



*Report of the Steering Committee for the*

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# NABP RESEARCH AND INNOVATION INSTITUTE

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## Report of the Steering Committee for the NABP Research and Innovation Institute

### Members Present

Kimberly Grinston (MO), *chair*; Ronda Chakolis-Hassan (MN); John Colaizzi (NJ); Cecil Cordle (GA); Reggie Dilliard (TN); Allison Hill (DC); Ricky Indovina (LA); Priyal Patel (OR); Rich Palombo (NJ); Denise Scarpelli (IL); Christian Tadrus (MO); and Bev Zwicker (NS).

### Others Present

Brad Hamilton, *Executive Committee liaison*; Micah Cost (Pharmacy Quality Alliance), Jeff Mesaros (NABP President), Greg Myers (Deloitte Consulting LLP), and Krystalyn Weaver (National Alliance of State Pharmacy Associations), *guests*; Lemrey “Al” Carter, Melissa Becker, Larissa Doucette, Andrew Funk, Eileen Lewalski, Neal Watson, Gertrude “Gg” Levine, and Maureen Schanck, *NABP staff*.

### Introduction

The steering committee met on November 12-13, 2024, at NABP Headquarters in Mount Prospect, IL. The steering committee was established to inaugurate the presidential initiative of NABP President Jeff Mesaros.

### Review of the Steering Committee Charge

Charge of the steering committee:

1. Review and discuss the goals of Jeff Mesaros’ presidential initiative, which establishes the new NABP Research and Innovation Institute;
2. Recommend any additional goals that should be considered through the initiative;
3. Evaluate tentative pathways for interested stakeholders to identify innovative processes for boards of pharmacy to consider in order to begin accomplishing these goals;
4. Recommend additional potential stakeholders and their possible roles in the initiative; and
5. Review submitted proposals from interested stakeholders and determine commitments.

### Background and Discussion

#### Introduction to the Institute

The discussion began with a review of the steering committee<sup>1</sup> charge and the recognition that the committee was created to launch Jeff Mesaros’ presidential initiative, which establishes the new NABP Research and Innovation Institute. The chairperson reviewed the meeting agenda, which called for an overview of the Institute’s purpose and goals, a discussion of its structure and utility to the boards of pharmacy and regulated entities, a review of the process for accepting proposals, and an assessment of two proposals that were submitted to the Institute.

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<sup>1</sup> During the course of the meeting, the committee discussed whether the Institute would benefit from the participation of additional stakeholders. Some suggested, for example, that it should include the input of pharmacy technicians.



The steering committee first explored the situational landscape leading to the Institute's formation. President Mesaros explained that, when it comes to pharmacy practice models that incorporate new innovation and technologies, boards of pharmacy often lack the data needed to make informed decisions about them. Boards of pharmacy sometimes reject proposals for new innovations because of uncertainty regarding patient risk. The purpose of the Institute, therefore, would be to serve as a resource for boards of pharmacy to access information about innovations and emerging technologies so that they can make informed decisions that enable practice improvements.

Organizers explained that this steering committee differs from a typical NABP single-issue task force in that it will span two years, meeting each quarter to focus on the initiatives of both the current and the next president. The first year will be primarily dedicated to discovery, including outreach to health care organizations, such as the National Council of State Boards of Nursing and the Federation of State Medical Boards, to determine their regulatory approaches to innovation, as well as outreach to stakeholders, such as associations of chain and independent pharmacies, to understand their needs and challenges. Plans include surveying the boards of pharmacy to identify the questions they are hearing from the industry regarding innovations and emerging technologies, the barriers they face in addressing such inquiries, and how the Institute can help them make informed decisions. Year two of the Institute will focus on implementing solutions.

### Purpose of the Institute

Committee members recognized the importance of bringing regulators and industry together to identify problems and solve them. The committee observed that one of the biggest hurdles that boards of pharmacy face is a lack of understanding of new technologies: how they work, how they can be implemented, and whether they are safe. Board of pharmacy members may lack the expertise to determine whether a proposed innovation is based on sound research. This lack of understanding can lead to the creation of regulatory barriers. The steering committee acknowledged that some boards of pharmacy are understandably hesitant to allow new technology to be implemented too quickly. Data provided to boards of pharmacy via the Institute may help to allay such uncertainties and build confidence in potential advancements.

