

# Self Regulation of the Practice of Pharmacy: Opportunities and Challenges

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North Carolina Board of Pharmacy

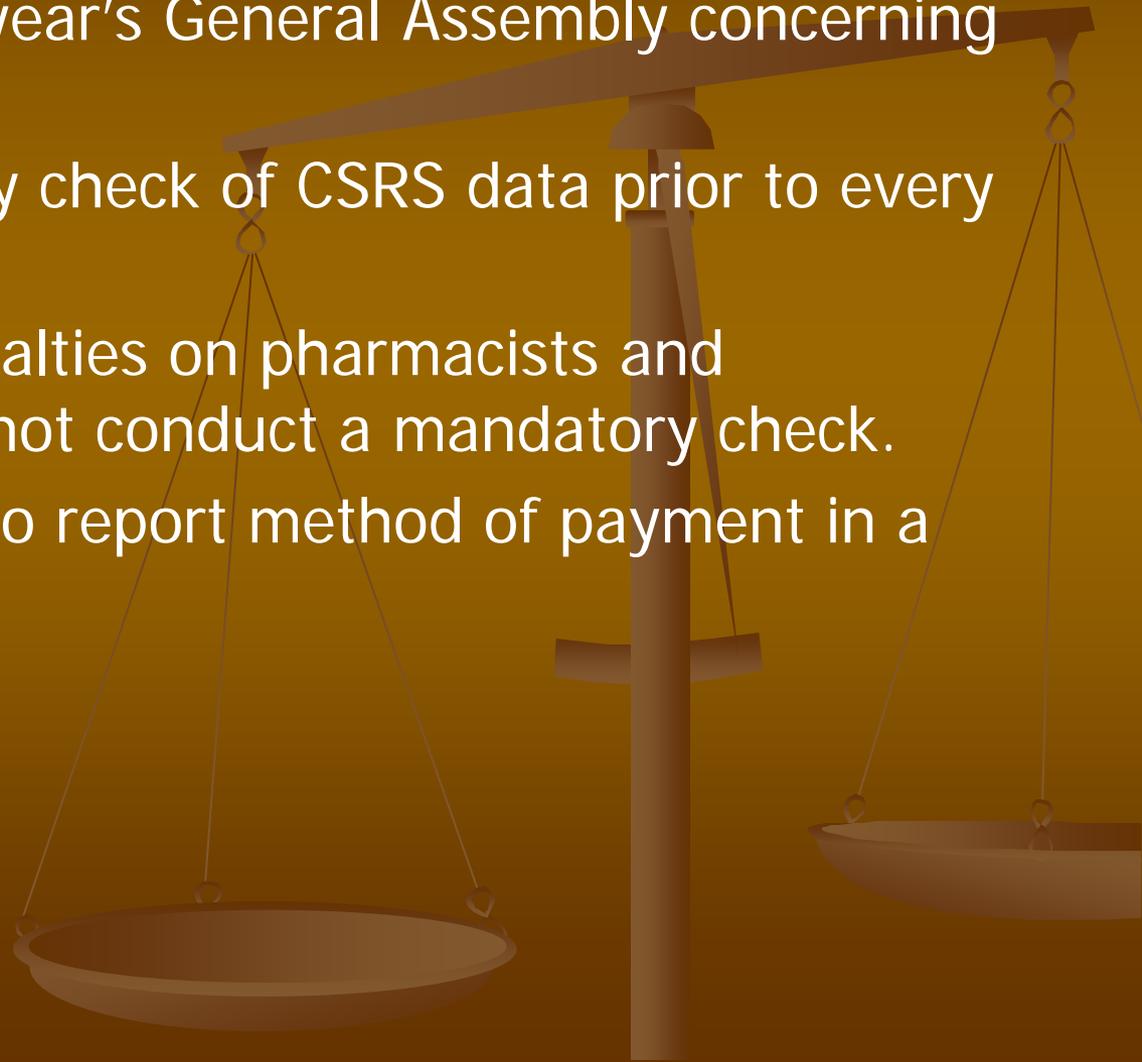




I have no relationships with commercial interests related to the content of my presentation.

# Assessment Questions

1. Bills passed by this year's General Assembly concerning the CSRS would
  - A. Require a mandatory check of CSRS data prior to every CS dispensing.
  - B. Impose criminal penalties on pharmacists and prescribers who do not conduct a mandatory check.
  - C. Require dispensers to report method of payment in a CSRS report.
  - D. All of the above.



