Summary of bills that passed in the 2014 Connecticut legislature that may be of interest in the pharmacy/medical world in which we practice:

HB 5262: AN ACT CONCERNING THE PHARMACY PRACTICE ACT AND COUNTERFEIT DRUGS

This bill was actively monitored by CSHP and the CT Hospital Association (CHA). We thank Jan Kozakiewicz and Michael Rubino for their input on various iterations of the bill's language as it went through the process. CSHP supported substitute language submitted by CHA and in the final version, much of the language was changed to our approval, however the final passed version may impact hospital pharmacy practice. The bill makes several changes to pharmacy law, here is a summary of the bill's content:

<u>Sterile Compounding</u>

a. The bill requires sterile compounding pharmacies to comply with USP 797, and maintain a policy and procedure manual that complies with USP standards, including among other things, sterilization methods and training.
b. A "sterile compounding pharmacy" is a pharmacy, including any located in healthcare institution, or a nonresident pharmacy that dispenses or compounds sterile pharmaceuticals.
c. The bill requires sterile compounding pharmacies to file an addendum to their pharmacy application with DCP before compounding sterile pharmaceuticals for use in the state. DCP, or the appropriate state oversight agency for nonresident pharmacies, must inspect the changes and DCP and the Pharmacy Commission must approve them before a pharmacy can begin compounding sterile pharmaceuticals.
d. The bill allows a sterile compounding pharmacy to provide patient-specific sterile pharmaceuticals only to patients, physicians, osteopaths, podiatrists, dentists, veterinarians; an acute care or long-term care hospital; or a Department of Public Health (DPH) licensed health care facility.
e. The bill requires sterile compounding pharmacies that provide compounded sterile products without a prescription or medical order to get a DCP manufacturing license and any required federal license or registration. A sterile compounding pharmacy may prepare and maintain on-site up to a 30-day supply of sterile pharmaceuticals. The 30 days start from the day compounding is completed, including third party analytical testing performed according to pharmacopeia standards.
f. The bill requires sterile compounding pharmacies to notify DCP at least 10 days before remodeling or relocating a pharmacy clean room.
g. The bill requires sterile compounding pharmacies, other than those in health care institutions, to give DCP a written report of any known violation or noncompliance with viable and nonviable environmental sampling testing, as defined by pharmacopeia standards, within one business day after discovery. A sterile compounding pharmacy within a health care facility must report the violation or noncompliance to DPH.
h. The bill requires sterile compounding pharmacies to notify certain people when they recall sterile pharmaceuticals. By the end of the business day following the recall, they must notify (1) each patient or patient caregiver, the prescribing practitioner, and DCP when the pharmaceutical was dispensed as a patient-specific prescription or medical order and (2) each purchaser of the pharmaceutical, DCP, and the federal Food and Drug Administration (FDA) for pharmaceuticals that were not dispensed as a patient-specific prescription or medical order.

Counterfeit Substances

The bill prohibits anyone from knowingly purchasing for resale, selling, offering for sale, or delivering a counterfeit substance in any manner. Existing law already prohibits several actions related to counterfeit or misbranded drugs.

Nonresident Pharmacy

The bill broadens the categories of nonresident pharmacies that must (1) register in Connecticut, (2) comply with pharmacy reporting requirements, and (3) provide patient contract information.

Drug Manufacturers

The bill requires pharmacies that dispense compounded drugs without a prescription or an individual medical order to register in Connecticut as drug manufacturers regardless of whether their principal place of business is located in the state.