Committee members noted that some retrospective work needs to be done in states that want to allow for practices or policies that are already in place in other states. Meanwhile, some states are struggling with weighing untested innovations. The Institute is intended to facilitate advances in either case by bridging the goals of boards and industry.

The steering committee agreed that the Institute can support the boards of pharmacy by compiling and disseminating information about innovations that have been allowed in some regulatory environments, therefore facilitating their advancement. Committee members discussed innovative practices and regulatory allowances adopted in their states after learning about allowances provided by another state. They also cited instances in which regulations prevented good ideas from being implemented, subsequently requiring rule revisions to allow those innovations to move forward.

Members agreed that the Institute will help to identify regulatory barriers and facilitate their removal, as to avoid blocking practice advancements and preventing patients from getting the best care. Of utmost importance, the committee observed that the Institute will provide the boards of pharmacy and NABP with the opportunity to be proactive and look to the future.

### Current Challenges for the Practice and Regulation of Pharmacy



As part of the discussion, the steering committee considered some of the challenges currently facing pharmacy practice, as well as those that may arise in the future. Members noted significant pharmacist shortages that are projected to worsen in the coming years due to a declining number of pharmacy school graduates. They also noted the increasing number of community pharmacy closures, creating pharmacy “deserts” in rural and urban regions and limiting patient access to pharmacy care.

Meanwhile, committee members noted that boards of pharmacy are consistently asked to relax rules to allow new business models. This is because innovation and public demand for such innovation are moving quickly, and regulatory changes cannot keep up. These dynamics call for new approaches to move regulation forward. Members agreed that boards of pharmacy need to consider how they can use innovation, data, and research to evaluate new business models while ensuring patient protection.

### Operation of the Institute

How the Institute would operate was a major topic of discussion for the steering committee. The committee agreed that the Institute would serve as a repository for data on pharmacy innovation and technology. It would provide a virtual library where boards of pharmacy can access this data, as well as information on the challenges that other jurisdictions faced, how they were addressed, and the outcomes that followed. Both successes and failures would be included to provide valuable insights and enable boards to avoid repetitive trials and errors. Boards would use this information to help make decisions when faced with similar problems and proposals.

The initiative would also encompass innovations for the boards of pharmacy themselves. For instance, a board could submit information that demonstrates how they went about adopting a certain technology to convert manual, time-consuming tasks to efficient electronic undertakings. In such cases, a similar assessment of the problem, solution, and outcome could provide useful guidance.

Discussion ensued on which roles NABP and the Institute would play in vetting the data that applicants provide. The steering committee determined that NABP would remain neutral, with respect to proposals submitted to the Institute. While further discussion will be needed to clarify the function of the Institute in relation to NABP, members agreed that the Institute’s role would be to collect, analyze, and make the data usable for pharmacy boards. It would identify pros and cons of a proposal and drive an understanding of the innovation, including advantages and disadvantages. Informed by the Institute’s assessment of whether the information is valid, accurate, and objective, decisions on whether to accept or reject a proposal or modify a policy would fall to the boards of pharmacy.

The committee acknowledged that, while a repository of problems, solutions, and outcomes would help boards of pharmacy weigh innovations, associated risks, and potential benefits, the information would quickly become outdated and would have to be continuously updated. They noted that this is a challenge that will need to be addressed.

### Communication About the Institute

To encourage boards of pharmacy to take advantage of the Institute, the steering committee agreed on the need to make them aware of it, its purpose, and its ability to support their public health mission. Committee members determined that the Institute should not only collect proposals for innovative practices and technologies but also have a component to disseminate the information it collects so that boards of pharmacy can benefit from it. They agreed that boards should be provided



with a mechanism to request information from the Institute about specific ideas they are considering. In addition, other opportunities for dissemination may include articles, reports, Annual Meeting speeches and presentations, and webinars.

Another means of communication regarding the Institute would be through a survey sent to the boards of pharmacy. In addition to gaining insight into the questions that boards of pharmacy are receiving from industry, the barriers they face, and how the Institute can help them make informed decisions, a survey could educate boards about the Institute. Such a survey might ask boards what their challenges are, what proposals they are hearing, and whether they are able to approve pilot projects, and, if so, what they are learning from them. Surveying the boards would help to identify information gaps that, when filled, could help to allay concerns about implementing new processes. The committee determined that compiling and disseminating this information would be useful to NABP, the Institute, and pharmacy boards.