# Assessment Question

2. Physicians and veterinarians are both exempt from reporting to the CSRS?

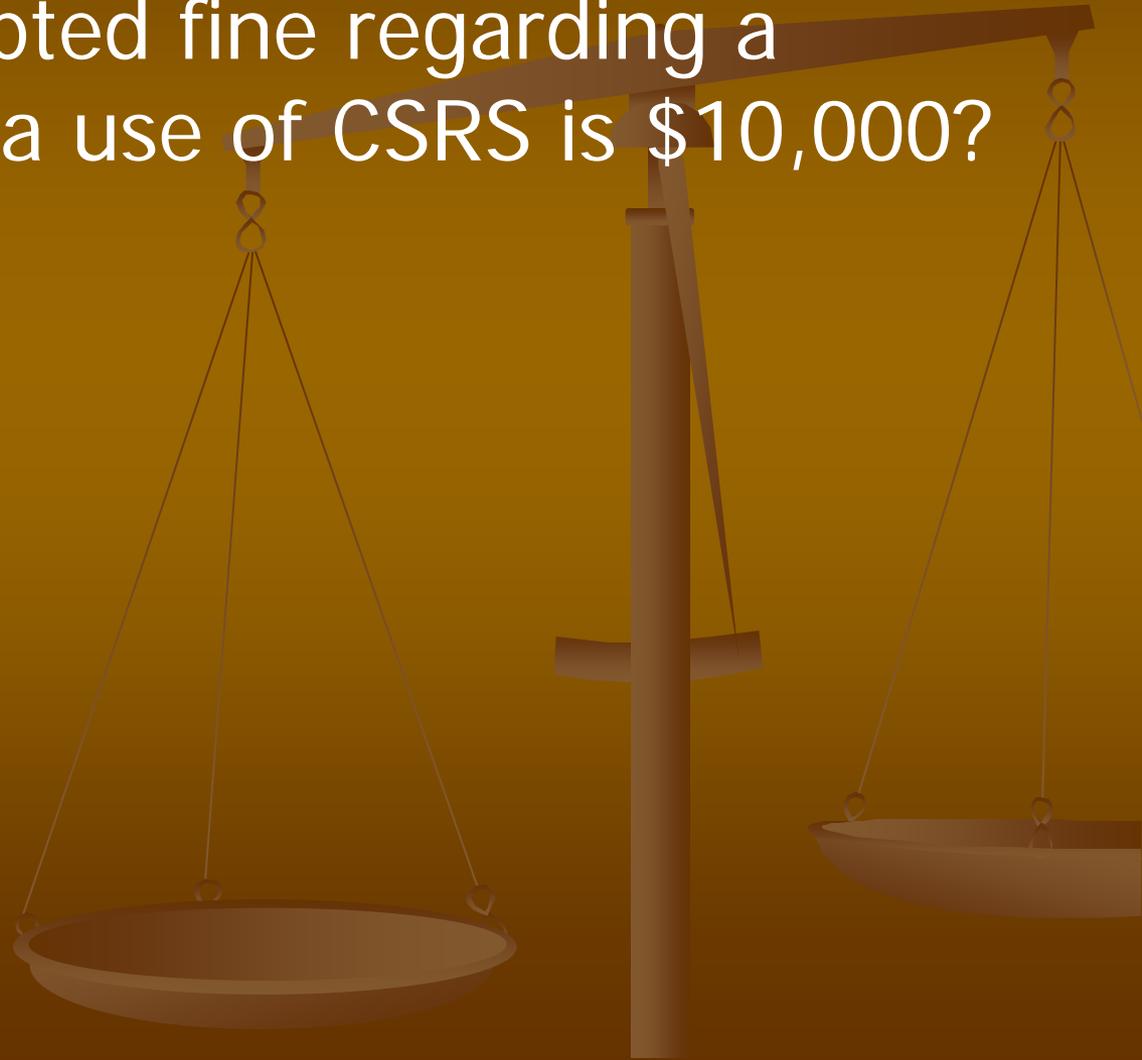
- a) True
- b) False



# Assessment Question

3. The newly adopted fine regarding a HIPAA violation via use of CSRS is \$10,000?

- a) True
- b) False



# North Carolina General Assembly



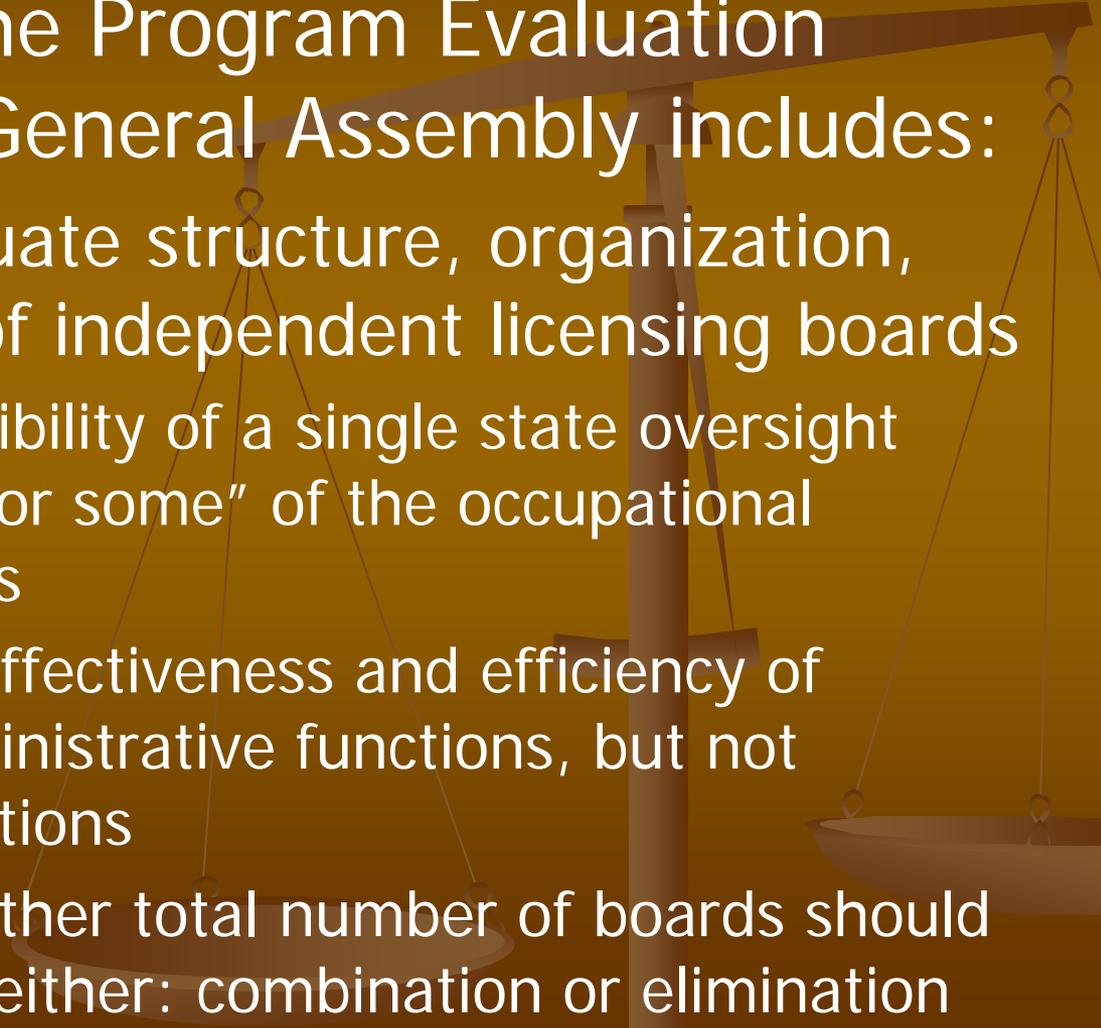
# Bills Passed That Impact the Practice of Pharmacy



# S.B. 33/ H.B. 167

- Use of Criminal History Records
  - Boards must consider the following for convictions that are not automatic disqualifiers of a profession, before denying a license:
    - Seriousness of and circumstances surrounding the act
    - Date and Age of applicant at the time of crime
    - Result of conviction (i.e. probation, prison, etc)
    - Repeat offenses
  - Refusal of Fingerprinting or Background Check is grounds for denying a professional license
    - Required by State or National Repositories of Criminal Histories
  - Signed by the Governor. SL2013-24.

# H74 – Regulatory Reform

- Work Plan for the Program Evaluation Division of the General Assembly includes:
    - A study to evaluate structure, organization, and operation of independent licensing boards
      - Determine feasibility of a single state oversight agency for “all or some” of the occupational licensing boards
      - Evaluate cost-effectiveness and efficiency of combining administrative functions, but not regulatory functions
      - Determine whether total number of boards should be reduced by either: combination or elimination
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# H.173/S.222

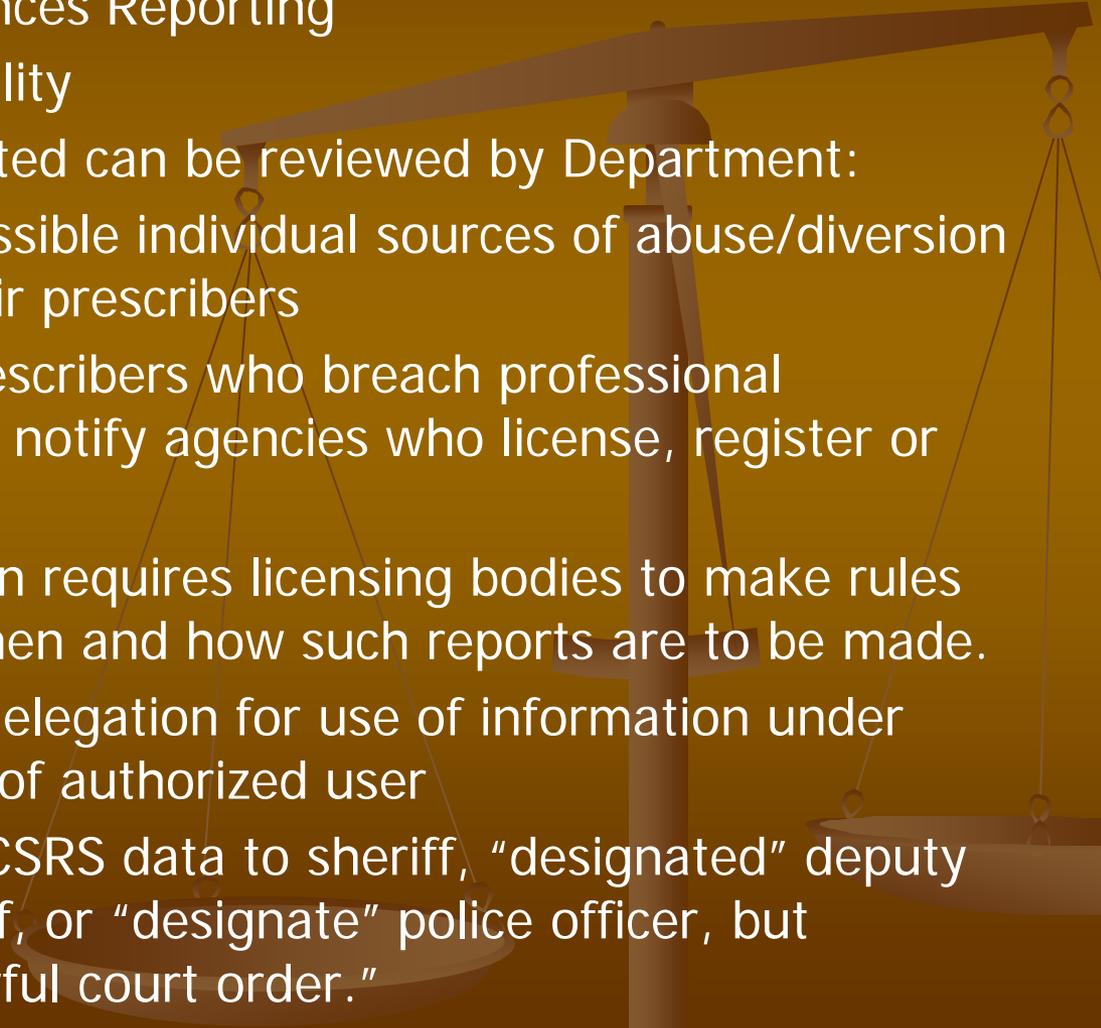
- **Revise Controlled Substances Reporting**
  - **Section 1: Definitions**
    - Eliminates the reporting exception for dispensing physicians.
    - Specifically exempts dispensing veterinarians.



