Thank you for the opportunity to be with you today. I am honored to deliver the lecture named for someone I met 21 years ago at a gathering of the Joint Commission of Pharmacy Practitioners (JCPP). I was the executive resident for the American Pharmacists Association, and I was pretty sure I would never again have the chance to sit in the same room as the brain trust of the profession gathered that day. That assumption proved wrong. I would have many opportunities to sit at the perimeter of the JCPP table and was fortunate to witness how a certain ASHP staff member deftly supported his principles, observed the discussion, and guided the discussion to an optimal outcome. It was my first exposure to the value of association staff in such a high-powered setting. I spent many meetings watching Bill and learning from him, and I am truly honored to present the William A. Zellmer Lecture.

How apropos to join ASHP during Policy Week, when members of our profession are engaged in some of the most important non-patient-care work possible. Your efforts to tackle many of the most challenging issues facing today’s pharmacists inspired my thoughts for today—how we can better synchronize or balance public policy and professional responsibility, particularly as we move from a volume-based fee-structure system to a value-oriented, risk-based payment system.

All the public policy in the world will not yield a well-functioning healthcare system, nor will a profession with a well-honed sense of ethical responsibility but a weaker understanding of the parameters of public policy, such as state pharmacy practice acts and Food and Drug Administration (FDA) regulations. Statutes and regulations serve as a foundation and “guardrails” for practitioners, but only by continually advancing pharmacy practice and professional responsibility can we hope to help produce a functioning and rational healthcare system.

By design, public policy lags developments in professional practice. State and federal laws and regulations tend to codify only well-established practices, while our delivery of healthcare continually changes and evolves. Part of that evolution comes from pharmacists fulfilling their professional responsibility—doing more than meeting the minimum required by law. Statutes and regulations form a baseline from which we may operate, but going beyond that minimum standard often better serves patients. For example, if the law authorizes me to supervise pharmacy technicians, how do I define the most-effective forms of supervision? If I can legally compound sterile injectable products, how exactly—and how often—should I assess my facility and refine my practices to ensure that my products contain all that they should and nothing they shouldn’t?

Professional responsibility informs and builds from public policy by providing the nuance and details that are ill-suited to the language of lawyers. I had an aha moment about this dynamic in a recent discussion in India regarding its drug regulatory system. After a robust debate about the legal standards for current Good Manufacturing Practices (cGMPs), we invested just as much time discussing the changes needed in employee culture and the additional education required to achieve the intent.
The William A. Zellmer Lecture
The William A. Zellmer Lecture was established in 2010 by ASHP in collaboration with the ASHP Research and Education Foundation’s Center for Health-System Pharmacy Leadership in honor of Zellmer’s contributions to health-system pharmacy policy development, advocacy, planning, and communications during his career on the staff of ASHP. The lecture is given annually during ASHP Policy Week by a distinguished individual who has demonstrated exceptional leadership in advancing health-care-related public policy that has improved the safety and effectiveness of medication use.

Lecturers
2014 Susan C. Winckler
2013 Dennis C. Wagner
2012 Scott F. Giberson
2011 Jimmy R. Mitchell
2010 William A. Zellmer

of cGMPs nationwide. Changing the system required more than updating the words on paper and complying with those words.

Professional responsibility fills the gaps of what is not—and arguably should not—be captured in laws, regulations, and guidance documents. If, for example, a pharmacist exercises her right not to dispense a drug she objects to, exactly how can she do so while respecting the dignity and choices of the patient and other healthcare professionals? If a crush of patients seeking an antiviral during an influenza outbreak outstrips the supply at my facility, how do I apply professional knowledge while still obeying the rules of the road.

In defining the pharmacist’s scope of practice, our profession has chosen a very detailed, step-by-step structure that can be quite restrictive. Our state pharmacy practice acts empower activity on a discrete basis: if the law says I may supervise a specific number of pharmacy technicians, I may. If the law says I may administer vaccines, I may. But if a certain activity is not explicitly authorized, I may not engage in it on my own, even if it is in the best interest of my patient.

Other professions have taken a different approach. State medical practice acts, for example, tend to be far shorter than those for the pharmacy profession and provide physicians discretion in how to best

Striking the right balance: Reading the situation
Striking the right balance of public policy and professional responsibility requires assessing each situation: the shortest and most familiar route may be narrow and twisting with lots of potholes, while several other routes are wider, smoother, and longer but may be quicker given the traffic and weather. The need to evaluate all of the options before starting may seem obvious, but it is not an inherent activity, particularly here in Washington, D.C.