### Charter Development for the Institute

As a next step, the steering committee agreed on the need to develop a charter describing the role of the Institute and a framework to assess technology and innovation proposals. For reference, the committee considered the Nova Scotia College of Pharmacists' "Prescribing in Accordance with a Research or Pilot Protocol: Guidance for Research and Pilot Project Teams." Members agreed that, like the Nova Scotia guidance, the charter should provide uniformity regarding information that the Institute collects, and the criteria it uses to review it objectively.

With this in mind, the committee began drafting a charter outlining the roles of the Institute. Specifically, the committee determined that the Institute would do the following: 1) serve as a repository of raw and impartial data; 2) act as a communication resource; 3) have a process for reviewing, encouraging, and sharing innovative pilot projects; 4) provide proactive education within and beyond the pharmacy community; and 5) have a process for researching and identifying regulatory barriers impacting innovation in pharmacy practice.

### Proposal Submission to the Institute

The committee then turned its attention to the Institute's process for accepting proposals from industry. While agreeing to avoid a complicated application process, the committee considered what information applicants should provide in a proposal. The committee discussed what boards of pharmacy would need to know to determine whether a proposed initiative is appropriate for a pilot project.

As a starting point, members reviewed the Research and Innovation Institute Proposal Form that applicants currently use, which is available on the NABP website. The form asks for a description of the applicant's organization, the advanced practice model and/or innovative use of technology that will be evaluated, how it will benefit patients (specific regulatory barriers), and how the Institute can help generate objective evidence and/or data to assist in removing regulatory barriers. The committee considered whether the current form is sufficient to garner the pertinent information, or whether it should include additional questions. NABP agreed to refine and enhance the proposal form using ideas and concepts from the Nova Scotia guidance document.

The committee then reviewed two proposals submitted to the Institute. One proposed the use of artificial intelligence to supplement patient counseling in the pharmacy. The other introduced an electronic mechanism designed to catch prescribing errors. The committee explored the pros, cons, and information gaps in each proposal and considered whether it is a viable and reasonable use



case. Ultimately, the committee concluded that both proposals have merit. Members also agreed that boards of pharmacy will want to know that these innovations are being discussed and will likely raise many questions.

The steering committee considered whether more detail is needed and brainstormed additional questions they might want to ask. For instance, additional questions might ask how the data was collected, the steps applicants have taken to ensure the data are correct, and the guardrails they have put in place to avoid mishaps. It was suggested that the two applicants could join the next steering committee call as a way for the committee to better understand the proposals and fine tune the Institute's processes.

Committee members also considered the reasons that industry stakeholders might submit proposals to the Institute. They agreed that the Institute could facilitate a pilot project between a stakeholder and a board of pharmacy that is interested in exploring the proposed technology. It was emphasized that the Institute's role would not be to conduct the research, but to bring the information to the attention of the interested stakeholder and board.

Regarding administrative issues, the committee considered whether the Institute should require applicants to sign a confidentiality agreement to prevent them from misrepresenting NABP as endorsing a proposal. The committee also contemplated whether the Institute should charge an application fee to cover the administrative costs involved in reviewing proposals. In the event that the Institute is inundated with a high volume of applications, the amount of work to review and analyze each one may require additional resources. The committee agreed to use the two proposals received as a barometer to determine how much time and work is required.

## Recommendations

After careful review and deliberation, the steering committee made the following recommendations:

1. Survey the boards of pharmacy to identify the challenges they are presented with, the questions they receive from industry regarding innovations and emerging technologies, the solutions industry stakeholders propose, the barriers the boards face in addressing inquires, what the boards have learned from dealing with these issues, and how the Institute could help the boards make informed decisions.
2. Create a repository of data focusing on pharmacy practice problems, tested solutions, and outcomes as a resource for boards of pharmacy.
3. Disseminate information to the boards of pharmacy about the Institute, its purpose, and, over time, the data it gathers.
4. Finalize the charter to establish the role of the Institute and its processes for assessing proposed innovations.
5. Refine and enhance the Research and Innovation Institute Proposal Form using the Nova Scotia guidance document as a reference.
6. Consider inviting the two applicants whose proposals were reviewed to participate in a future steering committee meeting to learn more about the proposals and further refine the Institute's application review process.