# H.173/S.222(cont'd)

- **Revise Controlled Substances Reporting**
  - **Section 2: Requirements for Controlled Substance Reporting**
    - Uploads will be required within three business days of fill (with daily reports “encouraged”)
      - Time limits have decreased progressively
    - Additional information to be reported:
      - Method of payment
  - **Exception:**
    - 1 time supply for <48h, distributed directly to end user
      - Will not require reporting

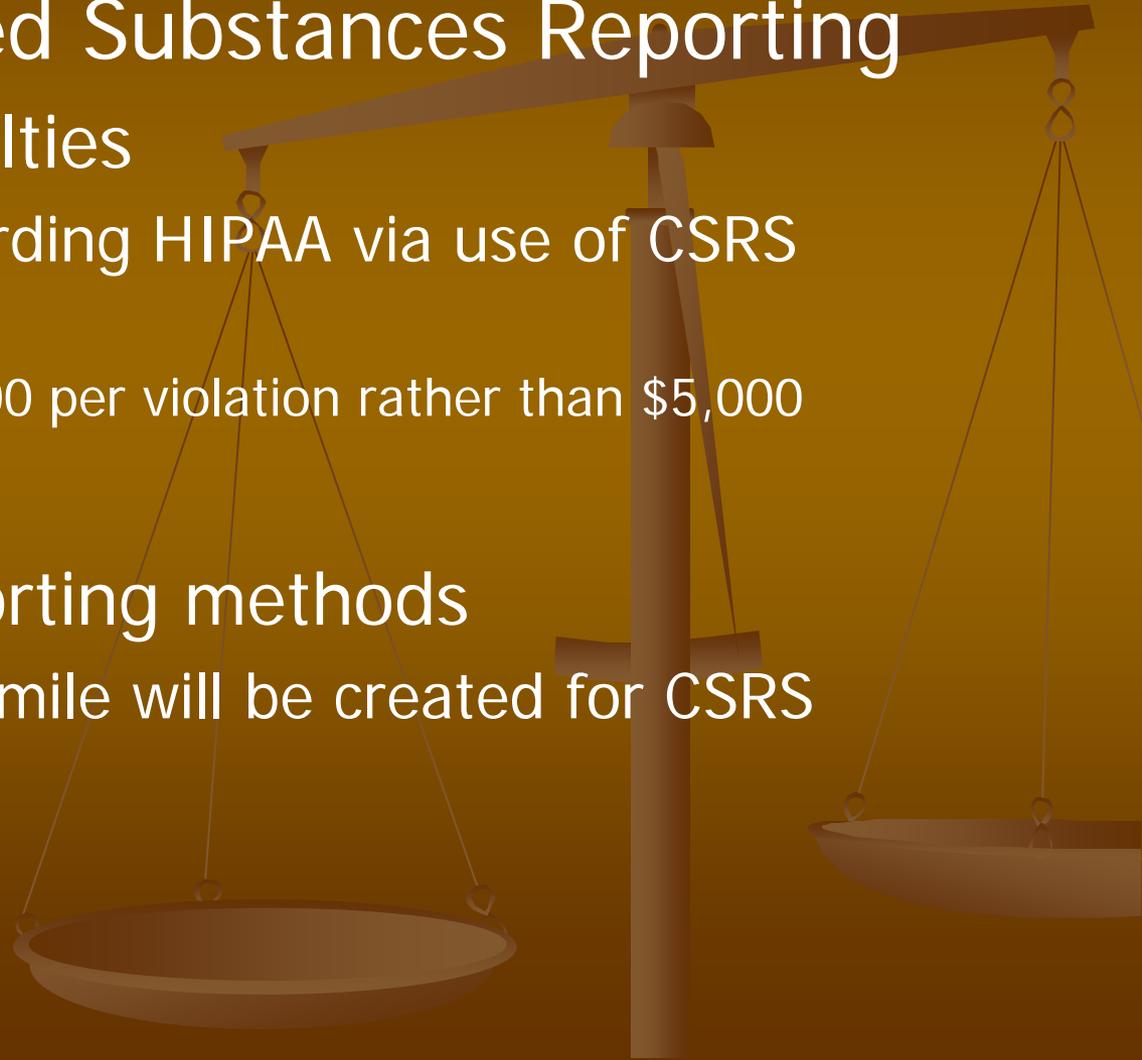
# H.173/S.222(cont'd)



- Revise Controlled Substances Reporting
  - Section 3: Confidentiality
    - Information collected can be reviewed by Department:
      - To identify possible individual sources of abuse/diversion and notify their prescribers
      - To identify prescribers who breach professional standards and notify agencies who license, register or certify them
      - Current version requires licensing bodies to make rules concerning when and how such reports are to be made.
    - Will allow some delegation for use of information under direct supervision of authorized user
    - Allows release of CSRS data to sheriff, “designated” deputy sheriff, police chief, or “designate” police officer, but pursuant to a “lawful court order.”

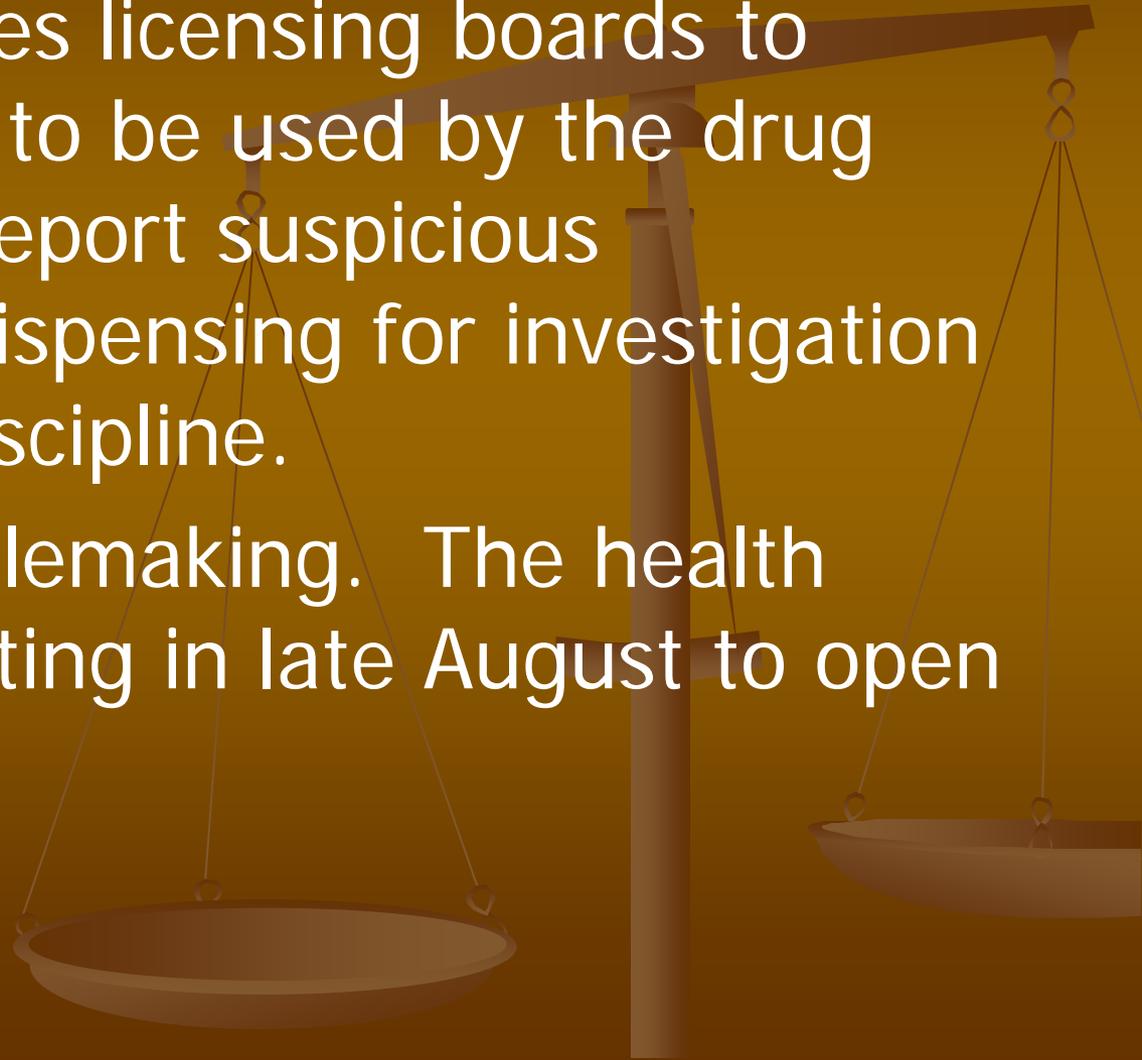
# H.173/S.222(cont'd)

