

TRANSLATING YOUR EXPERIENCE INTO ACTION

Your Guide to Grassroots Advocacy



Bristol-Myers Squibb

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ADVOCACY IN MOTION





CAN MY VOICE
REALLY MAKE A
DIFFERENCE?

INTRODUCTION

Can the power of your story have an impact? Whether you are a patient, family member, caregiver, healthcare provider, or an advocacy organization, the answer is YES.

In this guide, you will learn:

- 1) Basic understanding of advocacy
- 2) Why advocacy is important, particularly for healthcare issues
- 3) How your voice and actions can directly affect your community, your state, and the nation
- 4) The difference between advocacy and lobbying

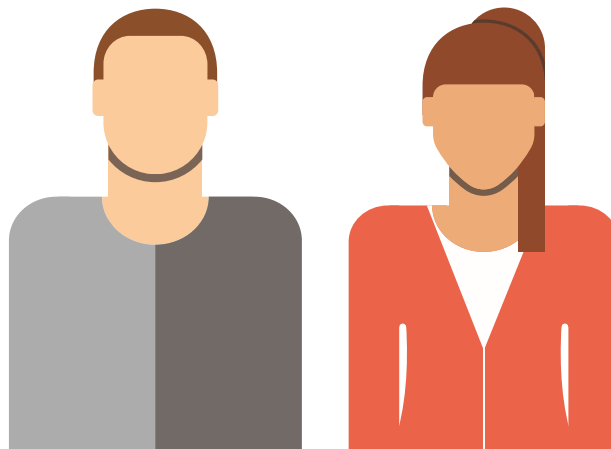
This guide will share the important steps to make sure your voice is not just heard, but heard by the right people.

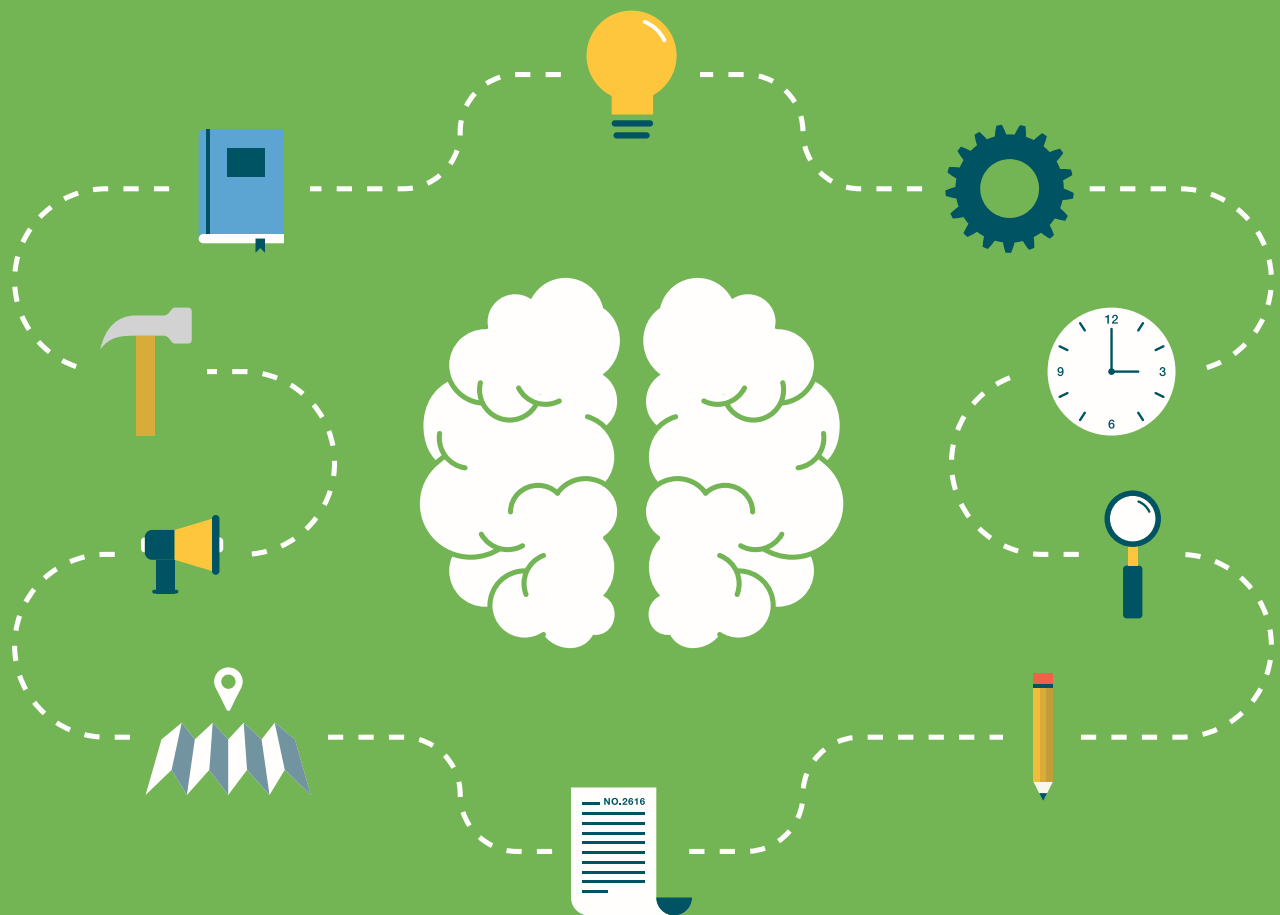
You and your story are an important part of the advocacy process. As you read through the guide, keep your story and experiences in mind, and you will begin to see how your voice, and the collective voices of those with common interests, can affect important healthcare issues.

Will sharing my story make a difference for others like me?

Do people really care about what I have to say?

Can my experiences really help others, and potentially influence the way future patients are treated?





LEARNING THROUGH ADVOCACY

BECOMING AN ADVOCATE

An advocate is an individual who stands up for – and supports the rights of – another individual or group of individuals. You can be your own advocate or you can advocate on behalf of other people with similar interests or concerns. Have you ever encouraged another person to learn more about a particular issue? You were an advocate, helping to educate others. Have you ever asked questions to your doctor about your own treatment, or the treatment of a loved one? You were an advocate, learning more about your disease.

Advocates can take on many different roles, including:

- Looking out for the best interests of a family member going through treatment
- Speaking in a public forum for a particular issue or cause that's important
- Meeting with an elected official, regulators, or other policy makers about an important healthcare issue

What Is Advocacy? /ad-voh-kah-see/

Advocacy is an opportunity to educate. Educate others about an issue or cause that is important to you and others. Advocacy can begin with the concept of an idea, and can continue all the way through the legislative process, until that law is passed. Then it can carry over into the development of rules and regulations through the regulatory process.

- Through advocacy you can engage with elected officials when they are in the process of making laws, and you can engage with regulators as they go through the process of implementing those laws.
- Through advocacy you can educate elected officials, regulators, and other policy makers when they make decisions that affect people's lives.

- Through advocacy you can use your personal experiences and experiences of those around you to collectively voice concerns to positively impact public policy.

The principal aim of advocacy is to draw attention to an important issue or cause by educating key decision makers about the impact of those decisions on everyday people. You can advocate on a state or national level by discussing issues directly with your elected officials, regulators, and other policy makers.

What Is the Importance of Your Voice and Actions?

As advocates, your voice and actions can be vital in delivering messages for those who can't, and it's your voice and actions that make a difference in shaping healthcare policy and initiatives. You have the ability to shine a spotlight on a cause or an issue that has previously gone unnoticed, and policy makers and regulators will pay closer attention when they hear stories from individuals about their own personal experiences. Your voice and actions can ensure that your rights are upheld, and that issues you think are important don't go unnoticed. Policy makers are always looking for ways to better understand the issues that are important to their constituents, and regulators are always open to hearing how the law and policies that they help to implement have a direct impact on patients. And it is your voice and actions that can help them do just that!

THE DIFFERENT TYPES OF ADVOCACY

There are many different approaches to advocacy. Each type of advocacy has the potential to build a foundation for another level of advocacy.



TOWN HALL MEETING: An organized meeting within your community.
LEGISLATOR: An individual who develops policy as an elected official on behalf of their community and/or constituents. Also referred to as policymaker.

CONSTITUENT: A member of a district or a community.
DISTRICT: An area of a county or city.



INDIVIDUAL & PERSONAL ADVOCACY

Personal advocacy can be done by an individual on their own behalf, or for a family member or friend. An individual or personal advocate looks out for the best interests of a patient as they move through the treatment of their disease.

A personal advocate can be a family member, close friend, co-worker, or healthcare professional. An advocate can help ensure a patient understands the different types of medications that are prescribed, assist in tracking the side effects of medications, and listen closely when meeting with members of the patient's healthcare team. This individual can also help a patient understand their rights and ensure those rights are understood and upheld.



FEDERAL & NATIONAL ADVOCACY

Advocating at the Federal and/or National level within the legislative process and the regulatory process are equally important. On a legislative front, it can be accomplished in your elected official's home district or on Capitol Hill in Washington D.C. Within the regulatory process, it can be accomplished through patient interaction with the FDA as well as other government agencies.

It is important that the people who are part of the legislative process and the regulatory process hear stories from those who are personally affected. It is your personal story tied in with facts about your own experience that can bring elected officials and regulators to become emotionally engaged with a particular issue. Your advocacy efforts may focus on a letter campaign or petition for change, or you may focus your efforts towards a congressional call-in. There are multiple ways to have your voice heard within both the legislative process as well as the regulatory process.

For examples of ways to advocate within the legislative process, reference Module 2, Engaging with Elected Officials.

For examples of ways to advocate within the regulatory process, reference Module 3, Engaging with Regulators.



STATE ADVOCACY

There are often opportunities to engage with elected officials and regulatory agencies at the state level. Research and determine if there are any state level advocacy organizations or associations that are already tackling the issue with whom you might consider collaborating before starting this journey on your own. The collective voice can be very powerful, and this may be a more effective way of accomplishing your goal than "going it alone."

Communication with your state legislators and regulators can have a direct effect on healthcare issues. As a resident of your state, you are a constituent to whom elected members of the legislature have a responsibility. Elected officials and their staff carry out that responsibility in part by meeting with their constituents and hearing their stories or concerns. On the state level, regulatory agencies carry out their responsibilities, in part, through state health departments, through state insurance agencies, and through state medical and pharmacy boards. An advocate's voice can make a difference within all of these agencies, and on all of these boards.

To learn about advocating within these regulatory bodies, reference Module 3, Engaging with Regulators.



COMMUNITY OR LOCAL ADVOCACY

Community or local advocacy involves bringing attention to a particular issue that might affect others within your community. It can involve the creation of programs and services to educate your community and raise awareness of the cause.

Through this type of advocacy, partnerships and collaborations can develop that help influence both the development and implementation of public policies. For example, by bringing people together in your local area or organizing a town hall meeting, you can increase the awareness of a healthcare issue through collective voices.

To learn more about organizing a town hall meeting, reference Module 2, Engaging with Elected Officials.

Why Advocacy Is Important in Healthcare

Healthcare is a complex issue. It commands the availability and timely delivery of safe and effective care and medicine to patients in need. It aims to deliver excellent quality in medications that should be delivered without disparity. Advocacy in healthcare is one way we can ensure that policies and regulations truly have the outcome that elected officials and regulators had initially intended—that patients receive the healthcare they need.

Healthcare today is different than it was five years ago. With the implementation of the Affordable Care Act (ACA), there has been a new emphasis on measuring patients' experiences of care and using that information to improve care. The ACA encourages healthcare providers and patients to work together to make more informed treatment decisions based on an understanding of available options, and each patient's circumstances, beliefs, and preferences. So now is a critical time for patients to be educated and engaged in their own healthcare.

Advocacy in healthcare is an important and ongoing process involving many stakeholders – the most important being patients. As the healthcare system continues to change, it is important to support and promote patient protections and to oversee healthcare policies and initiatives to ensure sound policy development.

Differentiating Between Advocacy and Lobbying

It is important to understand the difference between advocacy and lobbying. Lobbying is an attempt at influencing specific legislation, but advocacy involves a much broader range of activities.

Through advocacy, organizations and those they represent can help elected officials find specific solutions to persistent problems. Advocacy organizations can and should take advantage of their ability to advance issues important to their constituents, and education is a critical part of that success. Advocates help to educate.

Lobbying, on the other hand, involves activities that are in direct support of or opposition to a specific piece of introduced legislation. It is “OK” for advocacy organizations to engage in some form of lobbying; however, it is important to remember the IRS has very strict rules about what portion of an organization's budget can go toward lobbying activities without an organization losing their non-profit, 501 (c)(3) status. So before engaging in any sort of lobbying activities, check the laws in your state to ensure you are in compliance.



You might want to do some research online to learn more about established advocacy organizations in your local area, or on the national level, that might be tackling an issue that is important to you or a loved one. Many times, local and national advocacy organizations have their fingers on the pulse of healthcare issues. These issues may include removing barriers to accessing medications for patients who are in need. If so, that might be a more efficient place to start. Generally, advocacy organizations have a track record of looking out for the best interests of patients' healthcare rights.



DISPARITY: Lack of similarity or equality.

OK, I THINK I'M
READY TO BE
AN ADVOCATE.
WHAT'S NEXT?





DEVELOPING PARTNERSHIPS

A collaborative partnership involves people and groups working together to achieve a common goal. A collaborative partnership provides mutual benefits for each of its partners and allows each partner to utilize its resources more effectively.

The Benefits of a Collaborative Partnership

By thinking, planning, and working together, individuals and groups can achieve goals that neither can do alone. Partnering with others can not only increase the volume of your voice, but it can also provide some diversity to your messaging. A collaborative partnership will combine different perspectives from a variety of individuals or groups, and can lend credibility and strength to your end message or goal. In any collaborative partnership, it is important to identify the key stakeholders surrounding your issue and investigate whether collaboration with any of those stakeholders makes sense. Other individuals with a common interest may provide a perspective that you or your group has not yet thought of.

Partnering Effectively with Others

Before you consider the idea of a partnership, it is important to consider and identify your organization's strengths, your available resources, and your areas of expertise. This will allow you to seek out individuals and groups that will complement your mission or goal. Building effective and long-lasting collaborative partnerships takes time and trust.

