IACP
INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS

Our Position
IACP Position Statement

IACP Recommendations for State-Based Legislative and Regulatory Initiatives

The International Academy of Compounding Pharmacists (IACP) supports statutory or regulatory language changes to state pharmacy practice acts which address three key areas – inspection authority and adequate funding of all state Boards of Pharmacy; the compliance with laws and regulations by all pharmacists and pharmacy technicians in all practice settings as well as other health care practitioners involved in compounding; and, required adherence to quality standards.

IACP is committed to working in collaboration with state pharmacist associations as well as all state Boards of Pharmacy to develop and implement changes in pharmacy practice acts that protect the public health and preserve the professional decision making of pharmacists in the selection and preparation of customized medication solutions.

Our Core Principles

Inspection Authority and Secure Board Funding

IACP believes that all state Boards of Pharmacy have the authority to appropriately oversee the practice of pharmacy compounding. IACP supports actions to adequately fund each state Board to enable them to carry forward the enforcement of laws and regulations which protect the public. These include action in the following areas:

- **Increase funding and assured allocation of funding for State Boards of Pharmacy that is sufficient to hire and/or contract with qualified inspectors.**
- **Mandatory use of trained pharmacists for inspections by State Boards of Pharmacy.**
- **Provide for comprehensive training and certification for all inspectors used by State Boards of Pharmacy.**
- **Provide for comprehensive training and certification where appropriate for all inspectors used by State Boards of Pharmacy specific to sterile compounding and USP <797> standards.**
- **Establish a minimum annual inspection of all pharmacy practice sites that conduct sterile compounding (including hospitals, long-term care facilities, hospice, home infusion, specialty pharmacies, and others.)**
- **Require a minimum annual inspection of all non-pharmacy practice sites that conduct sterile compounding (including physicians, clinics, veterinarians, etc.)**
- **Require regular unannounced inspection of all pharmacy practice sites that conduct any type of compounding (including physicians, clinics, veterinarians, and others).**

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Compliance with State Laws and Regulations

Just as regulatory agencies are responsible for protecting the public, so too are the regulated pharmacies and pharmacists. IACP supports state legislative and regulatory efforts which:

- **Require non-resident pharmacy to comply with all state laws/rules and demonstrate proof of regular inspection by their Board of Pharmacy in original state.**
- **Require wholesalers/distributors that provide supplies to compounders be registered in the state they are doing business, quality and tracking requirements, unusual quantity alerts.**
- **Clarify regulations which permit the compounding and dispensing of prescriptions issued by authorized prescribers for "office-use" in their treatment of patients.**

Quality Assurance in Compounding

Consistency and recognition of core compounding standards are essential to the preparation of compounded medications as well as to the improvement of patient drug therapy management. IACP believes that all states should:

- **Require compliance with USP <795> for all non-sterile compounding by all pharmacy practice settings and pharmacists.**
- **Require compliance with USP <797> for all sterile compounding by all pharmacy practice settings and pharmacists.**
- **Require specific continuing education credit requirements in compounding for any pharmacist that provides compounding services to patients or prescribers.**
- **Require CQI and other quality assurance programs by all pharmacies involved in sterile compounding.**
- **Require CQI and other quality assurance programs by all pharmacies involved in any form of compounding.**
- **Clarify that all compounding must be conducted using either finished manufactured drug products or APIs (Active Pharmaceutical Ingredients) if they are either: a) components of an FDA approved drug; or b) an API that has a USP monograph or a monograph published in a recognized compendia; or C) is supplied by an FDA registered supplier and has a COA.**

For additional information regarding this or other IACP Position Statements, please contact:

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