- **Revise Controlled Substances Reporting**
  - **Section 4: Penalties**
    - Violations regarding HIPAA via use of CSRS increased
      - Will be \$10,000 per violation rather than \$5,000
  - **Section 5: Reporting methods**
    - Email and facsimile will be created for CSRS reporting



# H.173/S.222(cont'd)

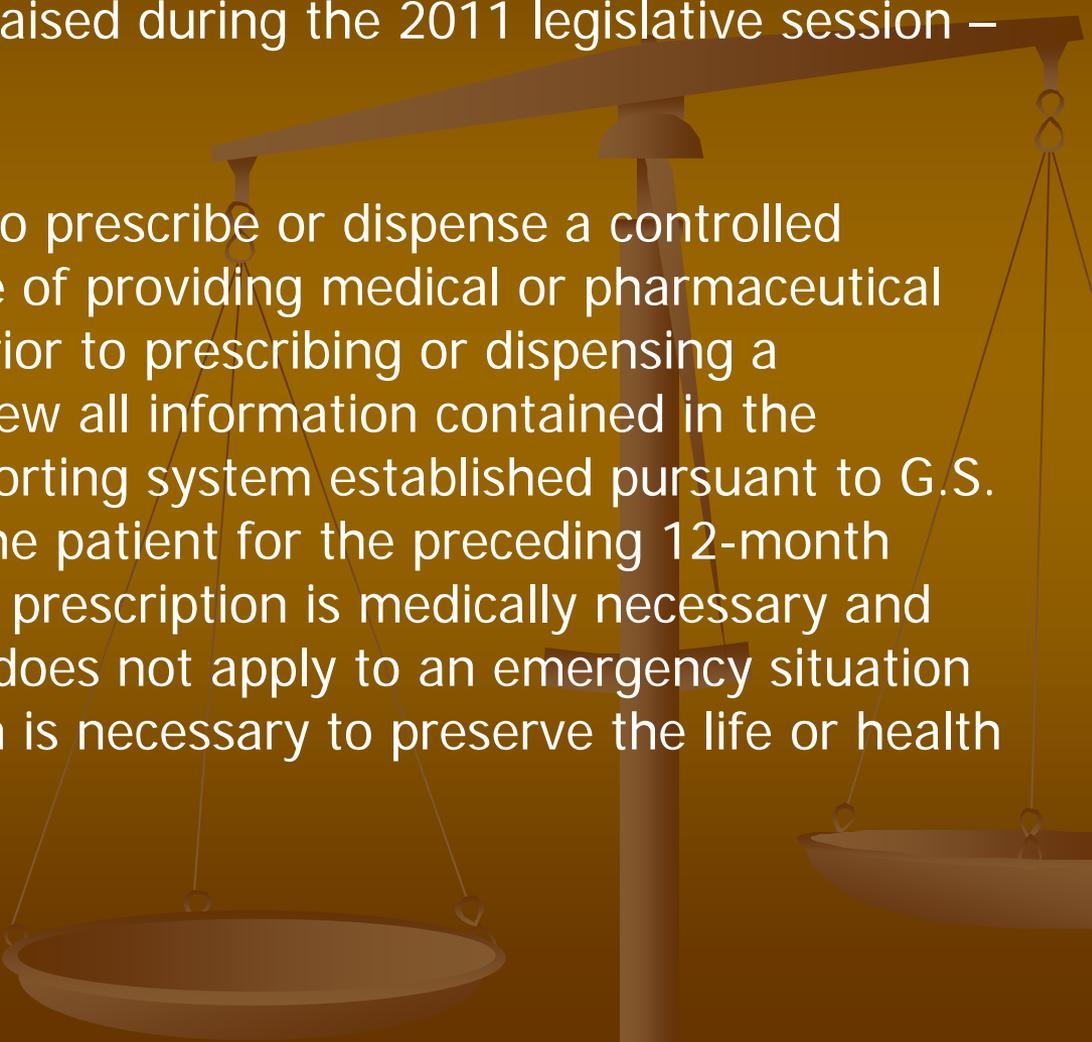
- Provision requires licensing boards to develop criteria to be used by the drug control unit to report suspicious prescribing or dispensing for investigation and potential discipline.
- This will be a rulemaking. The health boards are meeting in late August to open discussions.