Establishing collaborative partnerships can provide a structure for planning and implementing ideas while working toward a common goal. Here are some tips to think about when developing a successful collaborative partnership:

- 1) What do you hope to gain from this partnership?
- 2) Do you share common goals and expectations? Will this partnership allow you to stay true to your original mission or goal?
- 3) Have you established a clear understanding of the roles and responsibilities?
- 4) Is there a natural fit between the individuals or groups so they complement each other? What makes this relationship mutually rewarding?
- 5) Will you be able to trust and openly communicate with your potential partner(s)?

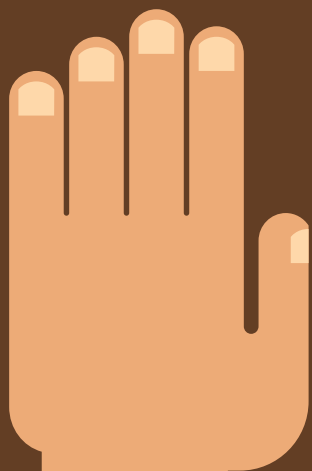
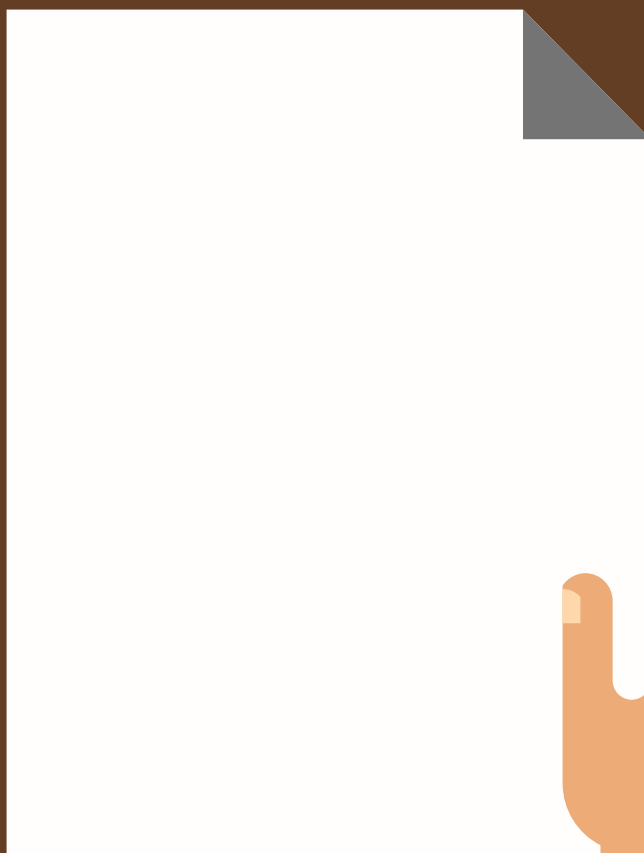


TIPS ON HOW TO PARTNER SUCCESSFULLY

- 1) Choose a partner that your organization has a connection to
- 2) Create a detailed plan of what you expect this partnership to accomplish and be specific
- 3) Promote your partnership online and in print materials



DIVERSITY: The quality or state of having many different forms or ideas; having people who are different races or who have different cultures.
STAKEHOLDER: One who is involved in or affected by a course of action.



TELLING YOUR STORY

HOW DO I TELL MY STORY?

1. PREPARE

Before you can begin to tell your story, preparation and careful planning is key. Preparation is important because as you begin to advocate for something or someone, the story you are about to tell is now part of a larger story.

Focus only on the “highlights” of your story – the meaningful parts that enable a listener to connect with you. This kind of preparation is hard but important. Practice telling your story in 10 minutes, then practice telling it in 5 minutes, and then envision having to tell in 2 minutes. Some of your greatest moments in advocacy might stem from the personal story you reduced to just a 2 minute sharing.

2. ASK

Always plan to “ask” your listener to do something. If talking to your community, your “ask” might be for them to learn more about an issue. When talking with patients, your “ask” might be to form a coalition. And if meeting with your elected official or a regulatory agency your “ask” might be as simple as “please consider my point of view.” Regardless of whom you are meeting with or talking to, be prepared and ask them to do something!

3. FOLLOW-UP

Follow-up may vary, but the act is crucial. For example, follow-up with individuals within your community might include sending additional information to them on the issue at hand. Or following-up with your elected official or regulatory agency may simply be a note to thank him/her for their time. If for no other reason, follow-up might be just to leave the door open for future communication or interaction. Contact them at your convenience with any questions they have, remind them of your visit, and tell them you are looking forward to the next time you meet.

For tips on crafting your own message, refer to the resource and support tool, A Planning Guide for your Advocacy Efforts: Crafting your message.

For more information on direct meetings with elected legislators and the legislative process, refer to Module 2, Engaging with Elected Officials.

CONCLUSION

Regardless of who or what you are advocating for, getting started and taking those first steps can be hard. At the end of this guide, we will provide you with resources and support tools to help get you started. Identifying clear steps to take when beginning any advocacy effort is crucial. This tool will serve as a guide for your advocacy efforts through consideration of all important aspects of your plan.

You have already taken the first step in effective advocacy: understanding what advocacy is, and how to go about it appropriately. Advocacy is crucial to ensuring that healthcare policies and initiatives are meeting the healthcare standards that were intended. People will listen. So whether you find yourself advocating for a family member or advocating for policy change, advocacy is important on every level.

Additional Online Advocacy Planning Resource Tools

American Planning Association
www.planning.org/advocacy/toolbox/advocacymeetings.htm

The Aspen Institute
www.aspeninstitute.org/policy-work/a pep/tools

Getting Started: A planning guide for your advocacy efforts will assist you in:

- Clarifying the goal of your advocacy efforts
- Defining your audience
- Developing your key messages
- Identifying potential partners who can assist you along the way
- Outlining what your advocacy efforts will accomplish

RESOURCES & SUPPORT TOOLS

A Planning Guide for Your Advocacy Efforts



A PLANNING GUIDE FOR YOUR ADVOCACY EFFORTS

1. IDENTIFY & PREPARE

A. UNDERSTAND YOUR VISION AND MISSION

B. IDENTIFY YOUR ISSUE

C. ASSESS YOUR AREAS OF STRENGTHS AND WEAKNESSES

2. WHAT IS YOUR END GOAL?

A. MOBILIZING OTHER ADVOCATES

B. INFLUENCING A STATE PROCLAMATION

C. ARRANGING A MEETING WITH A POLICYMAKER ON AN ISSUE

D. GETTING A CERTAIN NUMBER OF ADVOCATES TO PARTICIPATE IN A CALL IN

E. SUBMITTING COMMENTS TO A REGULATORY AGENCY

3. DEFINE THE TARGET GROUP

A. OTHER PATIENTS OR ADVOCATES

B. MEDIA (E.G., NEWSPAPER, RADIO STATIONS)

C. LOCAL COMMUNITY LEADERS AND CONSTITUENTS

D. LEGISLATORS OR REGULATORS

4. DO YOUR RESEARCH

A. WHO DO YOU NEED TO HELP YOU ACCOMPLISH YOUR END GOAL?

B. ARE THERE OTHER ORGANIZATIONS OR ASSOCIATIONS TACKLING THIS ISSUE?

C. DO YOU HAVE THE RESOURCES AVAILABLE TO ACCOMPLISH THE GOAL?

D. ARE THERE POTENTIAL COLLABORATIVE PARTNERSHIPS TO FORM?

5. DEVELOP YOUR MESSAGE

A. CONSIDER THE AMOUNT OF TIME YOU'LL HAVE TO DELIVER THE MESSAGE

B. DEVELOP CLEAR AND SPECIFIC TALKING POINTS

C. DETERMINE WHO WILL DELIVER THE MESSAGE

6. HOW WILL YOU DELIVER YOUR MESSAGE

A. IN PERSON

B. ON THE PHONE

C. EMAIL

D. LETTER

E. SOCIAL MEDIA (E.G., TWITTER, FACEBOOK)

7. HOW WILL YOU MEASURE YOUR SUCCESS?

A. DID YOU ACHIEVE YOUR GOAL?

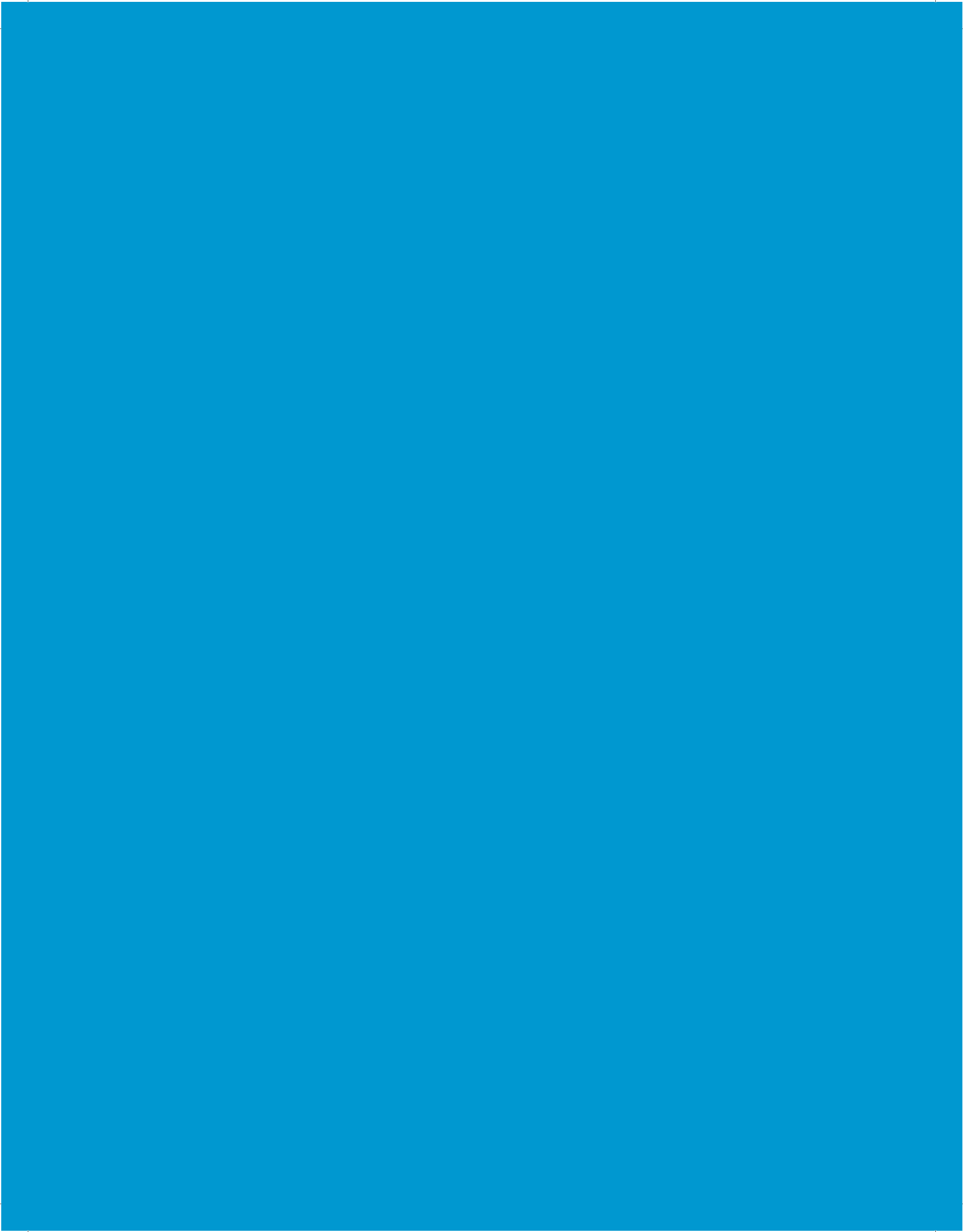
B. IF NOT, HOW WILL YOU MODIFY YOUR APPROACH?

C. WHAT WILL YOU DO DIFFERENTLY NEXT TIME?

D. WAS IT A SUCCESS?

NOTES

NOTES





ENGAGING WITH YOUR ELECTED OFFICIALS





“MY
STORY
MATTERS”

“MY VOICE IS
IMPORTANT”

“TOGETHER,
WE CAN MAKE
A DIFFERENCE”

INTRODUCTION

This guide is designed to help you develop an advocacy plan and execute it. There are different levels of success in advocacy – you will quickly see how the pieces fit together and how one success can lead to another.

Advocacy requires careful thought and planning to execute properly. This guide will review the importance of developing your own advocacy strategy prior to mobilizing your advocates. The first step to a successful strategy is creating an advocacy plan and learning where you can make a difference in the legislative process.

This guide will also help you understand the importance of state level and congressional committees, and will provide you suggestions on ways to engage with these committees. Whether you choose to engage by telephone, mail, email, or in person, this guide will provide specific suggestions on the most effective ways to accomplish your goals.

Finally, this guide will highlight additional strategies for meaningful communication, such as press releases, editorials, live testimony, and use of social media. Many elected officials utilize social media to communicate their priorities and keep a pulse on what is important to their constituents. Social media is another way to learn more about your elected official and to communicate what is important to you, their constituent.

This guide focuses on:

- 1) The importance of developing your advocacy plan
- 2) How the legislative process works
- 3) How and when to engage in the legislative process
- 4) Appropriate use of all channels of communication

Elected officials make decisions every day about healthcare issues that affect the lives of patients. Help inform their decisions. Embrace the process, plan carefully, focus on making the biggest impact, partner with others as you go and have fun along the way.

Your story CAN change lives.



PREPARE FIRST

DEVELOPING YOUR ADVOCACY PLAN

Your legislative advocacy plan is your road map to the end goal. This guide will focus on the impacts of your advocacy efforts within the legislative process and on Capitol Hill. Once you have mastered that process, you can apply those skills to other types of advocacy, such as in the regulatory setting or within your local government.

Your legislative advocacy plan (also referred to as legislative priorities) should align with the overall mission of your organization. Your plan should highlight your priorities to be addressed in legislation, and should outline the ways your organization plans to work with elected officials to ensure these issues are addressed.

Some issues are so important that they need to be solved by changing the law.

Setting Goals & Priorities

You or your organization may have different priorities that you hope to achieve. Aim high! Create goals that might take time to achieve, as long as you can clearly identify your goal and your plans to achieve it. In addition to long term goals, set short term goals – goals that you can achieve within a year or two. Your goal might be to simply increase awareness about an issue, or secure increased funding for a cause. It's important to have your legislative priorities set before you begin to engage others, because your goals will influence the ways in which you advocate.