Dispense as Written Prescriptions

a. The bill creates new requirements for prescribing practitioners and pharmacists when dispensing drugs that cannot be substituted for a generic version.
b. For written prescriptions, the bill requires the prescribing practitioner to indicate on the prescription form that the product is "brand medically necessary" or "no substitution." The bill specifies that no prescription form may default to these terms.
c. For telephoned prescriptions, the bill requires the pharmacist to write the phrase "brand medically necessary" or "no substitution" on the prescription or enter it in the electronic prescription record. The pharmacist must also record on the prescription (1) the time the telephone prescription was received and (2) name of the person who ordered the prescription.
d. For electronic prescriptions, the bill requires the prescribing practitioner to select the "dispense-as-written" code. The bill specifies that no electronic prescriptions may default to "brand medically necessary" or "no substitution."
e. For Medicaid recipients, current law requires prescribing practitioners to specify the basis on which the brand name drug and dosage form is medically necessary compared to a chemically equivalent generic drug substitution. The practitioner must write, in his or her handwriting, the phrase "BRAND MEDICALLY NECESSARY," on the prescription form or on an electronically produced copy of the form. If the prescription was ordered by telephone or electronically and the form did not reproduce the practitioner's handwriting, then (1) a statement to that effect must still be on the form and (2) written certification in the practitioner's handwriting with the phrase "BRAND MEDICALLY NECESSARY" must be sent to the dispensing pharmacy within 10 days after the communication date. The phrase "BRAND MEDICALLY NECESSARY" must not be preprinted, stamped, or initialed on the form.

SB 394: AN ACT CONCERNING REQUIREMENTS FOR INSURERS' USE OF STEP THERAPY

This bill bars certain health insurers that use prescription drug step therapy regimens from requiring their use for more than 60 days. Under the bill, "step therapy" is a protocol or program that establishes the specific sequence for prescribing drugs for a specified medical condition.

At the end of the step therapy period, the bill allows an insured's treating health care provider to determine that the step therapy regimen is clinically ineffective for the insured. At that point, the insurer must authorize dispensation of and coverage for the drug prescribed by the provider, if it is covered under the insurance policy or contract.
The bill requires insurers to establish and disclose to its providers a process by which they may request, at any time, an authorization to override any step therapy regimen.

HB5439: AN ACT CONCERNING BRAND NAME DRUG PRESCRIPTIONS FOR STATE MEDICAL ASSISTANCE RECIPIENTS

This bill eliminates a requirement that a medical practitioner submit a hand-written prescription to a pharmacist stating "brand medically necessary" when he or she electronically submits a prescription for a medical assistance recipient specifying that there can be no substitution for the brand-name drug prescribed. The bill instead requires the prescriber to select the code on the certified electronic prescription that indicates a substitution is not allowed.
The bill also broadens the exception to the requirement that a pharmacist dispense a generically equivalent drug for a brand name one to a medical assistance recipient. Under the bill, a pharmacist must dispense the brand name drug when the prescriber specifies that there shall be no substitution for that drug. Currently, pharmacists may dispense such drugs to medical assistance recipients only if the phrase "brand medically necessary" is ordered.

HB 5386: AN ACT CONCERNING CARE COORDINATION FOR CHRONIC DISEASE

This bill requires the public health (DPH) commissioner to develop and implement a plan to (1) reduce the incidence of chronic disease; (2) improve chronic disease care coordination in the state; (3) reduce the incidence and effects of chronic disease, and (4) improve outcomes for conditions associated with chronic disease.
The plan must address cardiovascular disease, cancer, lupus, stroke, chronic lung disease, diabetes, arthritis or another metabolic disease, and the effects of behavioral health disorders. It must be consistent with the (1) DPH's Healthy Connecticut 2020 health improvement plan and (2) state healthcare innovation plan developed under the State Innovation Model Initiative by the Centers for Medicare and Medicaid Services Innovation Center.
The bill requires the DPH commissioner, by January 15, 2015 and biennially thereafter, to report to the Public Health Committee

1. description of the chronic diseases most likely to cause death or disability, the approximate number of people affected by them, and an assessment of each such disease's financial effect on the state, hospitals, and health care facilities;
2. a description and assessment of programs and actions that DPH and health care providers have implemented to improve chronic disease care coordination and prevent disease;
3. the source and amount of funding DPH receives to treat people with multiple chronic diseases and to treat or reduce the most prevalent chronic diseases in the state;
4. a description of care coordination between DPH and health care providers to prevent and treat chronic disease;
5. recommendations on actions health care providers and people with chronic diseases can take to reduce the incidence of effects of these diseases.