# CSRS Proposals that Were Introduced, But Not Passed

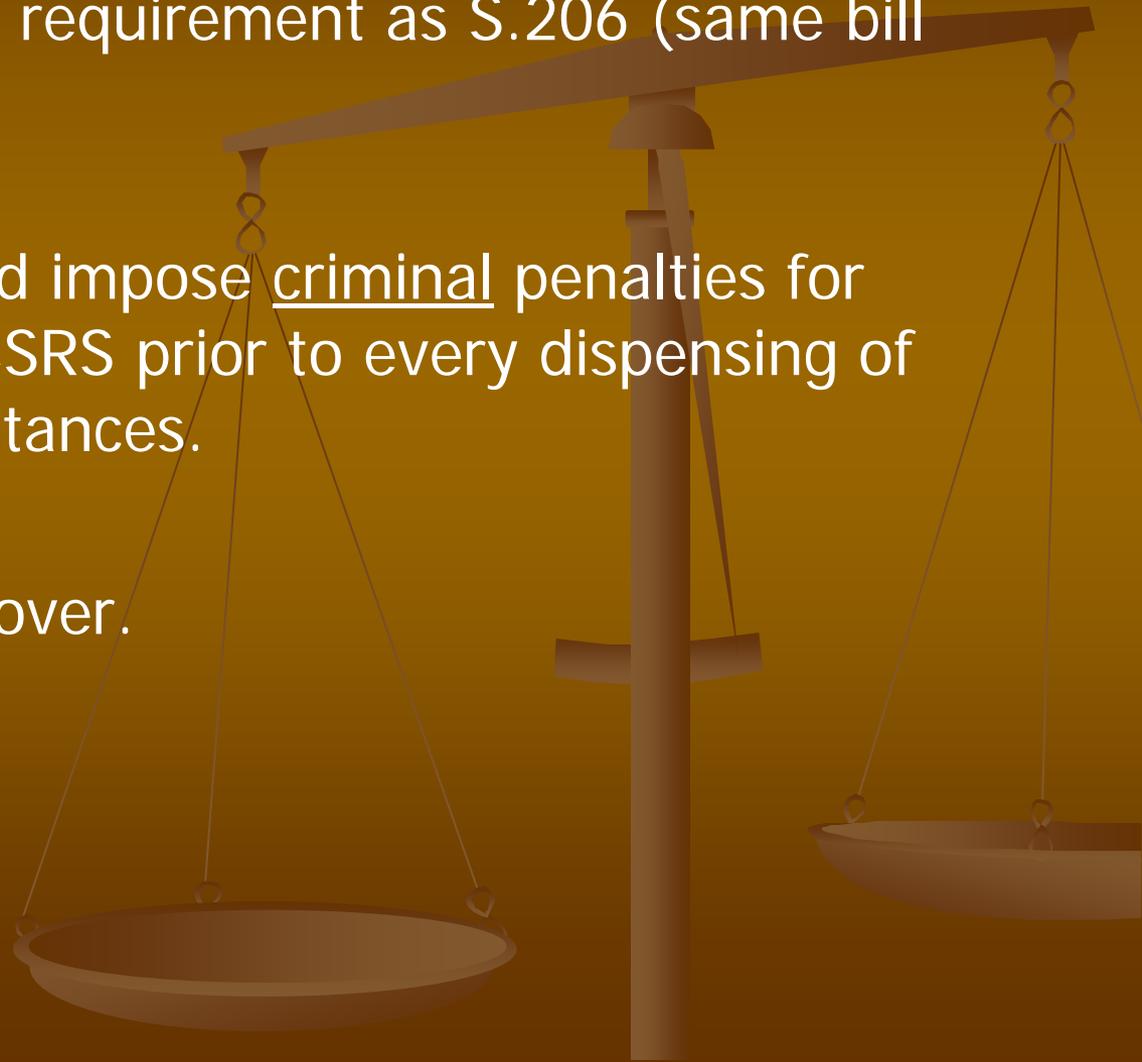


# S.206

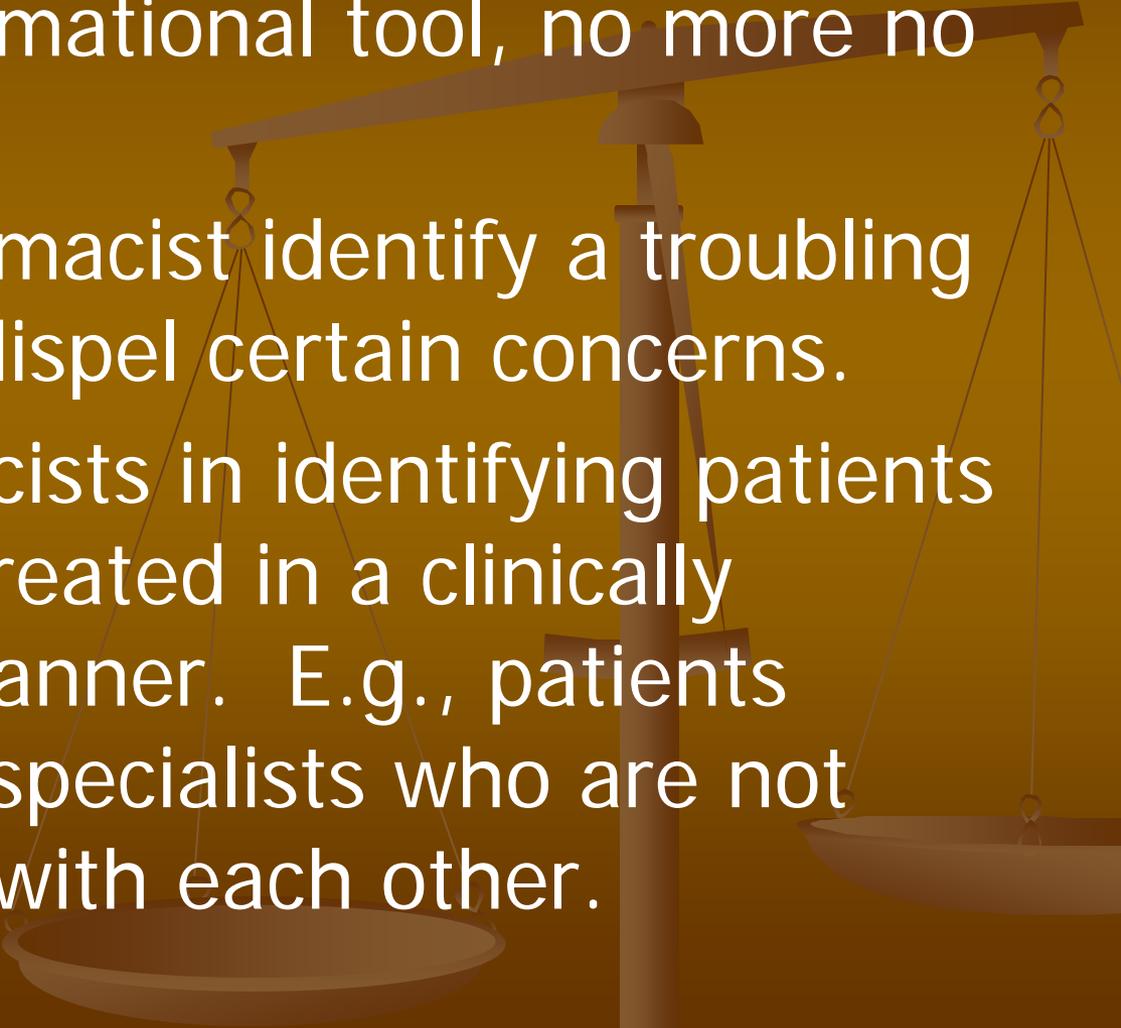
- Reintroduced a proposal raised during the 2011 legislative session – mandatory CSRS use.
  - “Each person authorized to prescribe or dispense a controlled substance for the purpose of providing medical or pharmaceutical care for a patient shall, prior to prescribing or dispensing a controlled substance, review all information contained in the controlled substances reporting system established pursuant to G.S. 90-113.73 pertaining to the patient for the preceding 12-month period to determine if the prescription is medically necessary and appropriate. This section does not apply to an emergency situation in which immediate action is necessary to preserve the life or health of a patient.”
  - Did not survive crossover.
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# S.286

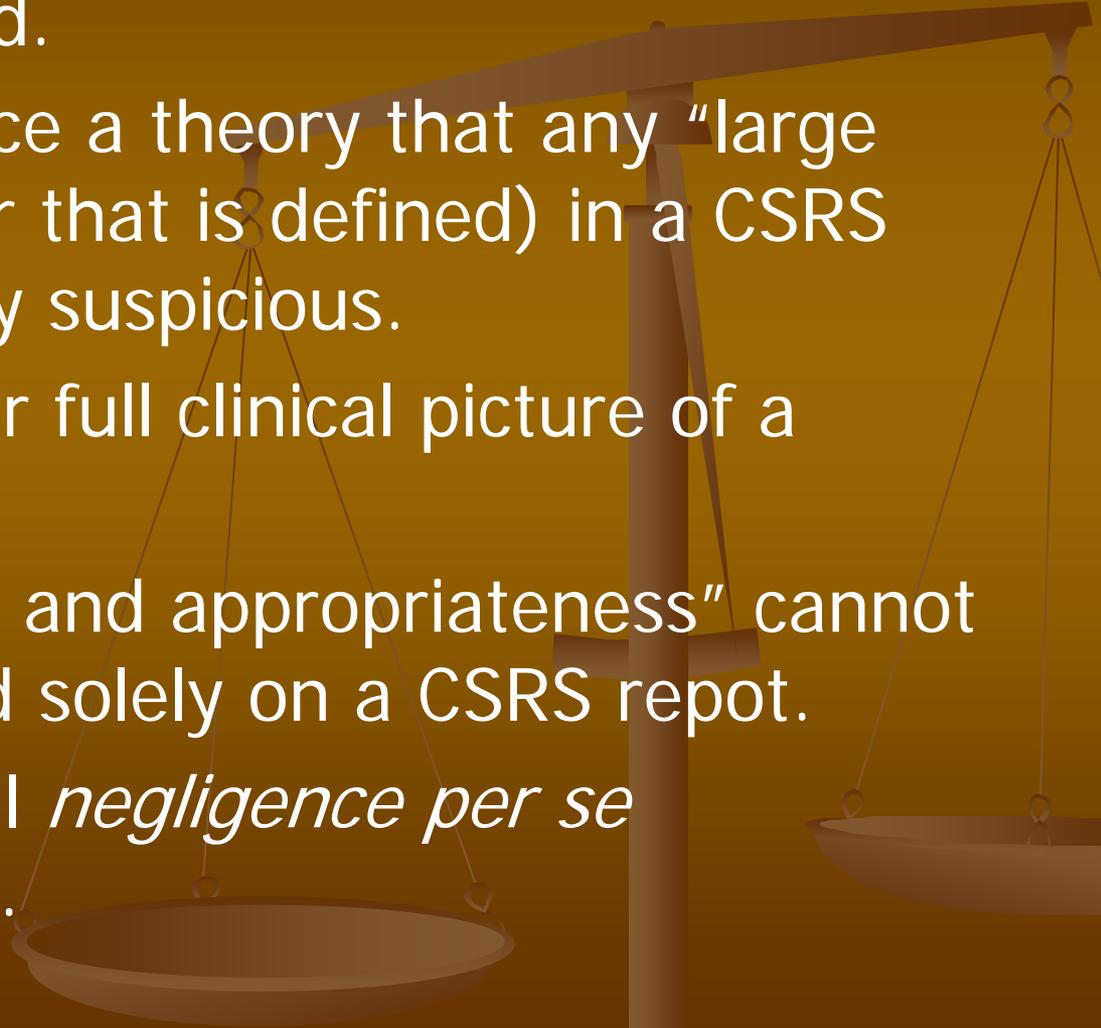
- Same mandatory use requirement as S.206 (same bill sponsor)
- S286, however, would impose criminal penalties for failure to check the CSRS prior to every dispensing of every controlled substances.
- Did not survive crossover.