Once you have established your legislative priorities, research which elected officials — either in your local government, state legislature, or in Congress — might help you champion your cause. When identifying which elected officials to engage, consider the following questions:

- Is there an elected official who has a personal connection to your issue?
- Is there an elected official you can influence?
- Is there an elected official who has engaged on this issue in the past?

Keep a list of these individuals. As you move forward with your advocacy efforts, you will know who to contact at the appropriate time.



REGULATORY: The rules of how a law is enforced through a government agency.

LEGISLATION: The process by which laws are made.

CHAMPION: Someone willing to support your cause.



1

A bill is written, given a bill number and introduced in either the House or the Senate.

The bill is assigned to a committee who is in charge of the topic or issue area.

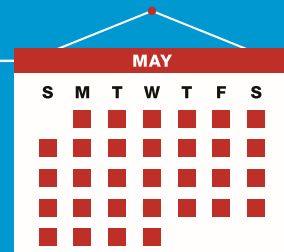
2



THE 5 BASIC STEPS IN THE LEGISLATIVE PROCESS

3

The committee meets and may review the bill, hold a public hearing on the bill, make any necessary changes to the bill and then vote on whether or not to approve the bill and send it to other committees for further review.



UNDERSTAND THE PROCESS

HOW THE LEGISLATIVE PROCESS WORKS

Gaining an understanding of how laws are made will help you determine where your advocacy efforts can have the greatest effect. Although there may be slight differences, there are five basic steps in the legislative process and it all begins with an IDEA. The idea doesn't have to come from an elected

official; it can come from an advocate or an advocacy organization. If you can gain the support of elected officials with your idea, they can initiate the process of creating a bill. And keep in mind, this process can take years.



BILL: A draft of a proposed law.

CHAMBER: Either the House of Representatives or the Senate.

4

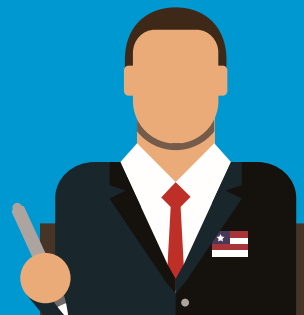
If the bill has continued support, it is placed onto the calendars of either the House or the Senate for debate, and also goes through budget approval with that chamber.

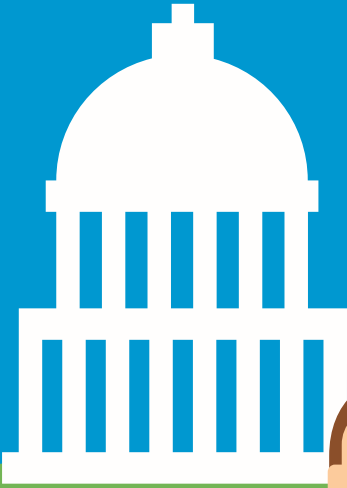


If the bill still needs continued support, it goes to the other chamber and repeats the process.

5

Once both chambers agree on the language of the bill, it goes to the Governor (or the President at the federal level) to be signed into law.





STATE-LEVEL ADVOCACY

UNDERSTANDING YOUR STATE LEGISLATURE

The process for the passage of a bill is similar at the federal and state levels. A bill passed by Congress is signed (or vetoed) by the President; a bill passed by your state's legislature is signed (or vetoed) by the governor.

Healthcare policies and initiatives are handled by both the federal and state governments. Effective advocates will build relationships with their elected officials at both levels.

Most state legislatures are structured similarly to Congress, where each state legislature has both a House and a Senate. Just like in Congress, state legislatures also have committees that focus on specific topics, such as healthcare policies. As more and more bills come through state legislatures or Congress, they rely on the expertise of committee members to determine how policy should be addressed and resolved. These committees can make adjustments and changes to a bill before it is voted on. They help to organize the most important work of legislation — considering, shaping, and passing laws to govern the state/nation.¹

To learn about your state's legislature structure visit: openstates.org/find_your_legislator/, and enter the name of your state.

Learn about your state's legislative structure and the committees in place that might review a bill of interest to you. Learn about the members of each committee, who serves as committee chair and learn about their staff. Committees hold public hearings on their respective areas of authority and these hearings are a great opportunity for advocates to make a difference.

If you have developed a positive relationship with your elected official's office, you can develop some

possible questions to be asked at the hearing, or attend the hearing and provide live testimony.

Getting to Know Your Elected Officials

Building a strong relationship with your elected official and their staff is an important aspect of advocacy. Before meeting with them, you will want to do some research. On your elected official's website, you can learn more about their positions on particular issues and different pieces of legislation. Learning more about them will allow you to effectively communicate with them by considering their background and areas of interest.

Here are some facts you will want to learn about them:

- What is their political party?
- How long have they been in office?
- Are they on any committees related to healthcare or other related issues?
- What have they said or written in press releases?
- What relevant healthcare legislation have they supported or opposed in the past?

Take the time to complete this important step. You will see the benefits of your research when you meet with them. Not only will they appreciate you taking the time to learn about their positions on certain issues, but it will allow you to focus on your issue.

¹ <http://www.ushistory.org/gov/6c.asp>



COMMUNICATE EFFECTIVELY

THE IMPORTANCE OF COMMUNICATION

Communication with elected officials is tracked by their offices and allows offices to keep a pulse on important things happening within their district and with their constituents. Phone calls about issues may be categorized, letters may be compiled, and emails may be counted. Officials care what their constituents have to say, and your communication with them can be vital in bringing attention to an issue that they may not be aware of. However you choose to communicate with elected officials (phone, mail, or in person) consider these helpful tips:

Communicating by Phone

Contacting your elected official on the phone is easier than you might think. If you are trying to connect with someone in your state legislature, visit their website and their number will be listed there.

Before you make a call to an elected official's office, be clear on the following:

- 1) Why you are calling
- 2) What issue you are calling about
- 3) What you would like them to do

Always ask to speak with your elected official, and if they are unavailable, talk with their staff member. Rest assured, your conversation with that person in his/her staff makes a difference! The office staff is very important, so get to know them well! They have the ears of the elected official and can help facilitate interactions with them.

Communicating by Mail or Email

Writing a letter or an email to an elected official can be a very effective form of communication. Your letter or email should have 5 basic parts:

- 1) Use the appropriate address and salutation

- 2) Begin your letter with what you are asking them to do
- 3) Include any relevant bill numbers
- 4) Tell your story; don't threaten, be polite, clear, and concise
- 5) Offer yourself as a future resource if they have any further questions



Given security measures surrounding mailed letters to elected officials, you might want to consider an email as your preferred method of communication, rather than a mailed letter.

Communicating in Person

Face-to-face meetings with elected officials can be a very effective form of communication. A personal connection engages them in a way that no other form of communication can. You can set up your own meetings by calling your elected officials office directly.

Once you have a meeting date set, begin your preparation! Organize your thoughts and develop key talking points. See below for tips on conducting your meeting. Most importantly, remember this isn't a political meeting. Leave politics out. The elected official should remember you and your story, not your political affiliation.

Conducting Your Meeting

Develop an agenda for your meeting. Here is an example of an agenda:

- 1) Introductions
- 2) Explain why you are meeting with them
- 3) Tell them your story or personal connection
- 4) Be clear on what you are asking them to do
- 5) Answer questions openly and honestly
- 6) Leave information behind that provides additional facts
- 7) Provide your contact information
- 8) Thank them for their time



The most important part of your meeting might not even take place while you're in the meeting. It can come in your follow up! This is a crucial part of the process. In this you can remind them of your visit, encourage them to look at your leave behind and ask if they have had a chance to do what you've asked. Your meeting and follow up with them is an important step in your advocacy efforts. Your successes may come at different times throughout this entire process. Recognize your successes along the way and celebrate them.

Do not underestimate the impact one effective meeting can have on the legislative process.

To learn more about training your advocates for meetings with their elected officials, reference Module 4, Growing in Advocacy.

TIPS ON STAYING CONNECTED VIA SOCIAL MEDIA PLATFORMS



FACEBOOK

Facebook is a social media platform that allows you to connect with others and share stories. Facebook has over 1 billion monthly users - even Congress has a Facebook page: www.facebook.com/congressorg. You can utilize Facebook to directly connect with your elected official and join in discussions by posting or commenting on their walls. Join Facebook at www.facebook.com



TWITTER

Twitter is a platform that allows you to share “snippets” of information in a limited number of characters, called “tweets.” Many congressional offices have Twitter accounts and you can “follow” them to see what important issues they are working on. Twitter allows you to use “hashtags” (#) to help you categorize topics that are important to you. And if you see a post that you like or support, you can “retweet” it and immediately share it with your other followers. Join Twitter at www.twitter.com

Example of a Facebook or Twitter post to your elected official: “I am a constituent in your district, and I support bill number XXX. Please consider supporting it too by co-signing.” If twitter post, follow it with the #.



YOUTUBE

YouTube is a video sharing platform where you can share your videos and view videos that others have taken. Many congressional offices have YouTube “channels” where they post important videos. If your Congressional office has a channel, you can subscribe to it to stay connected with them. Join YouTube at www.youtube.com

Here is an example of how you can keep up with your elected official via their YouTube channel. www.youtube.com/user/RepJoeBarton



INSTAGRAM

Instagram is a picture sharing social media platform. You can take pictures and videos and share them with your followers. Instagram can only be used with a smart phone, but it’s a fun way to share experiences and to see in pictures of what your followers are up to. Join Instagram at www.instagram.com



PINTEREST

Pinterest is a visual social media platform, similar to that of a virtual scrapbook. It allows you to visually share ideas or topics that are important to you. You can create “boards” for each area of interest. For example, if there is a cause that you are advocating for, you might create a message board for that cause that you can share with others. Join Pinterest at www.pinterest.com

Here is an example of how you can learn more and create boards for certain topics of interest: www.pinterest.com/search/?q=arthritis

UTILIZE ALL CHANNELS OF COMMUNICATION

CONGRESSIONAL CALL-IN

If advocates cannot make the trip in person to meet with their Congressmen/women, your organization can arrange for a “Congressional Call-in.” Through this form of communication, you can encourage anyone involved with the cause to call their Congressmen/women’s office on a specified day and ask for support for a particular issue or cause. This type of call-in can be effective in raising awareness of an important issue. Here are some tips on setting up a Congressional Call-in:

- Set a goal: For example - To flood Members of Congress with phone calls about an important issue.
- Pick a time period: Have it separate from regular lobby day to increase participation. It can be just one day, or last an entire month.
- Set up technology: Work together with a company who will set up the phone number and the automated system message.
- Partner: Partner with other groups or associations with a common interest in the cause.
- Promote: You will need to make hundreds of calls/callers to have an impact on offices. Promote via mailed fliers and social media.
- Make the call: Develop a script for your advocates to follow that includes short talking points for advocates. First thing they should do is identify themselves as a constituent, then say the talking points of why they are calling.
- Track your progress: Use online tools to update advocates. This will show which states/districts have called in and where you need more callers so they can recruit friends and family to call. Try to get callers from every state!

- Follow up: Have your advocates follow up after the calls with a thank you to the office for listening to their concerns. Repeat the ask from the call.

TOWN HALL MEETING

You can bring people together in your local area by organizing a town hall meeting. This event can help you increase the awareness of a healthcare issue by educating your community as a whole through the use of selected speakers, panelists, experts, and patient representatives. Here are some tips on setting up a town hall meeting:

- Develop a planning committee, meeting objectives, an agenda, and meeting materials to be distributed at the meeting.
- Identify staff, speakers, panelists, moderators, and media spokespeople for your event.
- Plan logistics: Find a location, set a day and time for your event, and create an invitee list.
- Promote your event within your community: Place signs around town and in community hospitals.
- Promote your event to the media: Create a press release, call local media outlets, and contact your local newspaper.
- Promote your event on social media: Provide information on how to register/attend.
- Execute: Arrive early to set up, set up a registration table, with sign in list and attendee contact information. Identify staff to welcome attendees, start on time, and finish on time.
- Follow up: Send a thank you to attendees with a summary of the event, including who attended, what was accomplished, and what the next steps are.

PRESS RELEASES

Don't be put off by the words 'press release.' You don't have to be a journalist to write a press release. Think of a press release as a way to educate a reader or help a journalist write an article about your event or issue. If written well, it might pique the interest of a newspaper or a news station to cover your event or story in more detail. Here are some tips on writing a great press release:

- Create an eye catching (accurate) headline

For example:

Good headline: Advocacy groups join forces to make a direct impact on saving the lives of patients.

Bad headline: Local group strives for change.

- Tell your story (briefly) and establish your connection to the issue
- Use quotes from someone impacted personally by the issue
- With their permission, quote an elected official, if they were involved
- Provide your contact information
- Tell the reader where they can go to learn more

OPINION LETTERS

An op-ed is an opinion piece usually written for a newspaper that is balanced with factual information. Write clearly and concisely, but assume the reader knows nothing about your issue. Your op-ed should focus on one point and have one objective, and help readers understand why this issue should be important to them. Every newspaper will have guidelines on how to submit an op-ed; know these guidelines and follow them. Here are some tips on writing a great op-ed:

- Create an eye catching (accurate) headline

For example:

Good headline: 55 Years of Advocacy: Told in 55 sentences.

Bad headline: How advocacy can make a difference.

- Tell your story (briefly) and establish your connection to the issue
- Get to the point quickly
- Develop 2-3 main talking points
- A powerful conclusion

LIVE TESTIMONY

Live testimony at a public hearing can provide information to elected officials about how a law (or change in a law) might affect you and others. All committees often hold public hearings, and this an area where advocates can have their voices heard.

By visiting the website for your local or state government, you can find the list of upcoming public hearings addressing key policy areas.

Here are some tips on preparing for a live testimony:

- State your name and any associations or organizations you are affiliated with
- Incorporate your story into the message
- State why this issue is important to you and others
- Support your story with facts about the issue
- Be specific about what you are asking them to do
- Thank them for the opportunity to speak

POSTCARD CAMPAIGNS

Postcards aren't just for telling your friends and family about the terrific time you are having on your vacation. Postcards can speak volumes to elected officials about issues important to their constituents. If there is an important issue to your organization, a postcard campaign can be a very effective and efficient way of allowing your advocates to express their opinions. Create a postcard with an eye-catching headline or picture that addresses your issue on the front, and allows your advocates to add their personalization of it on the back. Consider enabling your advocates to download the postcard from your website where you can provide instructions on completing and sending their postcard. Here are a few tips on creating a great postcard campaign:

- Create an eye catching cover
- Pre-stamp the postcard
- Develop a postcard slogan related to your cause
- Leave an area for personalization by your advocates
- Make sure your advocates include their name and mailing address
- Set a deadline for when advocates should mail their cards to their elected officials

SOCIAL MEDIA

Outside of the other forms of communication mentioned above, the rise of social media has changed the way we communicate with each other, the way we learn about events and the way we live our daily lives. You can share pictures and videos the minute you take them and you can make your opinion known within the instant that you form one.