In this town, the instinctive reaction to nearly any problem is to change the law (or, for the more nuanced, “amend the regulation”). So in our example, the cry from D.C. would be, “Well, just widen, straighten, and repave the old route.” That instinct is driven by the enormous presence and power of the federal government and the apparatus that ensures it functions. To lobbyists (and I have proudly been one), the “fix” is almost always a change in public policy. That fix, however, is not always the right approach, and it is the role of professional societies like ASHP to read the situation and achieve the right balance between trying to expand the public policy structure and honing the skills of pharmacists to exercise their vast professional knowledge while still obeying the rules of the road.

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care for their patients. In a nutshell, state medical practice acts define the practice of medicine as everything physicians do to care for a patient.

I am not saying that either approach is right or wrong but simply that they are different, and that difference can readily be seen at the intersection between public policy and professional responsibility when attempting to balance the two. For the “soccer mom” who is a physician, her professional training provides, in our metaphor, to have a superb car with the latest technology and she keeps it in top condition. But how she gets her child to the game is pretty much up to her. If new roads or bridges are built, she is free to try them out as long as she does not cross the double-yellow line or speed. In the practice act discussion, nearly every new development falls under the “practice of medicine”; the emphasis is on physicians’ professional responsibility to fulfill their roles in ways that best serve their patients and keep pace with ever-expanding knowledge and technology.

In pharmacy, our approach is more akin to using MapQuest. We type in the destination, and it lays out the route. It may not always be the best route or the quickest given the circumstances, but we know that if we follow it, we will not get in trouble with the authorities. Our state statutes provide us with deviations that are clearly marked if we exercise our professional judgment, but we often fear that alternative routes will contain more stop signs and red lights, so we often don’t deviate from the well-worn path. When we do deviate, there are often public policy warnings urging us to “return to the route.”

We practice comfortably within these parameters: we know our role, where to turn, when we can hit the gas, and when to yield and stop. Knowledge of our tightly controlled environment informs how we can affect change. Public policy intervention is required to generate change. Both state legislatures and boards of pharmacy like the control they have over our MapQuest. If we want change, public policy is the route to the programming. This is not to say that professional responsibility is absent—our practice acts provide very detailed elements, but how we carry out those roles requires well-honed skills and our best efforts to serve our patients.

An example where the balance rests with a higher quotient of professional responsibility and a lower bar of public policy is our commitment to lifelong learning. While most state regulators require a designated number of continuing pharmacy education units, the form and focus of those credits are less prescribed. This is where we have the responsibility to engage in programs that enhance our education and advance our practice rather than those that can be navigated in a 30-hour immersion into whatever credits can be completed in the last two days of the reporting period. I observed in my last round of renewing my license that there were more profession-supported structures to help me achieve that goal, to discern among the myriad offerings what might be most helpful to my work as a pharmacist.

As pharmacists, we must pursue education and skill development so that we can learn new routes to get to our destination and prepare for and respond to the challenges our patients face. Efforts to change pharmacists’ lifelong learning require some public policy grounding and a lot of individual pharmacist engagement.

Future of healthcare: Decreasing role of public policy on the horizon?

The challenge for our profession is finding the right balance in public policy and professional responsibility to provide the best care for our patients. In addition to assessing the discrete conditions of the day, we must monitor changes on the horizon. The transition from fee-for-service payment to risk-based payment (i.e., from payment for volume to payment for value) will, if successful, yield substantial changes in healthcare.

The emergence of value-based payment presents a new situation, a situation where we must find the right balance at the intersection of policy and professional responsibility.

Healthcare is changing, and pharmacy practice will change with it. We are moving from an era where compassion was key, where having the right patient story and the right pleas for assistance would carry the day, regardless of cost. We are moving to an era where economics will matter more, and there simply will not be enough resources for everyone to receive everything the healthcare system has to offer.

Now I am not talking about rationing care, but I am talking about rational care—healthcare and a healthcare financing system that will put patient health first but in the context of finite resources. The economics of healthcare are driving us away from a system that rewarded activity—where a higher number of dispensed prescriptions and laboratory tests conducted and more heads in hospital beds signified success, because they generated revenue. We are moving to a system that rewards outcomes—where the value of an intervention is based not on the incremental cost or billing opportunity but on the contribution of the intervention to the health of the patient. In this system, we reward patients’ physical activity, incentivize prevention and wellness activities, aspire to prevent hospital readmissions, and look at the long-term value of medication therapy. We are moving to a system where we care not only that patients received the right drug at the right time but that they understood
and were empowered to make that medication work to lower their cholesterol, to treat their depression, or to (someday) reduce the symptoms and progression of Alzheimer’s disease, for example.

