wall was the Director of Regulatory Affairs at the American Pharmacists Association. Ms. Schulte Wall began her career as a healthcare attorney at Feldesman Tucker Leifer Fidell LLP in Washington, DC, advising healthcare clients on corporate, regulatory, and transactional issues, with a particular emphasis on optimizing performance after the implementation of the Affordable Care Act.

Christopher Topoleski is the Director of Federal Legislative Affairs in the Government Relations Division. Chris joined ASHP as the Director of Federal Regulatory Affairs in March 2011. As Director of Federal Legislative Affairs, Chris positions ASHP as a credible, valued participant on medication use and pharmacy practice issues under consideration by the United States Congress. Most recently, Chris successfully worked to change the Food, Drug, and Cosmetic Act to amend compounding law at the Federal level and to address shortages of critical medications and is currently representing ASHP on Capitol Hill advocating for recognizing pharmacists as providers under Medicare. Chris has 22 years of health policy experience in Washington, DC, including positions in the biopharmaceutical industry and as a Budget Analyst at the Congressional Budget Office (CBO); he has also done both health policy and economic consulting. Chris received his Bachelor of Arts in Economics from Mary Washington College in Virginia.