Given the popular rise of this communication channel, social media is just another way you can stay connected to your elected officials. Many elected officials utilize social media to keep a pulse on what is happening in their districts and states, and you can utilize social media to ensure your virtual voice is heard.

Social media does not replace the other channels of communication, such as in person meetings, mailings, and emails. Discover how to use each platform and start reaching out.

STAY ENCOURAGED

When you advocate, you are pushing for change and this may take time. Advocacy is hard work and you will have to overcome obstacles. People will tell you no, and at some point may feel like your voice is not being heard. Don't get discouraged! Focus on what you have accomplished and the impact you have made, and let that be the driving force behind your work.

Remind yourself of who or what you are advocating for, and remember the passion which drove you to take on the challenge; allow this to carry you through the tough times. This will be the thing that carries you through the tough times and help you overcome any obstacles. Once you know your end goal, you

can take (follow) many different paths to reach it. Think of advocacy like a GPS. You enter in your destination, and it gives you options on how to get there. If you veer off track, it recalculates for you. Sometimes you will have to make those same recalculations in advocacy. Consider all options, and recalculate if necessary.

Be sure to talk with other advocates and share your successes and frustrations. Advocacy can be frustrating, but can also be incredibly rewarding. Have a well thought out plan; understand the legislative process; know where you can affect it and be persistent. You are making a difference!

CONCLUSION

Effective communication with elected officials is critical to advocacy success. Just like the legislative process, advocacy is a process, and it may take time to see change.

Carry something with you at all times that you can look at, feel, and touch to remind you why you spend your time advocating. Maybe it's a picture of a loved one, a token that another patient not strong enough to fight gave you, or maybe it's your own heart that has a story to share. Tell that story with every ounce of compassion you have. These are the things that will give you strength and carry you further,

even when you think you've reached the end of a road.

Push for change, stand up for those who can't, and demand attention. Your elected officials will appreciate the firsthand knowledge of how the policies they helped to create affect patients' lives. They thrive for information and you can be a resource for them. You can help to bridge the gap between elected officials and their constituents.

When the voice of an advocate enters the ears of an elected official, change will happen.

RESOURCES & SUPPORT TOOLS

Federal Engagement
Resources

Local Media Roadmap

Effectively Communicating
with Elected Officials

FEDERAL ENGAGEMENT RESOURCES

To learn about your member of Congress:

www.govtrack.us/congress/members

To learn about Congressional House and Senate sessions:

House schedule (annual)
www.majorityleader.gov/floor/#annual

House schedule (weekly)
www.majorityleader.gov/floor/#weekly

House schedule (daily)
www.majorityleader.gov/floor/#daily

Senate schedule (annual)
www.senate.gov/legislative/resources/pdf/2014_calendar.pdf

Senate schedule (weekly and daily)
democrats.senate.gov/floor/floor-updates/

To learn about important Congressional committees related to healthcare:

House Appropriations
appropriations.house.gov/

Senate Appropriations
www.appropriations.senate.gov/

House Energy and Commerce
energycommerce.house.gov/

Senate Health, Education, Labor & Pensions
www.help.senate.gov/

Senate Finance
www.finance.senate.gov/

House Ways and Means
waysandmeans.house.gov/

House Budget
budget.house.gov/

Senate Budget
www.budget.senate.gov/

To connect with your member of Congress on the phone:

- Call the Capitol! The switchboard will connect you to any of your members' offices, at 202-224-3121.
- Visit the website below, for a listing of phone numbers for each member of Congress:
 - Senators: www.senate.gov/general/contact_information/senators_cfm.cfm
 - Representatives: clerk.house.gov/member_info/mcapdir.aspx

To write to your member of Congress:

- The Honorable (insert name), followed by the U.S. House of Representatives, or the U.S. Senate
- Dear Representative (insert last name), or Dear Senator (insert last name)

To learn about Congressional Caucuses:

You will also want to know if there is a Congressional Caucus that might help you advance your particular issue. For example, there is a Childhood Cancer Caucus, Congressional Caucus for Women's Issues, a Congressional Hispanic Caucus, a Congressional Caucus for Parkinson's Disease, and a Crohn's and Colitis Caucus. When you do your research online about your elected official, it will list if they are a member of a Congressional Caucus.

Local Media Roadmap

Use this roadmap to guide you in your media outreach.

DEVELOP MEDIA TOOLS



- Define story angle and develop tools to help support engagement with media (i.e. email template)
- Reach out to reporters (define cause + interest to their readers)
- Answer the who, what, when, where, how, of your story
- Develop talking points

DEVELOP MEDIA TOOLS



RESEARCH & IDENTIFY MEDIA TARGET

- Browse local media websites, identify reporters covering industry/sector
- Understand current key trends
- Contact reporter around timely events

RESEARCH & IDENTIFY MEDIA TARGET



IDENTIFY OPPORTUNITY

Other Considerations

- Consider the reporting timelines of the media outlet you are targeting
- Try to understand their writing style
- Follow-up with your reporter
- Be strategic in your communication timing (i.e. coordinate outreach around key awareness events)

Prep your team for media interactions. This should include:

- One one-pager reporter briefing
- Position statements

IDENTIFY OPPORTUNITY



TELLING YOUR STORY



TELLING YOUR STORY



- Identify and work with the community to support your cause
- Identify a spokesperson to communicate point-of-view
- Develop key messages that communicate your story
- Prep spokesperson in advance about reporter, angle, and potential questions

Always have a clear goal in mind and stick to the plan.

Trust in your story and don't exaggerate it. It stands on its own merit!

Do your research before your meeting to get to know your elected official and understand their positions on issues.*

Always thank people for their time.

Always have an "ask" and make sure your "ask" is clear.

Use accurate facts when referring to your issue and provide specific examples.

Ask for a business card with contact information and be sure to follow up!

Have fun and always remind yourself why you are advocating. Your voice is important!

* Visit: www.govtrack.us/congress/members



EFFECTIVELY COMMUNICATING WITH ELECTED OFFICIALS

Speak honestly and passionately.

Start with your personal story and, if in a group setting, divide up the content as to who will deliver what messages.

Always provide an example of “why this is important” to your audience.

Get to the point and stay on message.

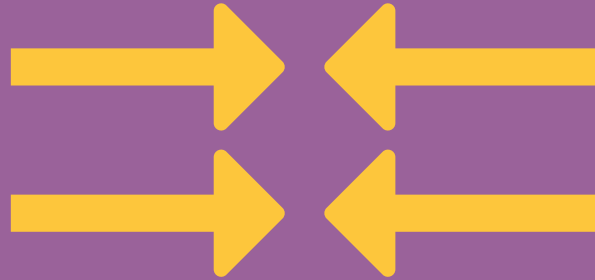
Remember that the staff in a legislative office informs and educates the legislators about important issues. The staff in an office are very important people!

Develop relationships with your legislative office and staff.

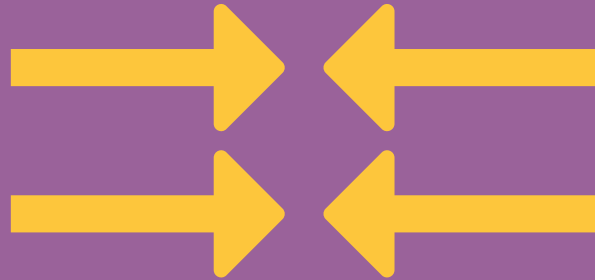
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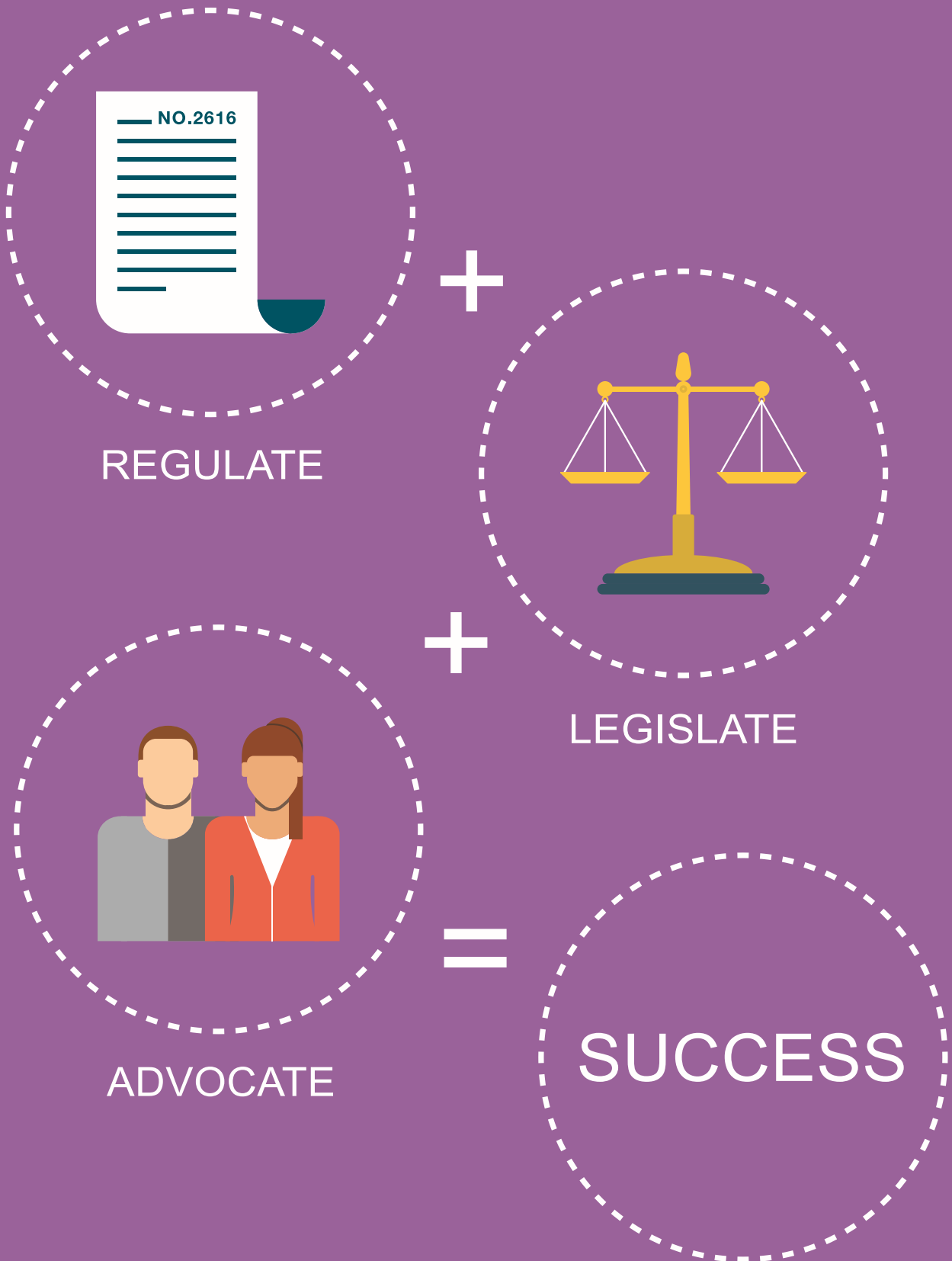
NOTES





ENGAGING WITH REGULATORS





INTRODUCTION

Advocacy is an opportunity to educate. In previous modules, you learned the ways you can advocate throughout the legislative process, but it is important you continue those efforts. At the end of the legislative process, the regulatory process begins.

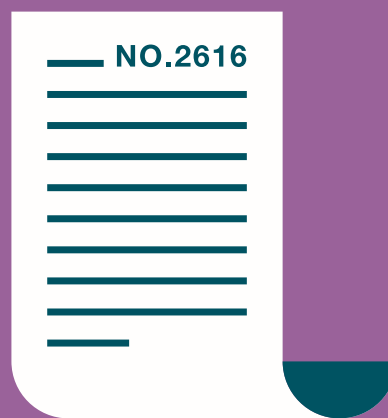
When a legislature passes a bill into a law, the regulatory process determines how that law is implemented. Where the law is vague, regulations must be specific, and it is the role of federal and state agencies to determine how that law is implemented.

In this guide, you will learn about the similarities and differences between legislative advocacy and regulatory advocacy, and why both are critical to your success for effective healthcare of all Americans. You will learn the basics of regulatory advocacy, and why this process is so complex. And last, you will learn how you and your organization can make an impact on the regulatory process.

You will discover the manner in which you advocated to elected officials is very similar to the way you will advocate with healthcare regulators. The actions and the opportunities are similar, but the difference is who you are telling your story to...



VS



REGULATORY ADVOCACY vs LEGISLATIVE ADVOCACY

Once a legislative body passes a bill, it becomes a law. Federal, state, and local agencies then create rules by which those laws should be implemented. These regulatory agencies carry out those laws through the development and enforcement of rules, also referred to as regulations.

Analogue: If you think about all aspects of an automobile – how it is built, what makes it run – the legislative and the regulatory processes are similar to that automobile. The legislation builds the framework of the car and the regulatory process builds the engine that makes it run.

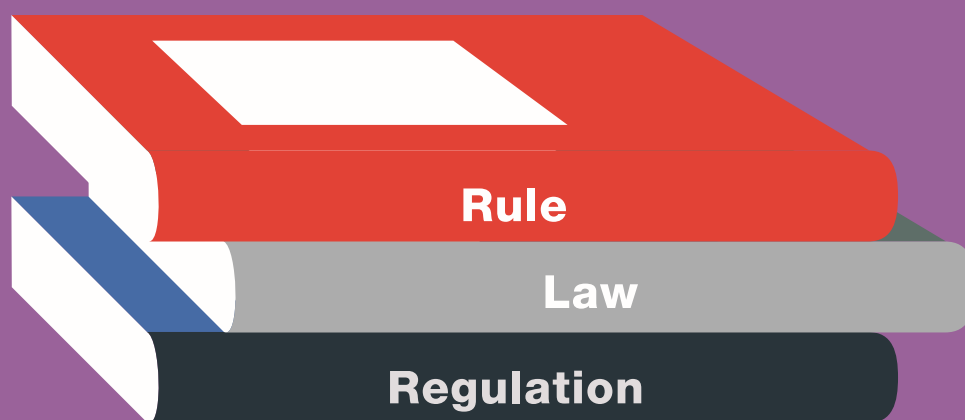
The Difference Between a Statute, a Regulation, and a Policy Guidance

On both a federal and state level, a law is referred to as a statute. A statute is a law passed by Congress or the state legislature. A regulation, or rule, is the details that outline how the statute will be enforced. The legislative process creates the law, and the federal agencies develop regulations. Regulations can be written by all levels of government: federal and state.