The transition from our fee-for-service system—or paying for activity—to risk-based payment, where we pay for outcomes and better health, will drive this change. In a risk-based system, healthcare providers are expected to practice at the top of their license, to intervene and work with patients to improve their health. With a physician, pharmacist, nurse, physical therapist, and dentist all contributing in their niche, there is no displacement, no turf war. The battle over “who does what,” stimulated by a focus on fee-generating activity, is replaced with the collective effort of an integrated interprofessional team where all members of the team play their position. At the risk of introducing another metaphor, the physician pitcher, the nurse catcher, the nutritionist third baseman, and the pharmacist first baseman (or perhaps we would rather be a shortstop) play well as individuals and excel as a team. And patient, and population, health improves.

In risk-based payment, public policy loses leverage: policymaker-level decision-making regarding what care should be provided when and for whom, or at least what is incentivized by a fee-for-service payment system, diminishes. In the Oregon Coordinated Care Organizations, for example, networks of healthcare providers receive per-capita monthly payments to serve Medicaid beneficiaries. Participating healthcare providers offer whatever services the members need to keep them healthy. The idea was that the coordinated care organizations could provide the right basket of services, including nonmedical assistance, such as buying asthmatic patients a vacuum cleaner to keep their homes free of dust or buying an air conditioner for patients with congestive heart failure to keep them cool in hot weather. The limits of what could be covered were lifted in an effort to allow the system to focus on patient outcomes.

This system creates many opportunities for our profession. If a vacuum cleaner presents a worthwhile investment, certainly intensive medication-focused intervention on admission and at discharge would meet that definition. But capitalizing on these opportunities is unlikely to come from explicit public policy interventions, because part of the drive away from fee-for-volume and toward fee-for-value was a desire to shift decision-making back to providers and away from policymakers and payers. In an era when policymakers are attempting to step away from mandates and specifying new covered services, the need for exercising our professional responsibility, creativity, and collaboration increases. In risk-based payment systems, creativity often carries the day when it is supported by a staffing plan, measurable goals, and an understanding of the costs and benefits of the intervention.

As health-system pharmacists, you bring tremendous expertise to the table. The continuum of risk-based payment includes, and emerges from, structures like bundled payments, a concept with which many of you are familiar. You understand the idea of consolidating services within a broader payment structure, of collaborating with your colleagues to care for patients, or assembling the right multidisciplinary teams to change practices or improve operations. You understand that the investment in the right medication intervention today can pay dividends in the future, even if you do not yet get credit for that in your pharmacy budget.

Now I expect that some of you are uncomfortable with this scenario, one where you walk in not with a mandate of “you must allow us to provide this service because the law says so” or “our services are now billable” to one where the conversation focuses on explaining our value. But I know you and our profession are up to the challenge. We must couch our conversation in terms of risk-based payment and the impact on patient outcomes, quality ratings, and costs. In these situations, the value of professional responsibility is higher than that of public policy. Risk-based payment is more akin to empowering us to choose the best route on the road and use more of our skills to get to the destination, but also to fail—spectacularly. The most successful endeavors will involve clarity of roles, strong collaboration, and careful measurement of the intervention and outcome.

More change on the horizon

As healthcare continues to change, opportunities requiring a heavier dose of professional responsibility and a lower impact of public policy will continue to emerge. Imagine the need for a new antibiotic stewardship program in your facility. Is that need best met by pursuing an amendment to state law to require that pharmacists provide such services? Or will a proposal that maximizes the contributions of infectious diseases specialists, pharmacists, nurses, and other personnel provide a greater opportunity to address this need? In the evolving healthcare system, the road is opening up a bit for us—requiring more individual engagement to stay within the guardrails and increase our speed, but with the opportunity to better contribute to patient care. We are on the cusp of upgrading beyond MapQuest, with a more powerful engine and many more options.

Some of you may also be asking, Why would she tell us this when we are here for Policy Week? After all, we convened to exercise our public policy muscles. You are, and you must. We require a strong public policy foundation to empower our
activities, and the right balance will be found only with intentional and continual review. I challenge you to think about the right balance of public policy (particularly statutes and regulations) and professional responsibility. Consider where we need guardrails and specific MapQuest routes, where we need well-trained and well-equipped professionals, and what training and equipment are required by any new structures. ASHP has an important role throughout this continuum, in supporting public policy interventions as well as supporting your professional responsibilities, and it can meet that role only with your input.

Thank you for the opportunity to share these thoughts with you today, and I hope I have stimulated some discussion. Let’s talk.