PCCA overview of HR 3089, the “Compounding Clarity Act of 2013”

On September 12, 2013, Representatives Morgan Griffith of Virginia (R-VA), Diana DeGette (D-CO) and Gene Green (D-TX) released a draft of a House Resolution 3089 called the “Compounding Clarity Act of 2013.” PCCA has put this document together as a factual overview of some of the key points of the bill for their member pharmacies and their patients. The full text of the bill can be found at http://bit.ly/150uv9o

HR 3089 sets forth the following:

- Clear definitions that compounding within the patient-pharmacist-prescriber triad is legal and not subject to FDA oversight.
  - Part of this definition is: “The drug product is compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician, for an identified individual patient based on the receipt of a valid prescription.”

- Allows for anticipatory compounding in limited quantities based on:
  - “Historical demand for the drug product” and
  - “A history of prescriptions for the drug product generated solely within an established relationship between” the compounder and “the individual patient” or the prescriber “who writes the prescription.”

- Allows for compounding for office use, as long as the following criteria are met:
  - “The drug product will be administered by a health care practitioner within a physician’s office, a hospital, or another health care setting” and
  - “Valid patient-specific prescriptions” or “valid patient names” are submitted back to the compounder no later than seven business days after the drug was administered and
  - Account for the total volume of drug product dispensed for office use and
  - During any six month period, not more than 5% of total drug products dispensed from the facility are compounded sterile drug products and shipped interstate and
  - Records of compounding for office use are kept for not less than three years and
  - The statement “Office Use Only” and “Not for Resale” appears on the compounded drug product.
  - Provides a good faith clause in which the pharmacy will not be found liable for prescribers who do not provide patient-specific prescriptions or valid patient names as long as the pharmacy does not continue to sell office use products to the facility.

- The drug product must be compounded in compliance with USP chapters applicable to compounding (including sterile preparations).

- Bulk drug substances (APIs) must meet one of the following criteria:
  - A USP/NF monograph exists and the API meets the requirements of the monograph or
  - Be a component of an FDA product approved for human use or
  - Be listed on a list of approved APIs that the FDA develops for use in compounding.
  - All APIs must be manufactured in an FDA-registered facility.
- “Ingredients (other than bulk drug substances)” must comply with an applicable USP or NF monograph.

- FDA maintains a list of “Drug products withdrawn or removed because unsafe or not effective.”

- Compounders cannot compound an essential copy of a “marketed and approved drug product” unless:
  - The drug product appears on the FDA drug shortage list or
  - The compound would produce a clinical difference for an individual patient as determined by the prescriber.

- Allows the FDA to create a list of drug products that are “demonstrably difficult” for compounding.

- Prohibits the act of wholesaling compounded drug products.

- Sets up a regulatory framework in which the State Boards of Pharmacy shall communicate the following to the FDA:
  - Actions taken against compounding pharmacies by the Board, which include:
    - Issuance of warning letters, or State sanctions or penalties pertaining to compounding
    - Suspension or revocation of a license or registration
    - Recall of compounded drug product
  - Board concerns that a compounding pharmacy is acting in violation of the bill
  - Similarly, the FDA must notify the State Boards of Pharmacy if they receive a complaint regarding a pharmacy.

- Sets forth inspection authority for the FDA over compounding pharmacy’s records if:
  - The inspection is performed in coordination with the Board of Pharmacy or
  - The FDA has evidence that the pharmacy may be in violation of the bill

- Creates a new category of pharmacy called “Outsourcing Facility” that would be applicable only to pharmacies that compound sterile products for office use, shipped interstate, in excess of 5% of the total volume of compounded drugs in any six-month period.
  - Outsourcing Facilities are subject to cGMP regulations.
  - These facilities may not compound standardized dosages, from bulk substances, that are not otherwise commercially available copies of a marketed and approved drug product.

- The bill considers repackaging as compounding and defines repackaging as taking an approved drug from the original container and placing the drug “in a different container of the same or smaller size without further manipulating the drug.”

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