Once you have advocated through the legislative process with success, it is important to follow the law through the regulatory process. Legislation might be very broad, but the regulations that accompany that law must be very specific. You can help educate healthcare regulators on the impact a regulation will have in your particular state or county, and they need to hear from you.

Regulatory agencies often need to create policies too, and you can advocate for changes to policies that aren't necessarily bound by either legislation or regulation. Policies are created within the legislative process, through the regulatory process and then through a sub-regulatory process

commonly referred to as policy guidance. Policy guidance happens when a regulatory agency uses their own discretion to make a decision or change, and these types of decisions do not require legislation or regulation. It is important to understand the differences before creating your action plans.



THE BASICS OF REGULATORY ADVOCACY

Regulatory Advocacy

Regulatory advocacy is a manner in which advocates can help educate regulatory agencies to ensure laws that have been passed by Congress and state legislatures are implemented in the way they were intended. Given the current healthcare system and the implementation of the Affordable Care Act (ACA), regulatory advocacy has become a more prominent type of advocacy. Now more than ever, it is important to ensure that the patient voice is represented in all facets of healthcare regulation. Regulatory advocacy is one way to ensure that government officials hear the issues or concerns of interest to you and other patients. At a minimum, regulatory advocacy should focus on patients' healthcare rights that ensure the delivery of safe and effective quality healthcare to all patients.

The Rulemaking Process

Rulemaking is the process that agencies use to implement laws that have been passed by Congress or State legislatures. Just like advocates can help educate elected officials on the implications of a piece of legislation, advocates can help educate regulators with the implementation of the law. Advocates have a right to be part of the rulemaking process, and it is your voice that can ensure, on both a federal and a state level, the patient's voice is represented. The rulemaking process is similar at both the state and federal level.

The Process of Rulemaking on the State Level:

- a) A state legislature passes a law.
- b) Once a law has been passed, it gives the agency (sometimes referred to as state

boards, commissions, departments, or other state government entities) the authority to create the rules on which to implement the law.

- c) The agency reviews the law.
- d) Through the agency who published the rule, the public can comment on the ruling. The standard comment period is 45 days, but can be shortened or lengthened. The public can submit comments to the agency who published the rule.
- e) The agency publishes the final rule with an implementation date.

The Process of Rulemaking on the Federal Level:

- 1) Congress passes a law.
- 2) Once a law has been passed, it gives the federal regulatory agency the authority to create the rules on which to implement the law.
- 3) The agency reviews the law and publishes a proposed ruling in the federal register.
- 4) Through the federal register, the regulatory agency takes public comments. The standard comment period is 60 days, but can be shortened or lengthened.
- 5) The regulatory agency publishes the final rule with an implementation date.

NOTE: Neither a federal nor state agency is required to make any changes to the proposed rule based on the comments they have heard/read from the public, but they must address them in the final ruling.

Definition of Federal Register: The Federal Register is a little bit like the newspaper of the federal government, and it is here you can find proposed rules and public notices. To learn more about the Federal Register and the rulemaking process, visit: www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf

Healthcare Regulatory Agencies

Working underneath the President of the United States is an advisory board called the Cabinet. The Cabinet consists of 15 advisory bodies, one of which is the Department of Health and Human Services (HHS). HHS is the regulatory agency tasked with protecting the health of all Americans and providing essential human services. In addition to administering Medicare and Medicaid, HHS also oversees the Centers for Disease Control, the Food and Drug Administration, and the National Institutes of Health, among others. Some regulators are government employees, and some are political appointees.

www.hhs.gov

Definition Medicare: Medicare is the federal health insurance program for people who are 65 or older and certain younger people with disabilities.

www.medicare.gov

Definition Medicaid: Medicaid provides free or low-cost health coverage to some low-income individuals, families and children, pregnant women, the elderly, and people with disabilities.

www.medicaid.gov

Did you know: Both Medicare and Medicaid provide health insurance to one in four Americans.

Federal Level Agencies within the Department of Health and Human Services

- a) AHRQ – The Agency for Healthcare Research and Quality is a federal agency within HHS whose mission is to improve the quality, safety, efficiency, and effectiveness

of healthcare for all Americans.

www.ahrq.gov

- b) CDC – The Center for Disease Control is a federal agency within HHS who works to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same. For example, the CDC was one of the very first agencies to address and help educate the public about the Ebola Virus.

www.cdc.gov

- c) CMS - The Centers for Medicare and Medicaid Services (CMS) is a federal agency within HHS that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program and health insurance portability standards.

www.cms.gov



CMS also has ten regional offices. To learn where these regional offices are located, visit: www.cms.gov/About-CMS/Agency-Information/RegionalOffices/index.html?redirect=/Regionaloffices/

- d) FDA - The Food and Drug Administration (FDA) is a federal agency within HHS that is responsible for protecting and promoting public health through the regulation and supervision of prescription and over-the-counter pharmaceutical drugs, vaccines, biopharmaceuticals, and medical devices. The FDA regulates drug safety, efficacy, and communication. They oversee the drug development process, they have the authority to regulate drug labels and promotional materials, they regulate drug

studies and clinical trials, and provide drug approvals and/or denials.

www.fda.gov



CMS also has ten regional offices. To learn where these regional offices are located, visit: www.cms.gov/About-CMS/Agency-Information/RegionalOffices/index.html?redirect=/Regionaloffices/

- e) NIH - The National Institutes of Health (NIH) is a federal agency within HHS and is the nation's medical research agency—making important discoveries that improve health and save lives. The National Cancer Institute (NCI) is part of the NIH. They coordinate the National Cancer Program; conduct and support cancer research; train physicians and scientists; and disseminate information about cancer detection, diagnosis, treatment, prevention, control, palliative care, and survivorship. Under the NCI is the Office of Regulatory Affairs, which serves as a conduit between NCI and the cancer advocacy community.

www.nih.gov
www.cancer.gov

State & Local Level Agencies

- a) Department of Public Health – Your state's public health department is a part of the government which focuses on healthcare issues important to citizens of your state. For example, the Departments of Public Health were responsible for the promotion of the flu vaccine, in that everyone six months of age and older should be vaccinated.

To locate and learn about your state health department, visit: www.statelocalgov.net/50states-health.cfm

To locate and learn about your counties health department, visit: www.naccho.org/about/lhd/

- b) Drug Utilization Review Boards – Within each state's health department, states are required to have a drug utilization review board or program that reviews and approves medications for patients. DUR boards may also require educational material be made available to patients on certain medications.

- c) State Health Insurance Commissioner – The State Health Insurance Commissioner is the regulatory agency that oversees insurance within each state. All 50 states have State Insurance Commissioners, and they are true advocates for the people living within their state. They help enforce state insurance laws. With the onset of the ACA, state insurance commissioners can play a role in instituting the healthcare reform as it applies to their state. To find the contact information for your states health insurance commissioner, visit: www.naic.org/documents/members_membershiplist.pdf



The National Association of Insurance Commissioners (NAIC) is a standard-setting and regulatory support organization. These state regulators work through NAIC to establish standards and best practices and to coordinate regulatory oversight.

- d) State Medical Board – State Medical Boards are responsible for the licensing and regulation of all physicians within their state. To locate your State Medical Board, visit: www.fsmb.org
- e) State Board of Pharmacy – State Boards of Pharmacy are responsible for the licensing and registration of all pharmacies

within their state. To locate your State Board of Pharmacy, visit: www.nabp.net

- f) Pharmacy and Therapeutics Committees – These committees are responsible for managing drug formularies within a healthcare system. Many P & T committees, on both the state and local levels, offer opportunities for patient advocate representation.

Advocating within Departments of Public Health

Many states have an office for the healthcare advocate. On their websites you will find information about your rights as a patient, including recent state and federal regulations, and resources for you to advocate on state healthcare issues. Engage with your state healthcare advocate to advance issues important to you.

Advocating with State Health Insurance Commissioners

The Office of the Insurance Commissioner protects patients and oversees the insurance industry. You can work with the office to file a complaint or report suspected insurance fraud. They will work with you and advocate on your behalf.

Advocating with Drug Utilization Review Boards

Similar to other state commissions and boards, the Drug Utilization Review Board (DURB) meetings are open to the public. The Board promotes patient safety through an increased review and awareness of outpatient prescribed drugs. Advocates have the opportunity to submit public comment on proposed rules and regulations to drug utilization review boards.



THE INTRICACIES OF THE REGULATORY PROCESS

WHY HEALTHCARE REGULATION IS COMPLEX

Healthcare regulation is a multifaceted process. It involves government agencies on the federal, state and local levels, as well as hundreds of private organizations. These organizations include the Joint Commission and medical specialty boards. At times, the collaboration of these government agencies and private organizations is critical to the successful implementation of the laws they are charged with executing. Healthcare regulation is structured, purposefully, with this balance of public and private partnerships, and thereby ensures that each facet in the process has a represented voice. Here are just a few examples of why healthcare regulation is so complex:

Definition of Joint Commission: Works to improve healthcare for the public in collaboration with other stakeholders by evaluating healthcare organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.

www.jointcommission.org

There are patients who are insured through Medicare, Medicaid, their employer's insurance plans, or through the ACA marketplace. And those insurance plans may be paid for by the federal government, the state government, an employer, or by the individual patients themselves. Healthcare providers within each plan are paid differently, and the codes by which healthcare providers bill for services are different. Some hospitals and organizations are for profits, non-for profits, and some are run by the federal government (i.e., the Veterans Administration). And the organizations and agencies who oversee all of these entities are different.

Despite all these many moving parts, the one constant is the patient. Healthcare agencies, both public and private, are focused on providing the utmost quality of care to patients in need. The system is set up to hear from all interested stakeholders, and advocates are stakeholders too, so allow your voice to be part of the regulatory process.



ADVOCACY STRATEGIES FOR INTERACTING WITH REGULATORY AGENCIES

ADVOCATES CAN MAKE A DIFFERENCE

- Advocates can and should monitor activities at CMS and FDA and other agencies, and provide either written or public comments where appropriate. Here is an online resource that can help you track and provide comments on proposed regulations. To learn more about submitting comments or petitions to a proposed ruling, visit: www.regulations.gov or www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm?utm_source=rss&utm_medium=rss&utm_campaign=comment-onproposed-regulations-and-submit-petitions
- FDA Patient Representative Program – The FDA encourages patients and patient representatives to participate in the FDA decision-making process. They recruit patient representatives on an as needed basis. To learn more about applying for this program, visit: www.fda.gov/ForPatients/About/ucm412709.htm
- Providing comments to items published in the Federal Register is a great opportunity for advocates to participate in the rulemaking process, to tell regulators the possible effects of the proposed ruling for patients. To learn more about the Federal Register, visit: www.gpo.gov/fdsys
- Most states have state health regulatory boards, which include committees like the state Board of Medicine and the state Board of Pharmacy. Advocates can monitor when public hearings through their states health departments are being held. They

will be published in the state register. Public hearings are an opportunity for advocates to express their views on important issues.

To learn about your state Medical Board, visit: www.fsmb.org

To learn about your state Board of Pharmacy, visit: www.nabp.net

- Many state health departments allow for advocates to provide comments, either written or in person, to the states Drug Utilization Review Board. This is a terrific way for advocates to express their opinions regarding patient access to medications, or other drug-related issues. In addition to providing comments, many states also offer opportunities for consumer advocates to hold an official position on these review boards. To learn more about these potential opportunities, visit your states health department website.

SUCCESS IN REGULATORY ADVOCACY

A SMALL GROUP OF ADVOCATES MAKING A DIFFERENCE

How a small group of advocates can make a difference.

In January 2014 the FDA Cardiovascular and Renal Advisory Committee held an open public hearing to make a recommendation for or against approval of a drug to treat multiple system atrophy. A coalition of advocacy organizations, in combination with physicians and dozens of patients suffering from the same condition, provided comments to the FDA on the lack of benefit most patients experience from the only one FDA approved drug to treat this condition. Collectively, they told their stories and urged the FDA to recommend the drug for approval.

At the end of the hearing, the committee voted and recommended approval, 16-1. During the committee comments after the vote, members made it very clear that the patient testimony played an important role in their vote. Thanks to advocacy by a small group of patients, more patients will have access to a new treatment option.

To learn more about this success, visit: www.multiplesystematrophy.org

CONCLUSION

Healthcare is a highly regulated industry, as it spans the gamut from drug development, hospitalizations, individual insurance, medical tests, outpatient care, lab tests, cancer treatment, disease prevention, prescribed medications, and more. Thus, advocacy, as it relates to healthcare delivery, is vitally important.

Regulation plays a major role within healthcare delivery. It is there to ensure that patients have access to the healthcare they need, and that that care is delivered with the utmost of quality. Compliance with laws and regulations is critical to the delivery of high quality healthcare. It is important to stay on top of new regulations and policies as

they relate to healthcare and engage and comment where appropriate. Advocacy through engagement with both your state and federal regulators will help them to better understand issues important to patients. Your actions will help regulators to ensure that the laws that have been created are implemented in the fashion by which they were intended.

RESOURCES & SUPPORT TOOLS

Guide: Drafting Comments to
Regulatory Agencies

Guide: Key Websites for
Additional Information

GUIDE: DRAFTING COMMENTS TO REGULATORY AGENCIES

BEFORE WRITING, READING OR SUBMITTING COMMENTS:

1. Read and understand the implications of the regulatory action.
2. Be familiar with the deadline for commenting on the action.
3. Familiarize yourself with the submission process.

IN YOUR WRITTEN OR ORAL COMMENTS BE SURE TO INCLUDE:

1. Your name and your connection to the cause or issue.
2. Provide any credentials or experiences you might have (personally or professionally) that would separate your comments from others.
3. Provide any necessary disclosures.
4. State whether you are for or against the regulatory action. Be specific about how the action would either negatively or positively affect patient lives.
5. Provide background information (facts, statistics, etc...) with supporting documentation.
6. If presenting comments in person, know the length of time you have to read your comments. Many times, the time permitted is 5 minutes, so be sure to prepare your oral comments with that in mind.
7. Be clear what action you would like to see taken.
8. Always keep a copy of your written comments.
9. Track what happens to the regulatory action.

