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Testimony concerning SB 328
Committee on Senate Public Health and Welfare
Presented by Debra Billingsley
On behalf of
The Kansas Board of Pharmacy
January 30, 2012

Chairman Schmidt and Members of the Committee:

My name is Debra Billingsley and I am the Executive Secretary of the Kansas State Board of Pharmacy. The Board is created by statute and is comprised of seven members, each of whom is appointed by the Governor. Of the seven, six are licensed pharmacists and one is a member of the general public. The Board of Pharmacy ensures compliance with state and federal laws related to the compounding and dispensing of controlled substances in Kansas.

In 2009, the American Recovery and Reinvestment Act authorized payments to prescribers participating in Medicaid or Medicare if they used electronic prescribing. The incentives to practitioners began in 2011.

The Drug Enforcement Agency (DEA) revised their regulations to provide practitioners and mid-level practitioners with the option of writing prescriptions for controlled substances electronically. The regulations permit but do not mandate pharmacies to receive, dispense, and archive these electronic prescriptions. Senate Bill 328 does not replace existing rules but attempts to recodify federal law and provides pharmacies, hospitals, and prescribers with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances. Pharmacies have been using electronic prescribing for non-controlled substances and they do not have to meet these requirements for drugs that are not scheduled.

The DEA requirements require prescribing practitioners to have specific software applications, identity proofing, set access controls, and electronic signature capabilities. The pharmacies are required to have specific software applications, set access controls, processing capabilities and archive prescription capabilities. Both practitioners and pharmacies must undergo a third-party audit or certification to determine whether their software application meets DEA requirements. A number of auditing companies or

services are available such as Web Trust, SysTrust, SAS 70 and they provide a report or certification to the prescriber. The prescriber must provide these reports to the pharmacy. Likewise, each pharmacy needs to have a report or certificate.

Some of the safeguards and requirements that are in place are that a prescription that is for a controlled substance will have to be transmitted as soon as possible after it is signed. The prescription must remain electronic and cannot be converted to a fax. The prescription may be printed after the signature so long as it is labeled "copy only- not valid for dispensing". Information may be transferred to electronic medical records. Transmitted prescriptions may be printed for manual signature if the practitioner was notified that the transmission failed, but it must indicate that the original was electronic, the name of the pharmacy, and the date and time transmitted. All records must be maintained electronically.

The bill adds new definitions to the existing definitions. The definitions generally came from 21 CFR §1300.03 related to electronic orders of controlled substances and electronic prescriptions for controlled substances. The Board added the definition for the Drug Enforcement Agency. We added the definition "electronic transmission" from language found in the Iowa laws. We expanded the definition of "pharmacy intern" so that it was clear that we meant a pharmacy student, a pharmacy resident, and a foreign pharmacist graduate. We also expanded prescription or prescription order and combined them so that it described them better.

The bill deletes the majority of K.S.A. 65-1637 on page 11 under Section 2 but it is restated on page 13 in new section 3. We did not add any new substantive requirements other than those pertaining to electronic prescribing of a controlled substance as found in the federal law. The new section was meant to provide better explanation of current practices.

After the bill was drafted we did meet with various agencies to address their concerns. We asked for a balloon amendment to address those concerns. In various places we needed to change the word "practitioner" to "prescriber". The federal rules use the term "practitioner" but based on our current definitions we needed to use the term "prescriber" so that it included both practitioners and mid-level practitioners.

On page 14 on line 18 we deleted "certified pharmacy technician" from the bill because pharmacy technicians cannot accept a new prescription in Kansas. On the same page on line 36-38 we deleted the whole section. That section was not applicable to Kansas.

The electronic prescribing has been very complicated. The functionality was only available in a limited area so that the vendors could determine if there would be insurmountable barriers or problems. It is available now in Kansas but most of the prescribers and pharmacies have not received their certificate by the third party auditor. These statutory changes should provide some additional guidance to practitioners and pharmacies as they complete their certification processes. The changes required a great deal of coordination among pharmacies and prescriber technology vendors.

The Board would request that SB 328 be voted on favorably for passage. I would be happy to yield to questions.