# Benefits to Pharmacists' CSRS Use

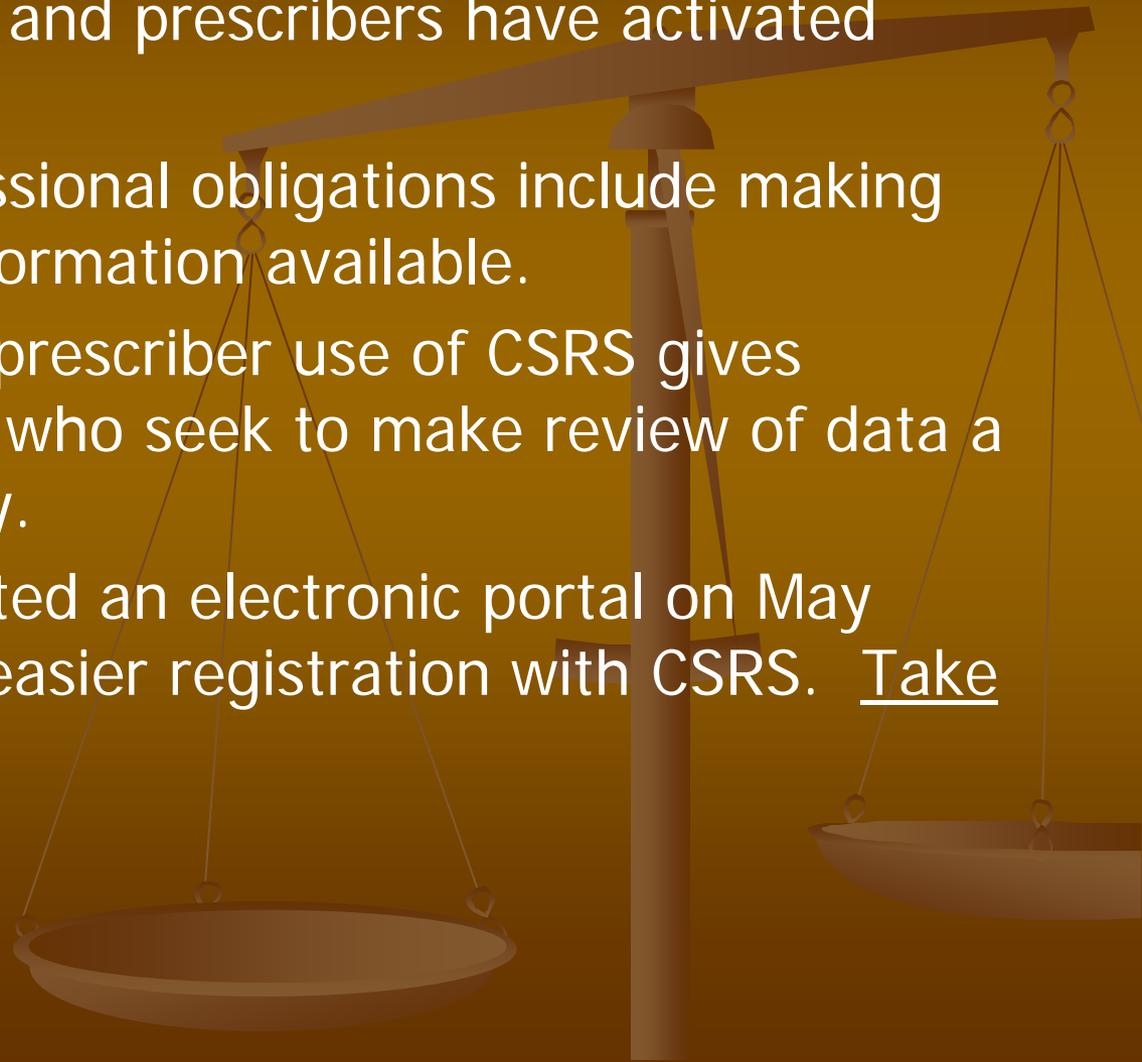
- CSRS is an informational tool, no more no less.
  - Can help a pharmacist identify a troubling prescription or dispel certain concerns.
  - Can aid pharmacists in identifying patients who are being treated in a clinically inappropriate manner. E.g., patients seeing multiple specialists who are not communicating with each other.
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# Drawbacks to Mandatory CSRS Review

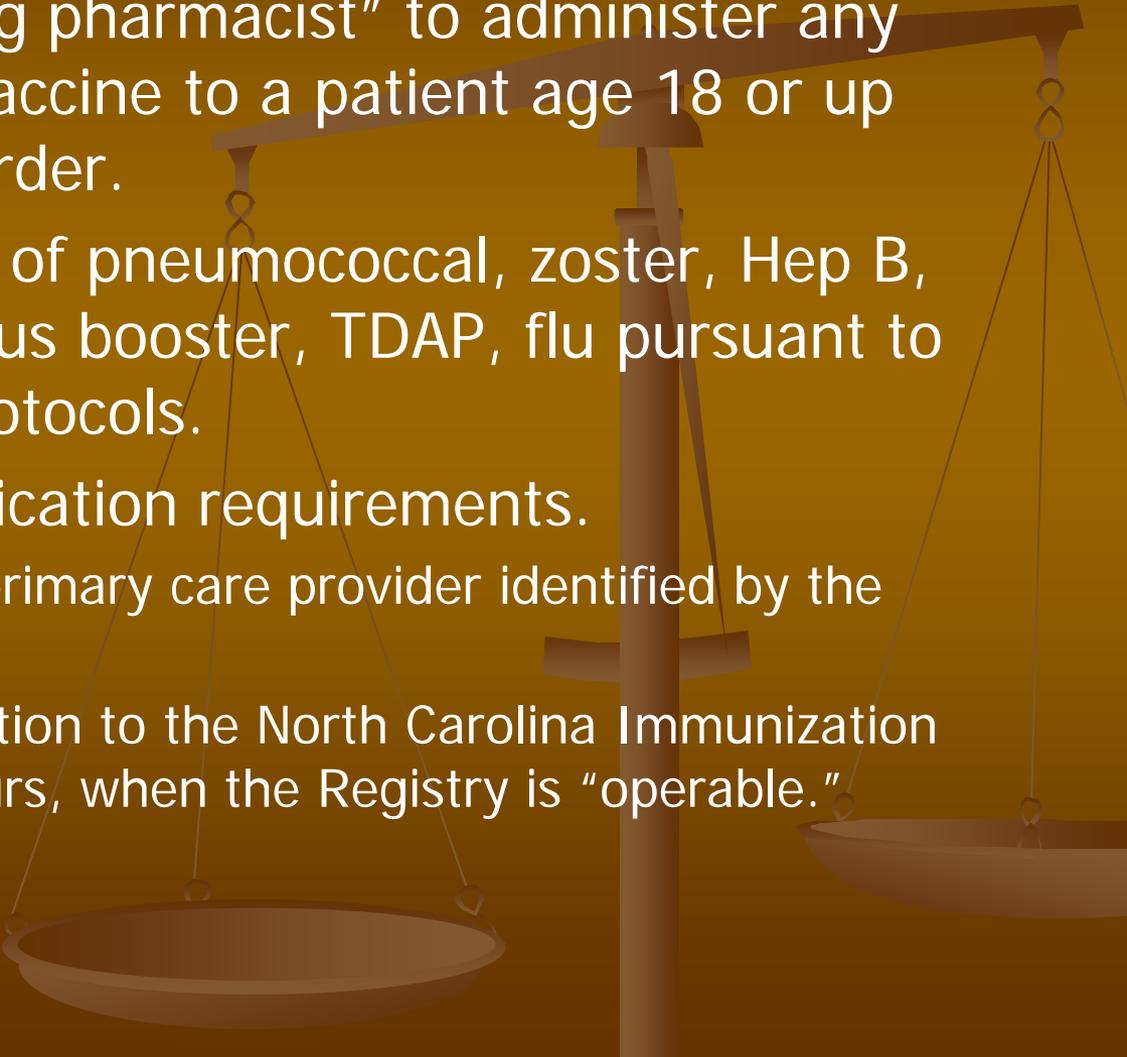
- Time and workload.
  - Appears to embrace a theory that any “large number” (however that is defined) in a CSRS report is inherently suspicious.
  - Fails to account for full clinical picture of a patient.
  - “Medical necessity and appropriateness” cannot be assessed based solely on a CSRS report.
  - Creates a potential *negligence per se* malpractice action.
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# Use of CSRS

- Too few pharmacists and prescribers have activated their CSRS access.
- A pharmacist's professional obligations include making reasonable use of information available.
- Low pharmacist and prescriber use of CSRS gives ammunition to those who seek to make review of data a nondiscretionary duty.
- The Board implemented an electronic portal on May 2013 that facilitates easier registration with CSRS. Take advantage!