CONSTRUCTIVE COMMENTS CAN MAKE A DIFFERENCE. TAKE THE TIME TO PROVIDE COMMENTS ON ISSUES IMPORTANT TO YOU AND OTHER PATIENTS.

GUIDE: KEY WEBSITES FOR ADDITIONAL INFORMATION

Engaging with Department of Health and Human Services

<http://www.hhs.gov/regulations/>

Submitting Comments to the Federal Register

http://www.fda.gov/RegulatoryInformation/Dockets/Comments/default.htm?utm_source=rss&utm_medium=rss&utm_campaign=comment-on-proposed-regulationsand-submit-petitions

Paths to Engaging with the FDA

<http://www.accessdata.fda.gov/cder/sb-navigate/topic2/topic2/index02.htm>

Engaging with Office of Regulatory Affairs at NIH

<http://www.cancer.gov/aboutnci/organization/oar>

Submitting Comments to CMS

<http://www.cms.gov/Medicare/Coverage/InfoExchange/publiccomments.html>

Learn More about the Rulemaking Process

https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf

Sample of a Letter of Public Comment to State Insurance Commissioner

<http://rareadvocates.org/public-commentneeded-on-two-model-insurance-regulations/>

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GROWING IN ADVOCACY



TURN
UP THE
VOLUME

SHOUT IT
FROM THE
ROOFTOPS

TELL
EVERYONE
YOU KNOW

INTRODUCTION

Once you find something you really believe in, something you know needs to change, you want to tell everyone about it, right? It is a natural feeling, and something you want from your advocates. Educating your advocates on how to garner the support of others plays a crucial part in your advocacy success.

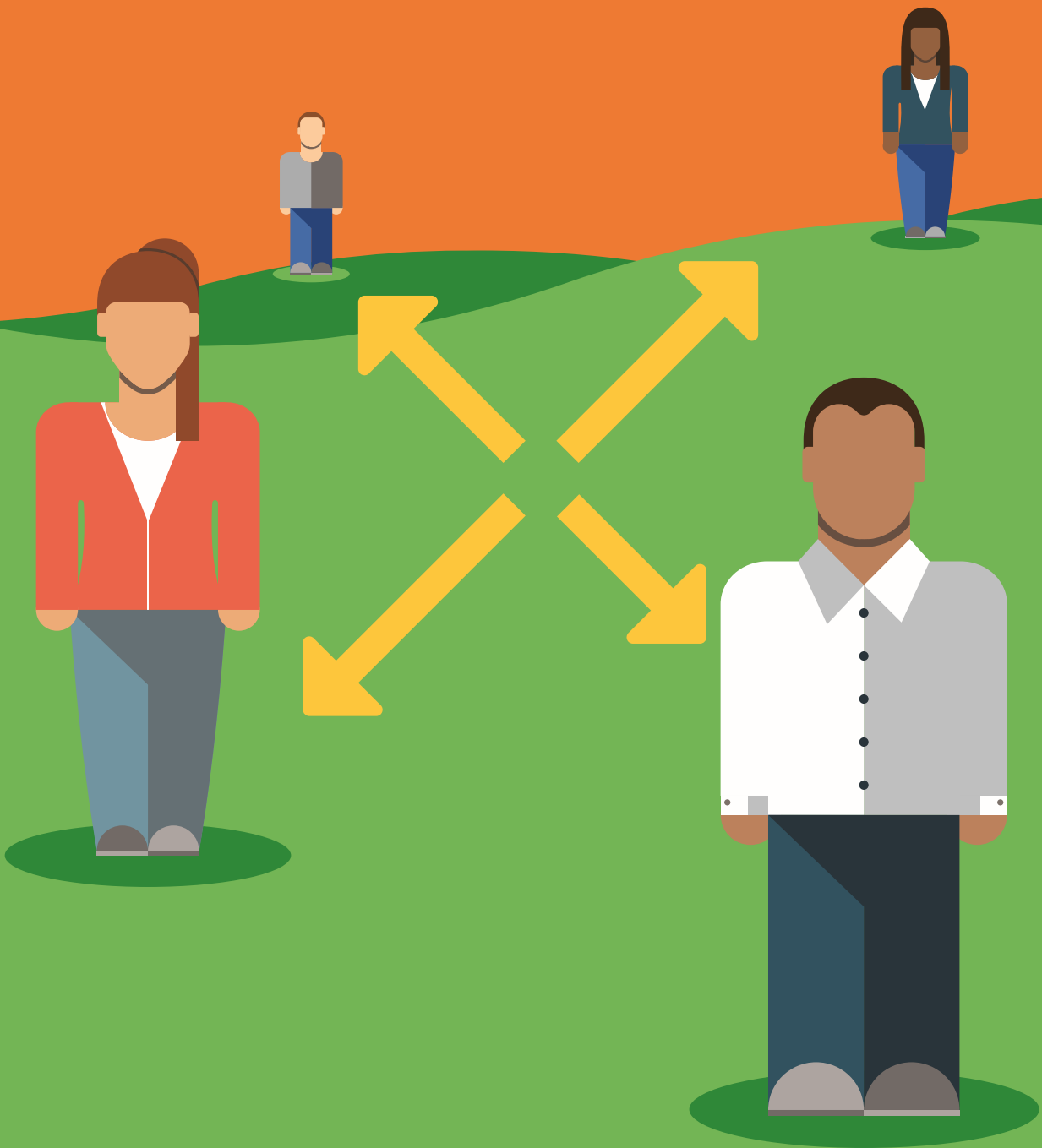
This guide will help you identify:

- A core group of advocates that will help engage others
- Ways to engage your advocates throughout the year
- Ways to create opportunities for your advocates important messages with others

Advocates can carry messages into their communities and into the ears of their families and friends. If they support your organization and believe in the cause, a passionate and enthusiastic advocate will carry your message EVERYWHERE, and it is your role to provide them the resources required to succeed. This guide will help you do that.

Advocates who believe in your message will naturally encourage others to join the cause. Provide them ways to stay connected with you and your organization throughout the year, and create ways to celebrate their successes with others along the way.

The final thing you will learn in this guide is about success stories when you spend the time equipping your advocates with the tools they need to succeed. Read those stories, be empowered by their results and soon you and your advocates will have a success story to share.



EXTENDING YOUR OUTREACH

THE IMPORTANCE OF GETTING OTHERS INVOLVED

Over the years, the role of patient advocacy organizations has become increasingly important. Now more than ever, patient advocacy organizations are being asked and encouraged to play a critical role in the healthcare process. Patient advocacy groups are considered key stakeholders in healthcare policies and regulations, scientific research, some guideline committees, and patient education. The voice of an advocate is becoming more influential and prominent in the way healthcare is designed and delivered to patients.

A strategy for getting others engaged with your organization should always be a part of your advocacy plan. Once your mission and advocacy plan are in place, it is important to get others involved in spreading your message.

Identify a core group of advocates (your ambassadors) within your organization, and task them with engaging others. True ambassadors will share your messages with their families, friends, and communities. Train your advocates on ways to educate others about the work you are doing and keep those messages short, simple, and personal.

Your ambassadors will share your organization's mission, the work you are doing, and an example of ways that other people can get involved, in just a few minutes.

Keep this in mind:

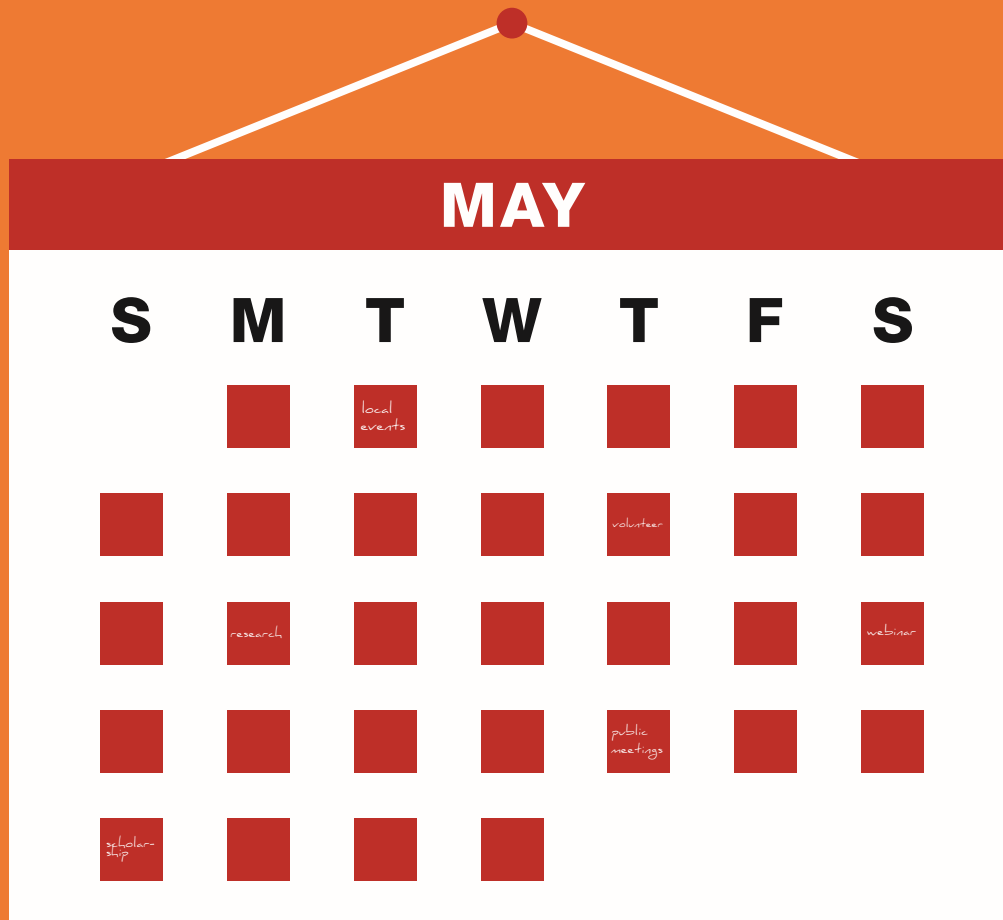
- Only a small percentage of the people you come into contact with will support you
- Only a small percentage of those who support you will get involved
- Only a small percentage of those who get involved will become advocates¹

For a resource and support tool to help you with engaging new advocates refer to the “How-To Guide on Developing Other Advocates” at the end of this guide.



AMBASSADOR: A person who acts as a representative or promoter of a specified activity.

¹ www.americantrails.org



ENGAGEMENT THROUGHOUT THE YEAR

Advocacy is not a one-day affair. It is important to ensure that your grassroots advocacy efforts happen all year long. Whether you have 10 advocates or 10,000 advocates, keeping them engaged throughout the year is essential. Here are some examples of how you can keep them connected to one another, as well as to other potential new advocates:



Local Events

Develop a toolkit for your advocates to utilize at any hometown event, such as a local fair or a community event. This toolkit can include things like a tablecloth with your organization name on it, printed education materials to distribute about your organization and a few takeaways for people directing them where to go to learn more.



Community Fundraising

Create a fundraising event your advocates can hold locally. Maybe it is a barbeque, or an evening at a local pizzeria, where a certain amount of the proceeds go to your organization. Encourage your advocates to share their ideas and suggestions with you. Listen to them, as they know what would work best in their local communities.



Research Advocacy Program

Develop a research advocacy training program where interested advocates can learn more about the science of their disease to better represent other patients. Guideline committees and regulatory government agencies are often looking for patient advocates to sit on panels to represent the patient voice. Participation on those committees or panels can be the first step in the process of having your voice heard among other organizations, scientists, healthcare professionals, and government agencies.



Congressional District Meetings

For members of Congress, August is their Congressional Recess. So, when you and your advocates think of August, think “locally, it’s time to get to work!” This is a terrific point in your journey to help your advocates schedule meetings with their members of Congress, and the good news is, they won’t have to go far. Local district meetings are imperative to your success in legislative advocacy. Advocates who have met with their members at home will tell you it’s a different dynamic and a great place to deliver important messages. Encourage your advocates to spend time building relationships with their Congressional leaders while they are on recess.



Volunteering

Keep a running list of ways advocates can help volunteer with your organization. Maybe you could use volunteers to provide administrative duties for your annual fundraising campaign or maybe share educational literature at their local hospital. Here, other patients with a direct connection to your cause can learn about your advocacy efforts. And, at times, the voice of an advocate is needed either at a legislative briefing or a regulatory hearing. Collect the names of those advocates willing to volunteer within these settings so when the time comes, you will know who to call.



Lobby Day or Advocacy Day

Organize a lobby or advocacy day. If your advocacy plan involves affecting legislation, arrange meetings with their elected officials and equip your advocates with the messages you need carried. It is the constitutional right of a citizen to petition the government officials about a specific issue. Exercise that right, and educate your advocates to do the same. They will tell your story, and their story, and their elected officials will listen.



Webinar Series

Webinars are a terrific way to educate your advocates about what is happening within your organization, and can also be a wonderful resource or outlet for patients and advocates to hear from healthcare professionals about their disease. You can also archive these on your website so others can view them later. Tip: www.gotomeeting.com has an easy to use program to host your webinars.



Social Media

Provide your advocates with suggestions on ways to best utilize social media outlets. Encourage your advocates to use social media to invite people to a local event, or post pictures of the meetings they have with their elected officials. They can also use social media to share important news stories. You can make it super easy for them to post information by providing sample posts, such as watching a video and providing the link, or encouraging them to take action.



Public Meetings

Encourage your advocates to attend local legislative and regulatory meetings in their hometowns that are open to the public. They can visit the government website for their county or state to learn about upcoming public meetings. You can assist them by working together on crafting the appropriate message for each type of meeting.



Advocacy Scholarships

Tell your advocates that patient advocacy scholarships are available. Very often companies and organizations will provide patient advocates scholarships to attend scientific meetings to learn more about their disease. Here are some examples of scholarship programs:

www.diabetesmine.com/2014/05/announcing-the-diabetesmine-2014-patient-voices-scholarships-contest.html

www.cancer.net/research-and-advocacy/patient-advocates/conquer-cancer-foundation-patient-advocate-scholarship-program

www.patientadvocate.org/index.php?p=69

www.aakp.org/media-files/press-releases-media/item/limited-patient-scholarships.html



Online Calendar

Provide an online, yearly calendar of events that your advocates can view and add their own events to. This is a great way to inform your advocates about your organization's activities. Encourage them once a month to check the calendar to learn more about on-going activities.



