The American Pharmacists Association Academy of Student Pharmacists (APhA-ASP) is proud to present Operation Diabetes, a national patient care project focused on the prevention of diabetes and the complications associated with it. By participating in public awareness campaigns, community outreach activities, and individual patient assessment and education, student pharmacists can help patients understand their risk for diabetes. With your support, student pharmacists involved in the Operation Diabetes campaign can empower patients with the knowledge and management strategies necessary to reduce their risk for diabetes.

As APhA-ASP Chapter Advisor, you serve as a consultant, advocate, and a point of continuity for your chapter and its leaders. To assist you in these roles, please review the following sections for information on:

- Safety and Other Regulatory Considerations
- Screening and Photo Release Forms
- Operation Diabetes Reporting Guidelines

The information in this planning guide is meant to serve as a foundation for organizing an Operation Diabetes campaign but should not be considered comprehensive. In addition to federal requirements, many states and local agencies (e.g., state boards of pharmacy, local health departments) may have additional regulations. Please assist your chapter leaders with consulting these entities prior to conducting community events.

As an APhA-ASP Chapter Advisor, you play a vital role in both the success of your chapter’s Operation Diabetes campaign and the personal and professional development of student pharmacists. APhA would like to thank you for your continued support of student pharmacists and their activities.

**Regulatory Considerations**

Operation Diabetes presents student pharmacists with a unique opportunity to positively impact public health while promoting the profession of pharmacy. While the disease state screenings reviewed in this guide allow for a more comprehensive assessment of patients in the community, they may also be subject to additional laws and regulations. To reduce potential liability associated with patient care activities, you should ensure that student pharmacists participating in Operation Diabetes are appropriately trained (and when necessary, supervised by a trained health care professional) when performing disease state screenings or providing individual patient education. Additionally, student pharmacists should adhere to all applicable local, state, and national regulations and safety procedures. Examples include the following:

- Ensure patients understand the information and services being provided to them. In some states, informed consent may be required before patients may participate in certain activities. Patients should also understand who is providing the information or service (e.g.,
student pharmacists) and that these activities should not be viewed as a substitute for evaluation by their primary care provider.

- Ensure student pharmacists obtain appropriate training (i.e., recognized by professional and regulatory bodies) prior to providing patient education or performing disease state screenings and other patient care activities. While students may receive some training as part of the pharmacy curriculum, it may be beneficial to provide additional training prior to Operation Diabetes events. (See the “Planning Events” section for suggestions on training approaches.)

- Follow standards and other safeguards required by your state board of pharmacy and other federal, state, or local regulatory agencies. For example, supervision by a licensed pharmacist may be required. Additionally, pharmacists participating in community events are encouraged to hold personal liability insurance.

Institutional Review Board

Some patient information may be collected and shared with APhA and other organizations as part of the Operation Diabetes campaign. Based on the definitions employed by your school or college’s Institutional Review Board (IRB), this may constitute “research” and may therefore be subject to IRB review or approval. As APhA-ASP Chapter Advisor, you should guide your chapter leaders through this process. Additionally, ensure that all patient information is properly destroyed after project reports are completed.

Safety & Blood Exposure Risks

If student pharmacists perform blood glucose screenings as part of the Operation Diabetes campaign, these activities must comply with standards regulated by the Occupational Safety and Health Administration (OSHA). These requirements are designed to reduce the risk of exposure to blood-borne pathogens, such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). One approach to these regulations is known as “universal precautions”, where all human blood and other potentially infectious materials are considered infectious. Regulations became more rigorous in 2001 with the implementation of the Needle Stick Safety and Prevention Act, which requires entities to use safer needle devices and maintain a log of injuries from contaminated sharps. All health care professionals, including student pharmacists and other trainees, must comply with the updated regulations. Other safety strategies may include the following:

- Ensure student pharmacists are trained on the safe and appropriate handling and disposal of sharps devices (e.g., needles, lancets). For example, syringes and needles should not be separated or recapped after use. Instead, they should be placed in a designated sharps or biohazard container.

- Consult applicable regulations concerning the disposal of sharps containers. For more information, also consider contacting a waste-disposal company in your area.
Several states now encourage or require use of specially-designated safety needles/lancets that reduce the risk of needle-stick injuries.

Federal legislation requires that institutions develop a policy that addresses pre-exposure vaccination, post-exposure management (e.g., hepatitis B vaccine, HBIG), as well as medications appropriate for acute post-exposure management of HIV-infected blood. Ensure student pharmacists understand and comply with this policy during their patient care events.

Student pharmacists should keep the work area clean. Student pharmacists are encouraged to wear gloves and should consult policies recognized at local health clinics.

For more information on needle stick prevention, be sure to visit the following web site: http://www.osha.gov/SLTC/bloodbornepathogens/standards.html.

CLIA Waivers

All laboratory testing performed on humans is subject to regulation by the US Centers for Medicare & Medicaid Services (CMS) as part of the Clinical Laboratory Improvement Amendments (CLIA). The goal of CLIA is to ensure the safety and quality of laboratory measurements. CLIA regulations are categorized by test complexity as being waived, moderate, or high. Most point-of-care tests conducted as part of community health screenings are considered CLIA-waived and only require certification/training to perform. Examples include point-of-care tests to evaluate blood glucose and lipid levels.

Student pharmacists should observe good laboratory practices when conducting disease state screenings and other patient care activities. Such practices may include the following:

- Keep the manufacturer product insert for each laboratory test and ensure it is available at all times. Always use the product insert for the kit currently in use. Read the product insert prior to performing a test.

- Follow the storage requirements for the test kit. Do not mix components of different kits.

- Assemble all required reagents and equipment before performing each test.

- Become familiar with the test procedure. Perform each step in the proper order.

- Know the time required for performing the test and achieving an optimal result.

- Be able to recognize when the test is finished.

- Follow manufacturer instructions for ensuring quality-control prior to testing samples.

- Follow manufacturer instructions for specimen collection and handling (e.g., temperature and container requirements).
• Be sure to label the specimen with an identifier unique to each patient.

• Inform the patient of any test preparation (e.g., fasting, clean catch urines).

• Record test results in the proper place rather than on unidentified notes or pieces of scrap paper, which could be misplaced. Include the name of the test, the date the test was performed, and the initials of the testing personnel in the test record. If the same test is performed on a patient multiple times in one day, include the time of each test.

• Record the results according to the instructions in the product insert.

• If the test is qualitative, spell out positive or negative results, as symbolic representations can be altered (the “–” can be altered to a “+”).

• Perform instrument maintenance as directed by the manufacturer.

Additional information on CLIA is available at http://www.cms.hhs.gov/clia.

Screening & Photo Release Forms

Samples of screening evaluation sheets, logs, and participation forms have been provided in this planning guide. These samples should be adjusted to meet the needs of each chapter. You may want to consider consulting the legal team at your school or college of pharmacy to develop a photo release form for any photos taken during your events, especially if you intend to show participant faces in your photos.

Operation Diabetes Reporting Guidelines

As a Chapter Advisor, you must review and approve the Operation Diabetes report prior to its submission to APhA. For a full description of the Operation Diabetes reporting requirements, please see in the Reporting Guidelines section.