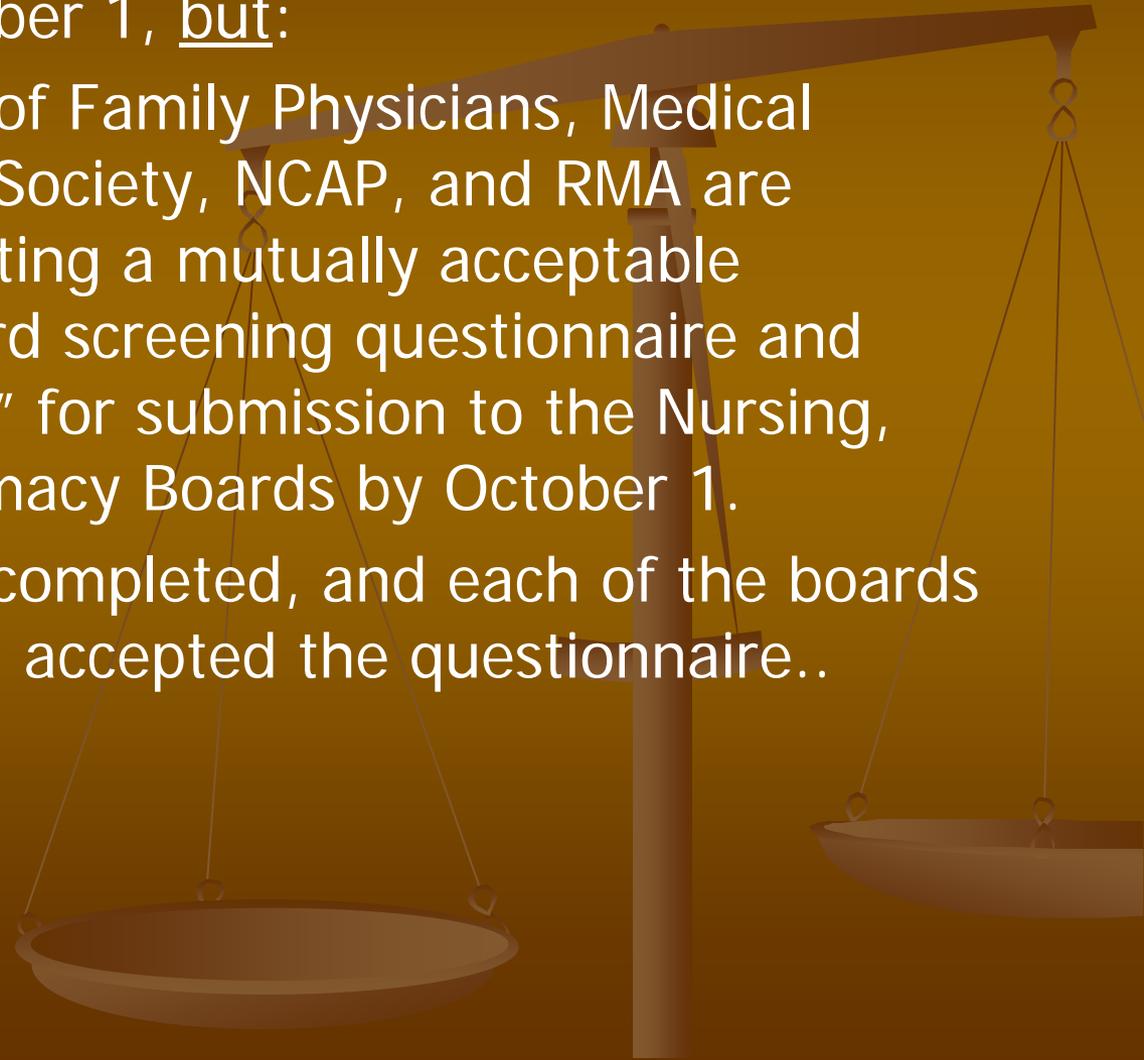
# H.832 Expanded Immunization Authority



- Allows an “immunizing pharmacist” to administer any CDC recommended vaccine to a patient age 18 or up upon a prescription order.
- Allows administration of pneumococcal, zoster, Hep B, meningococcal, tetanus booster, TDAP, flu pursuant to standing orders or protocols.
- Contains certain notification requirements.
  - Within 72 hours to a primary care provider identified by the patient.
  - Record the administration to the North Carolina Immunization Registry within 72 hours, when the Registry is “operable.”

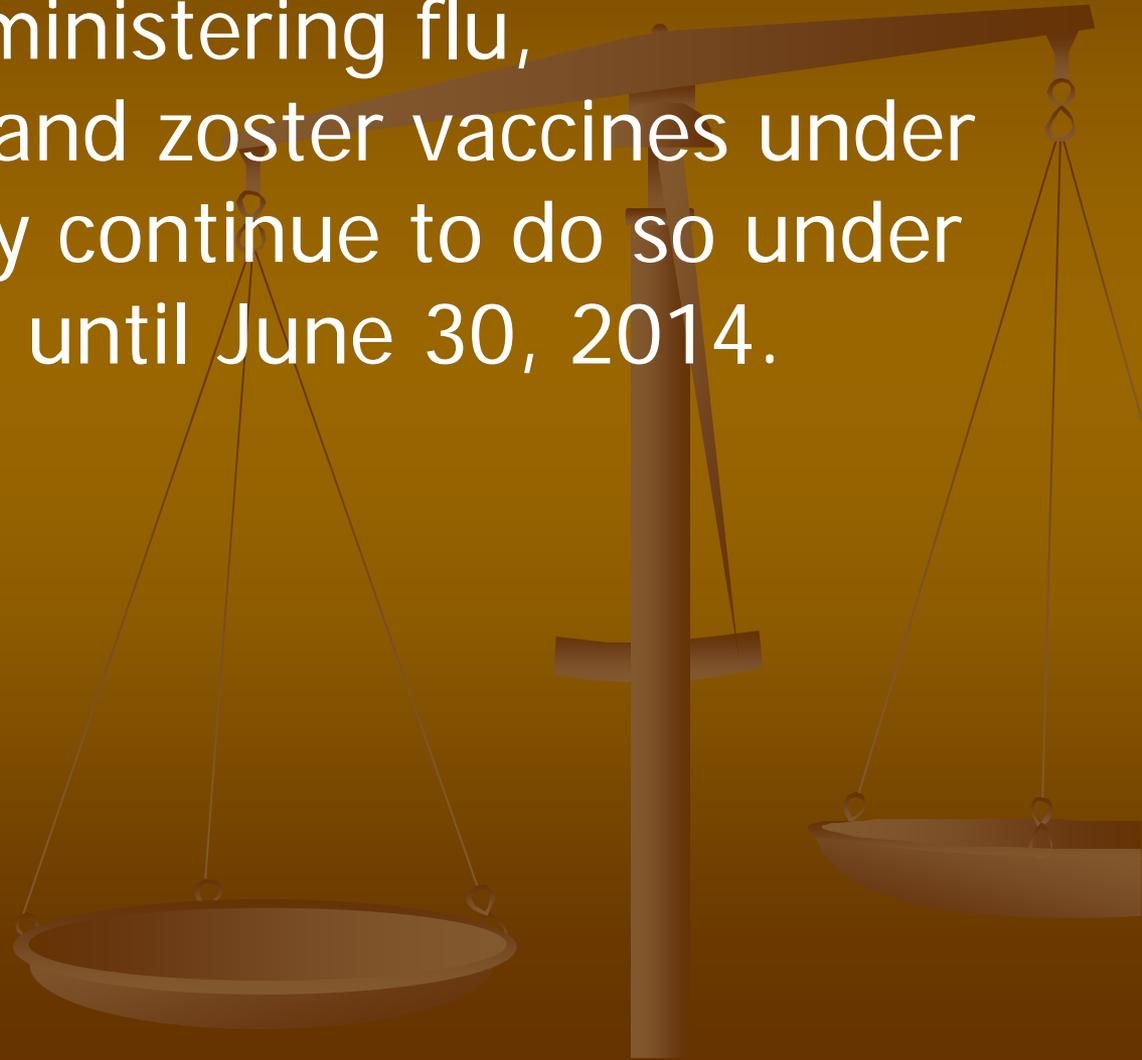
# H.832 Expanded Immunization Authority

- Law is effective October 1, but:
  - The NC Academy of Family Physicians, Medical Society, Pediatric Society, NCAP, and RMA are charged with creating a mutually acceptable “minimum standard screening questionnaire and safety procedures” for submission to the Nursing, Medical and Pharmacy Boards by October 1.
  - This process was completed, and each of the boards have received and accepted the questionnaire..