PETITION: A request that addresses of a person or group of people in authority.

YOU DID IT!



THE IMPORTANCE OF CELEBRATING YOUR SUCCESSES

Success in advocacy isn't about just getting a bill passed into law and ensuring that law is implemented in the way it was intended. There are other steps along the way, and celebrating your successes throughout the entire process is very important. Progress IS success. And because very little happens quickly in legislation and regulation, you should enter the advocacy process with a "never give up" attitude. When you celebrate your successes, you remind your advocates to focus on the positive, not the negative.

When you celebrate your successes, you remind your advocates of the goal you set out to achieve and it reminds everyone that you are all working toward that one common goal. Lastly, it allows people to believe in the concept of when you set realistic goals, you can accomplish anything.

Encourage your advocates to celebrate their small successes as well as their big ones. Dedicate a section of your website for success-testimonials and stories. A place where they can go to learn about what other advocates have been up to, and a place where they can share what they have been doing on a local level. Make it easy for them to share! Create a template where they can enter the key information, and then allow for an area to share their experience.

To learn more about creating a template, reference the "Advocate Template for Sharing Stories and Successes" resource and support tool at the end of this guide.



EXAMPLES OF WHAT SUCCESS CAN LOOK LIKE

- Raising awareness about an issue
- Gaining support for a piece of legislation
- Speaking out on behalf of patients who needed a voice
- Developing positive relationships with state legislators and their staff, so come the time you need something, they are there to help
- Educating elected officials and regulatory agencies about the importance of an issue to you and others

When you have these successes, it is important to both share and celebrate them. It will unite your advocates, inspire them and remind them that they are all working toward one common goal.



THE LOOK OF SUCCESS

Arthritis Foundation advocates successfully fought to maintain \$557 million in research funding at the National Institutes of Health and Centers for Disease Control and Prevention.

www.arthritis.org

Leukemia Lymphoma Society advocates gained co-sponsors for HR 460 (Patients' Access to Treatments Act) by speaking up about the importance of stopping unfair cost-sharing practices from keeping crucial medications out of reach for many cancer patients, and 72 members of Congress listened. They are now hearing from both sides of the aisle about Congressmen/women who are interested in supporting HR 460.

www.lls.org

American Heart Association advocates met with members of Congress and provided them with information about their constituents. Through the various discussions, they were able to clearly illustrate the value of their work and the impact they have had on patient outcomes. They are also hopeful that this will continue to position them as a resource to Congress and the administration on quality improvement.

www.heart.org

American Lung Association advocates fought for measures to improve air quality and discourage tobacco use in the Upper Midwest. They educate legislators, engage through their e-advocacy network and provide people with a forum to make an impact in smoke free, healthy air and taxation of tobacco products.

www.lung.org

National Brain Tumor State Lead Advocates are a distinct set of highly engaged individuals that work hard to recruit and motivate other advocates. Each State Lead serves as a mentor and leader within their community, meets with elected officials both on the state and federal level, and brings their shared voices to the fight.

www.braintumor.org

Lupus Foundation of America, Indiana Chapter is one of 333 patient groups from around the country that signed onto a letter to Secretary of Health and Human Services (HHS) Sylvia Mathews Burwell calling for immediate measures to reduce barriers to care for patients who have purchased policies through the Health Insurance Marketplace (the "Exchanges"). The letter came as some patients with chronic conditions have faced difficulty accessing crucial medications and other health services they need in some Qualified Health Plans.

www.lupus.org

CONCLUSION

Advocacy takes work, and the more advocates you have, the more fun that work becomes. Keep your messages simple, and they will in turn be simple to share. One of the most important things to remember is with advocacy comes change, and change takes time.

Identify your ambassadors and learn from them by asking them these five questions:

- 1) What made them interested in your organization?
- 2) At what point did they make the decision to want to make a difference for others?
- 3) Why do they think getting others involved is important?
- 4) Why do they believe in your mission?
- 5) How do they think is the best way to both obtain and engage other advocates?

Knowing the answers to these questions will help you to identify other advocates. As the number of your advocates increase, so will the number of people you reach.

Bottom line: Believe in your mission, get others to believe in your mission and change will happen.

RESOURCES & SUPPORT TOOLS

How-To Guide on Developing
Other Advocates

Advocate Template for Sharing
Stories and Successes



A PLANNING GUIDE FOR YOUR ADVOCACY EFFORTS

I'M AN ADVOCATE FOR

OUR MISSION IS TO

WE ARE A PATIENT ADVOCACY ORGANIZATION THAT

WE DO THIS BY

I GOT INVOLVED BECAUSE

YOU TOO CAN GET INVOLVED & HERE'S HOW



TEMPLATE FOR SHARING SUCCESSES & STORIES

DATE

NAME

COUNTY & STATE

WHAT WAS YOUR GOAL?

DID YOU ACHIEVE THAT GOAL?

WHAT HAPPENED? SHARE YOUR STORY

FOLLOW UP NECESSARY FROM A STAFF MEMBER OF THE ORGANIZATION?

IF SO, PROVIDE THE CONTACT INFORMATION

YOUR CONTACT INFORMATION, SO OTHER ADVOCATES CAN REACH OUT TO YOU & LEARN MORE

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TOOLKIT

Example Advocacy Material

PRESS RELEASE

For Immediate Release: (Date)
Contact: (Contact Information)

Physician Surveys Find Health Insurer Step Therapy Protocols Harm Patient Care; Organizations Urge Lawmakers to Establish a Fair and Expedited Override Process

(City, State) – Today (Organization) and (Organization) announced the findings of recently conducted surveys on health insurer step therapy protocols for prescription medications. Responses were received from over 400 physicians practicing throughout (State) and across many physician specialty areas. Each organization issued its own survey to members yet the physician responses were remarkably consistent. The surveys found that existing insurer step therapy protocols delay and adversely affect patient care, are challenging and time consuming and limit clinical judgment in determining what medication will be most effective for patients. 90% of physicians indicated that step therapy protocols at least “sometimes” adversely affected their patients and 46% indicated that it “frequently” adversely affected patients. The surveys also found that 94% of respondents support the concept of requiring insurers to provide an expedited process to exempt patients from step therapy protocols when the drug they prescribed is medically necessary.

“Imposition of step therapy protocols, also known as ‘fail first’, are one way among many that insurance companies are limiting needed patient care and treatments to enhance their bottom line” stated (Name, Title) of (Organization). “We have heard from many physicians regarding the difficulties they face from insurers when they and their staff seek to assure their patients have coverage for the prescription medications they need. The surveys further demonstrate the frequency by which insurer rules that require patients to ‘fail first’ on certain medications can have serious consequences for their health. We need legislation or regulatory action to assure our patients can get the medications they need without having to needlessly wait weeks or months to comply with insurance company protocol.”

Step therapy is a utilization management tool that health insurers commonly use to control spending on prescription drugs. It functions as a coverage restriction placed on prescription drugs by health plans. These policies require that before the insurer will cover drugs initially prescribed by a physician, the patient must first try other (sometimes multiple), generally less expensive drugs to treat the patient's condition to see if they will be effective. “The survey findings are very disturbing. Patients are being forced to fail multiple times, sometimes for months at a time on ineffective medications before health insurers will cover the right medication to treat conditions,” stated (Organization, Title, Name). “Our members view it as central to our role as family physicians to be advocates for our patients. Time is often of the essence for our patients with serious and debilitating illnesses. We need a clear, fair process that puts medical decision making back in the hands of physicians so patients get the medications that most effectively address their needs.”

As supported by the (Organization) and (Organization) surveys, step therapy restrictions are imposed by most health insurers in the State and are applied to prescription drugs treating a wide range of diseases and conditions including autoimmune diseases, cancer, diabetes, HIV/AIDS, mental health, treatment of pain and many others. Included in the list of drugs identified by physicians as being subject to step therapy even included medications such as suboxone which is used to treat opioid addiction- a major focus in (State) this year. Patients need access to these medications without hurdles or delays.

Legislation has been introduced in (State) to address this serious and widespread issue. The bill (name of bill) is sponsored by Senator (Name) and Assemblyman (Name) and would establish two simple patient protections:

- A clear and abbreviated process that prescribers may use to override a step therapy protocol in cases where evidence demonstrates that it is medically necessary
- A limit on the amount of time a patient can be required to try different medications

This legislation applies to commercial plans regulated by the State and is supported by (Organization) and a coalition of patient advocacy organizations, other health providers including (Organization) and others. It is currently under review in the Insurance Committee in each house.

Key Findings of the Surveys:

- Over 64% of physicians said only some health insurers permit them to attempt to override a step therapy protocol and 30% said none of the insurers they work with allow them to do so
- Over 93% of physicians said it was “challenging” or “extremely difficult” to override health insurers’ step therapy protocols to assure their patients get the medications they need
- Over 98% of physicians said the process to exempt patients from step therapy requirements was “challenging” or “extremely challenging”
- Over 50% of physicians said it can take a minimum of 2 days to more than one week to override an insurers’ step therapy protocol
- Over 56% of physicians said the process to exempt patients from step therapy protocols can take a minimum of 1–2 weeks or longer
- 65.5% of physicians said that they had to repeat a step therapy protocol for the same patient
- When asked how step therapy policies affect patients, more than 95% of physicians said they delay access to appropriate therapies, 64% said they decrease medication adherence, and nearly 61% said they increase non-medication costs

Comments Provided in Surveys:

- Drugs that insurers require patients to fail first on were often not in the same class as the drug initially prescribed and there are potentially adverse drug to drug interactions
- Step therapy restrictions are now the most time consuming issue in his/ her practice
- A recent example was provided of a patient who ended up in the emergency department with a seizure after the insurer did not approve (Product Name)
- Step therapy requirements cause physical and emotional harm to patients before forced to trial cheap ineffective drugs
- One insurer requires patients to try four atypical antipsychotics for three months before the newer brand name drug will be covered
- Patients often have to wait several weeks to receive anti-cancer drugs, during which the cancer progresses and they deteriorate
- A physician noted that he/she has been forced to use a medication that he/she knew would be harmful in order to get the one he/she wished to prescribed for children
- A physician said that every year the insurer’s step therapy policy starts over so he/she has had to take patients off medications they have been stable on, calling this a dangerous policy

Examples have been provided by advocacy and professional societies and have been de-identified. For illustrative purposes only.

COALITION LETTER

(Date)

(Recipient Name & Address)

Dear (Name):

Collectively, we are writing in regard to the (State Committee)'s planned review of 11 oral oncology medicines during its scheduled (Date), meeting in (Location). As the President of (Organization), an organization representing over three hundred physicians, nurses, and professionals all dedicated to the treatment of cancer we are taking this opportunity to express our concern and the concerns of multiple statewide provider, patient and advocacy groups on the proposed review of oral oncology medications. (Organization) and the above listed organizations are frequently called upon to comment on state-based policy and legislation.

We are concerned that by adding oncology drugs to the P&T Committee's review, the State will begin to restrict access to cancer medicines for Medicaid Fee-for-Service program patients. We are also concerned that there are no oncologists on the P&T Committee.

Oncology drugs, even those within a group of drugs treating the same tumor type, are not interchangeable. These drugs often have different mechanisms of action, different side effects, and could be targeted to different sub-populations within a tumor type. Additionally, oncologists recommend treatment based on the expected clinical benefit for the particular patient's clinical profile. Establishing barriers restricts our ability to make the best medical decision for the care of our patients who are facing a life threatening illness.

Medicaid cancer patients already have poorer survival rates than patients who are commercially insured. Restricting access to necessary medication might only exacerbate these disparities. We are also concerned about Medicaid patients living in rural areas. Oral drugs are a more convenient way for them to receive therapy than requiring them to travel great distances, particularly when they are very ill.

Collectively, we urge the (Committee) to reconsider its decision to review oral oncology drugs. Thank you for your consideration.

Respectfully submitted by the following patient and provider advocate organizations on behalf of their (State) chapters and/or constituents.

(Name)

(Title/Organization)

LETTER TO A P&T COMMITTEE

(Name)
(Address)

Dear (Name):

Collectively, we are writing in regard to the (State Committee)'s planned review of oral oncology medicines during its scheduled (Date), meeting in (Location). We appreciate the P&T Committee not reviewing oral oncology drugs last year. As (Title) of (Organization), an organization representing physicians, nurses, and professionals all dedicated to the treatment of cancer, we are taking this opportunity to express our concern and the concerns of multiple statewide provider, patient and advocacy groups on the proposed review of oral oncology medications this year. (Organization) and the above listed organizations are frequently called upon to comment on state-based policy and legislation.

Two years ago, the Committee recommended that all oral oncology drugs be designated as preferred on the Preferred Drug List (PDL) and that all would require prior authorization. We believe this is a reasonable policy to allow patients to have access to the best drugs available while ensuring effective utilization oversight.

Cancer therapies are not interchangeable. They often have different indications, different mechanisms of action and different side effect profiles. The physician takes several factors related to both the medicine and the patient into account when considering treatment options: evidence of the drug's efficacy and safety from the drug label and other published studies; patient tumor type, state of disease, biomarker status if applicable, and health status. Adding formulary status to the decision making process introduces non-clinical factors that may compromise quality patient care.

The federal government has explicitly endorsed oral cancer drugs as one of only six "protected classes" in the Medicare program. Federal law requires health plans to cover "all or substantially all" oral oncology medicines. The federal government has found that this class requires special protections given the life threatening nature of cancer, and the lack of interchangeability among treatment options.

Cancer patients on Medicaid already have poorer outcomes compared to both commercially insured and the uninsured. Restricting access to necessary medication might only exacerbate these disparities.

Collectively, we urge the (Committee) to not restrict access to these life-saving drugs beyond what was determined in the last review.

Respectfully submitted by the following patient and provider advocate organizations on behalf of their (State) chapters and/or constituents.

(Name)
(Title/Organization)

Examples have been provided by advocacy and professional societies and have been de-identified. For illustrative purposes only.

WRITTEN COMMENTS TO THE FDA

(Date)
(Name)
(Address)

Dear (Name):

As the largest non-profit health organization addressing the needs of the more than 50 million adults and 300,000 children living with arthritis in the United States, (Organization) urges the FDA to adopt a policy of distinguishable names for all biologic products, including biosimilars. Biologics have revolutionized the treatment of rheumatoid arthritis and other inflammatory forms of arthritis, preventing joint damage and preserving function and mobility for many people. However, not everyone has access to biologics due to high costs and/or limited availability. (Organization) welcomes the potential for increased access to biologic therapy when biosimilars enter the market.

Since the FDA has accepted the first application for a biosimilar, and other companies are planning to follow suit, the issue of naming biosimilars must be addressed promptly. As the FDA finalizes its guidance on licensing biosimilars, (Organization) urges the agency to hold patient safety as the highest priority. We believe that requiring distinguishable names for all biologic products would ensure that patient safety is given the highest priority.

There are a number of reasons distinguishable names are important to patients:

- Biosimilars are not bioequivalent. Biosimilars are not exact replicas of the innovator biologic. There will be subtle product variations in cell lines and manufacturing processes that can have significant and serious consequences. Further, biologic medications often work differently for different people. The inherent challenge of treating these complex diseases and predicting the response of a particular patient would increase exponentially if the identities of the therapies were not clear. Likewise, risk for the patient increases as delay in finding an effective therapy means potential ongoing joint destruction.
- Shared names can cause confusion among physicians. A 2014 survey of physicians in Europe¹ suggests that many physicians believe that drugs with shared nonproprietary names are approved for all the same indications. The study further suggests that 61% of physicians who prescribe both biologic and biosimilar medications believe two products that share a name are approved for the same indications. Because biologics and biosimilars are inherently different, this misunderstanding can have a severe impact on patients. The easiest way to avoid this type of misunderstanding is to require distinguishable names for all biologic products.
- Distinguishable names allow for transparency in notification and substitution. Since biosimilars are not exact replicas of biologics, distinguishable names will help make it as clear as possible for the pharmacist, patient, and physician to know exactly which product the patient is receiving. (Organization) believes the patient and prescribing physician should be notified within 24 hours by the pharmacist when a substitution has taken place, and the pharmacist and the prescribing physician should keep records of any substitutions made for a minimum of 5 years. Such records may be invaluable in case the patient's condition changes over time, or an adverse reaction or disease evolution occurs.

¹ Generics and Biosimilars Initiative Journal, vol. 3 issue 2 (2014), available: <http://gabi-journal.net/asbm-2013-european-prescribers-survey-report.html>.

- Distinguishable names will strengthen adverse event tracking and post-marketing surveillance. It is important that adverse events are tracked separately for biologics and biosimilars. The licensed health care practitioner needs to know exactly which product his/her patient is receiving in order to monitor efficacy, adjust dosages and accurately report adverse events if they occur. Long-term, post marketing, registry-based data collection is necessary to monitor for less common—but nonetheless important—adverse events. In the case of an adverse event, the patient needs to be able to communicate to his/her health care provider exactly what is being injected or what was infused. This would be complicated, if not impossible, if the patient or his/her physician is unaware of the specific product the patient received.

The complexity of the care of arthritis patients and the complexity of biologic medications make a policy of distinguishable names for biologics and biosimilars critical for maintaining the highest level of patient safety. We believe the FDA shares our commitment to making patient safety a priority and we would welcome an opportunity to continue to dialogue on this topic. Please contact (Name, Title, Organization) at (phone number) or (email address) with questions or for more information.

Sincerely,

(Name)

(Title)

(Organization)

Examples have been provided by advocacy and professional societies and have been de-identified. For illustrative purposes only.

TESTIMONY TO A PUBLIC HEALTH COMMITTEE

(Date)

Testimony of (Name)

(Committee/Organization Name)

Senator (Name), Representative (Name), and members of the committee; I appreciate the opportunity to testify before you today. I'm (Name), the (Title) with the (Organization), (State)'s only statewide HIV/AIDS organization. We work to ensure that the 10,000 people living with HIV/AIDS in our state have the housing, care and supportive services they need in order to live their lives in dignity.

I'm here to lend my support to (Name of Legislation) with friendly substitute language for (Section) "Hepatitis C screening test" means "a laboratory test that detects the presence of hepatitis C virus antibodies in the blood."

We suggest the following - "Hepatitis C screening test" shall mean "any FDA-approved laboratory screening test, FDA-approved rapid point-of-care test, or other FDA-approved tests that detect the presence of hepatitis C antibodies in the blood."

There are a tremendous number of parallels between HIV and Hep C. Routine assessment and screening of Hepatitis C in baby boomers, like routine HIV testing, helps to identify people who are infected and may be completely unaware of their status, all the while Hepatitis is wreaking havoc on their liver and other systems, which, eventually, can lead to cancer or, if left untreated, death. Early detection and care of Hep C results in much better health outcomes, and easily demonstrates far greater savings over time. While the cost of treatment can be pricey (\$80,000 per course of treatment) it is far less expensive than treating liver disease over time, and a fraction of the cost of a liver transplant (\$575,000).

Co-infection of HIV and Hep C is common (50–90%, according to the CDC) among HIV positive injecting drug users. A recent CT research study conducted by (Names and Title of Researchers) from (Organization) found that 40.5% of the participants (n=462) in the study were Hep C+, and of those, only 43% (78) were aware of their status.

The (State) Department of Public Health, has been forward thinking on this topic for some time. DPH funds three syringe exchange programs, one of which is a program of (Organization). They routinely offer Hep C and HIV screening and testing, and because they're with the client at the time of the results, are able to immediately refer someone to care.

The treatments for Hep C have vastly improved over the years and new medications have very recently been approved for use. These new treatments have much fewer side effects, a shorter treatment regimen, and a 90–100% cure rate in most people.

Please support (Name of Legislation) so that we can detect Hepatitis C early on, and save lives.

Thank you. I'm happy to answer any questions you might have.

LIVE TESTIMONY

(Date)

To: (Recipient)

From: (Speaker)

RE: (Subject)

Thank you for the opportunity to speak today. Let me begin by saying that (Organization) and its advocacy affiliate, (Organization), who I represent, are obviously concerned about any policy that does not allow for treating individuals with cancer who are deemed too ill or too terminal or by any other similar description. It is particularly disturbing when these policies are targeted at the most vulnerable populations, with individuals who often do not know the system and/or how to advocate for themselves, or their loved ones, regarding issues surrounding health care and treatment decisions.

We are also concerned about an arbitrary process that deems a patient's disease to be advanced, or otherwise wrongfully denies access to cancer care that is otherwise routinely and generally accepted as appropriate by cancer care experts and the constituencies we serve.

We understand that you have a difficult task, but we ask that any policies be grounded in reasonable respect for human life and for the comfort and well-being of all patients, regardless of income. We also ask that any policy that is ultimately established have a robust and transparent appeals process so that medical professionals with all the facts about an individual's situation can make those facts known and understood by those who may be making the ultimate decision to deny or alter care. Appeals must also be heard in a quick, timely fashion given the seriousness of the situation for most cancer patients.

Finally, as we have done in the past, we again ask the committee to carefully consider and evaluate what these policies are doing to patients, care providers and the overall impact on communities in general before proceeding further.

We stand willing to work with you but we also stand first and foremost for the well-being of all cancer patients no matter their place in society.

Thank you.

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TESTIMONY TO CONGRESSIONAL COMMITTEE

(Date)

Testimony of (Name)

(Title)

(Organization)

On House Bill (Number)

Thank you, Chairman (Name), Chairman (Name) and Members of the Committee on Health Care Financing for the opportunity to testify this afternoon.

My name is (Name) and I am the (Title, Organization). (Organization) represents (number) members, comprised of companies, teaching hospitals, and academic institutions, the majority of which are directly engaged in research, development, and manufacturing of novel therapies and technologies that improve lives around the world and contribute to the economic strength in the region. (Organization) is proud to be part of (State)'s vibrant biomedical research and development community, which by most accounts, ranks first in the world for medical discovery and innovation.

I commend you for your consideration of House Bill (Number). In particular, I would like to applaud the work of Representative (Name) and you, Chairman (Name) for taking the time to learn about this complex issue, and leading this effort to provide the necessary pathway for patients to access lower cost interchangeable Biosimilars, while also ensuring that patients and physicians are notified of medication changes.

(Organization) worked with (Organization) and our member companies to develop a set of five principals that we believe should govern the substitution of Biologics. I would like to mention the five principles and highlight that (State) is in a position to once again be a leader in creating another groundbreaking law related to health care.

The first two are fairly straight forward:

- Substitution should occur only when the FDA has designated a biologic product as interchangeable
- The prescribing physician should be able to prevent substitution

The other three are vitally important to protecting the patients who are benefiting from these breakthrough therapies:

- The prescribing physician should be notified of the substitution
- The patient, or the patient's authorized representative, should, at a minimum, be notified of the substitution
- The pharmacist and the physician should keep records of the substitution

We are extremely pleased that House Bill (Number) includes all five of our principals, and therefore ask you to support the passage of this important bill.

As you have heard in other testimony, biologic medicines are different from the traditional chemically synthesized small molecule medications that you are used to dealing with from a policy perspective. Biologic

medicines emanate from living organisms and because of that, Biosimilars that are derived from different cell lines and separate manufacturing processes will be slightly different than the innovator products they seek to replicate. This is not a safety issue, as the FDA will deem Biosimilars safe and effective. However, they cannot be an exact copy of an innovator biologic the way generics medicines are to small molecules products.

In actuality, there will be three types of biologics in the marketplace: innovator biologics, interchangeable Biosimilars and Biosimilars. All three types of Biologics will play a critical role in the delivery of healthcare in the years to come. When crafting the legislation, Congress understood that Biosimilars could not be an exact copy of an innovator biologic; however, they tasked the FDA with the development of a heightened standard called interchangeable Biosimilars that will - with confidence, interact in patients nearly the same way as the innovator product. It is intended that only Biosimilars that meet the heightened standard of interchangeability will be allowed to be substituted at the pharmacy. For instance, in Europe they do not allow product substitution at the pharmacy because they did not develop an interchangeability standard. EU policymakers recognized that Biosimilars could be too different from the innovator product to be freely substituted at the pharmacy.

The provision in House Bill (Number) that allows only interchangeable Biosimilars to be substituted at the pharmacy is critical. The transparency measures that are in House Bill (Number) are just as important.

As I mentioned biologic medicines are different than small molecule drugs in the way they interact in the body. Because they are derived from cells often found in our own bodies, biologics are generally safe and well received by patients. However, biologics are different than small molecules in that adverse reactions may occur after a patient has been on the product for a long time. Also, it is possible for the body to build up an immune response to the medicines after prolonged use. For this reason, transparency is vital across all three types of biologics. The bottom line is that patients and their physicians should know what products they have received from the pharmacy. Personally, I also want to know what medication is being infused into my son's body and I want to know that my son's doctor is aware of any change in medication for him.

Legislative efforts in states around the country have had mixed results. I am proud to say that because of your leadership and vision, we can accomplish these goals around transparency through (Section) of the (Name of Legislation), as proposed in House Bill (Number). By utilizing electronic medical records to address the notification and record keeping aspects, we prove once again that (State) is ahead of the curve.

We are confident that we will pass groundbreaking legislation on which others states can model their initiatives to pursue both patient access and patient safety.

Examples have been provided by advocacy and professional societies and have been de-identified. For illustrative purposes only.

WRITTEN COMMENTS TO STATE HEALTH DEPARTMENT

(Date)
(Name)
(Title/Organization)
(Address)

Dear (Name),

It has come to my attention that the Department of Health Services is considering the addition of an HIV drug class to the Medicaid preferred drug list (PDL). I write to ask that you remove HIV drugs from consideration for the PDL because the unintended consequences of placing any kind of limitation on access to HIV medications may be significant for HIV patients and may generate costs for Medicaid that exceed potential cost savings.

Today, HIV patients have the chance to live long and healthy lives provided they (1) can receive quality health care from providers knowledgeable in the treatment of their disease and (2) have access to the best medications. Without access to treatment and appropriate medications HIV patients will likely have disease progression, require expensive hospitalizations and face early death. These are serious life-threatening consequences for HIV patients and potentially costly consequences for Medicaid.

Advancements in antiretroviral (ARV) treatment allow infectious disease physicians to have a continually increasing and improving collection of medications to use in the treatment of their patients. By finding the right mix of current and new HIV medications, infectious disease physicians are helping HIV patients strengthen their immune systems to fight off the infections and cancers that led to the high death rates experienced by HIV patients in the early days of the AIDS epidemic. These patients now live longer and healthier lives and have a substantially reduced need for costly health care services.

Today, HIV patients need continual ARV treatment and often require medication adjustments to be successful in suppressing the replication of HIV in their body. Unfortunately, adherence to complex ARV regimens can be very difficult and failure to adhere is a significant barrier for successful treatment.

One of the most significant barriers to ARV adherence is the number of pills that an HIV patient needs to take on a daily basis. Creation of the HIV class of drugs on the PDL may ultimately force patients away from highly effective single pill regimens to multi-pill regimens that will reduce adherence. Further, multi-pill regimens complicate existing barriers to adherence such as adverse drug events, ability to get prescription refills, the number of prescriptions needed by patients, and many health and psychosocial issues such as chronic mental illness, drug addiction, homelessness and poverty. Reducing adherence will diminish patient health and increase Medicaid costs.

By creating a PDL for ARV drugs, DHS would be complicating important medication adherence strategies and potentially increasing Medicaid costs by impacting the ability of HIV Medicaid patients to get prescriptions filled and, when necessary, quickly accessing alternative medications to address adverse drug events and drug resistance. While prior authorization might ultimately be achieved for an ARV drug not on the POL, if a prescription or a prescription change is needed quickly and is delayed, strict adherence to

medications is jeopardized which can result in patient resistance to medications and health problems that involve costly emergency room visits or hospitalizations.

From a Medicaid cost perspective, while HIV medications are expensive, a 2006 study by Chen, Accortt, and Westfall clearly demonstrated that HIV patients with low CD4+ counts require approximately \$20,000 more in annual health care when compared to HIV patients with healthy CD4+ counts (Chen RY, Accortt NA, Westfall AO, et al. Distribution of health care expenditures for HIV-infected patients. Clin Infect Dis. 2006;42:1003-1010.).

Medicaid has a financial interest in supporting health care strategies that keep HIV patients healthy. Quick access to the full collection of current and emerging HIV medications is essential to this goal. Medication resistance and poor medication adherence can cause unnecessary disease progression with costly hospitalizations and emergency room visits. Given these important considerations, the best Medicaid strategy to keep HIV costs as low as possible is to keep the HIV drug class off the PDL.

I hope you will concur and remove HIV from PDL consideration.

Sincerely,

(Name/Title)
(Organization)

Examples have been provided by advocacy and professional societies and have been de-identified. For illustrative purposes only.

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