# H.832 Expanded Immunization Authority

- Pharmacists administering flu, pneumococcal, and zoster vaccines under existing law may continue to do so under these standards until June 30, 2014.



# H.675

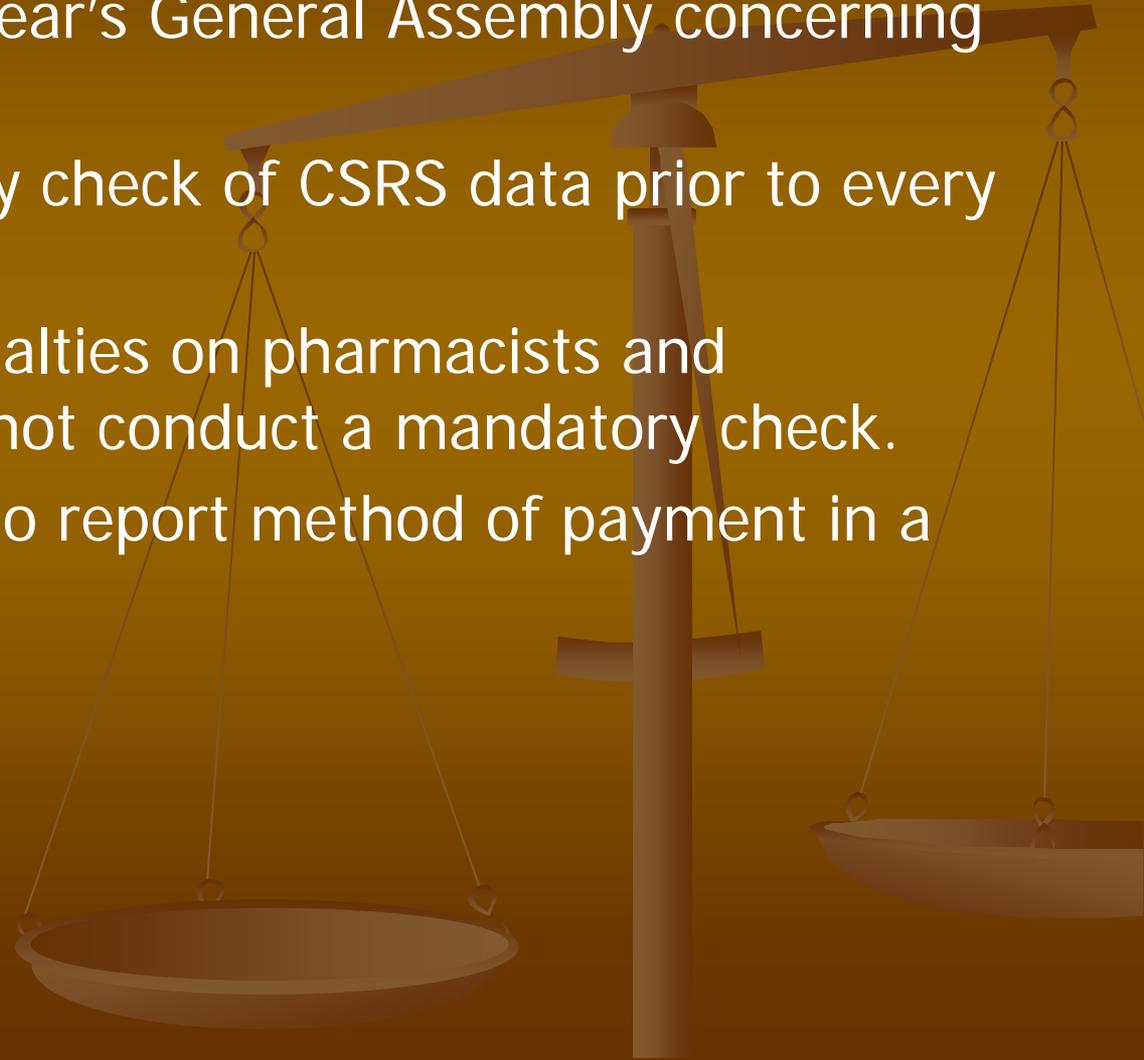
- Three issues:
  - Allows certified technicians to register with the Board of Pharmacy independent of specific technician employment and makes clear that PTCB certification satisfies statutory training requirements.
  - Adds additional procedural protections for pharmacies being audited
  - Places a six-month “expiration date” on Schedule II prescriptions



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**Answer: C**



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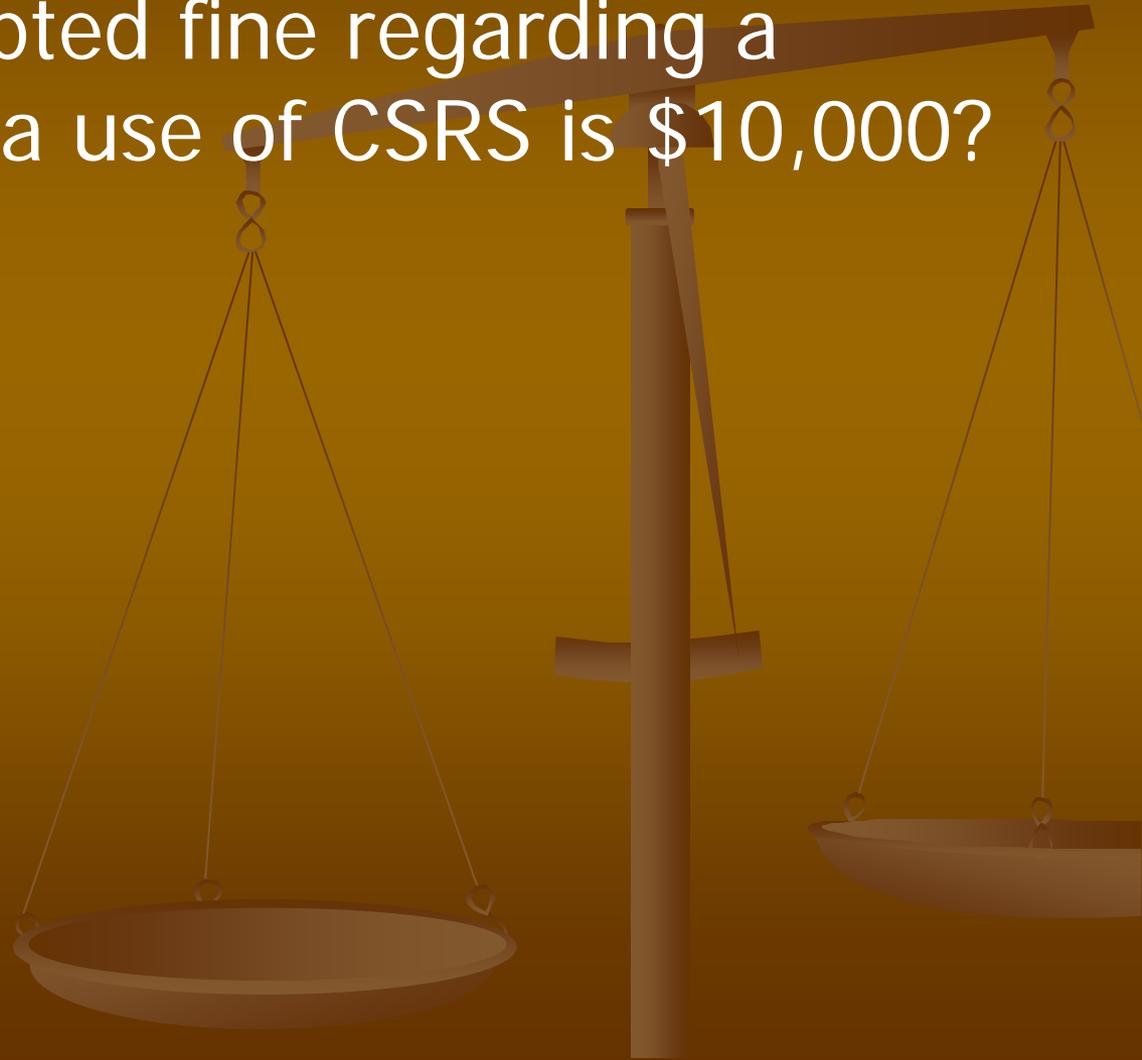
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# North Carolina Board Of Pharmacy Update

Sunday, February 9, 2014



# 6TRN

