PHARMACY LAW-
“ALPHABET SOUP”

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DISCLOSURE

* Information discussed in this presentation has not been sponsored or supported by any pharmaceutical or software corporation. This material is to be used for educational and informational purposes only.

OBJECTIVES

* Identify various national governmental organizations that affect pharmacy practice
* Learn which laws affect pharmacy technician practice
* Discuss the responsibilities of technicians to governmental organizations
* Discuss how pharmacies are affected by governmental regulations

MAJOR COMPONENTS OF HIPAA (1996)

* Title I - Health Care Access, Portability and Renewability
* Title II - Preventing Health Care Fraud and Abuse, Medical Liability Reform, Administrative Simplification
* Title III - Tax Related Health Provision
* Title IV - Group Health Plan Requirements
* Title V - Revenue Offsets
### IT'S A LITTLE COMPLICATED....

- Pythagorean Theorem: 24 words.
- Lincoln’s Gettysburg Address: 286 words.
- Declaration of Independence: 1,300 words.
- HIPAA Privacy Regulations: **401,034 words.**

### HIPAA 1996

- To amend the Internal Revenue Code of 1986
- To improve portability and continuity of health insurance coverage in the group and individual markets,
- To combat waste, fraud, and abuse in health insurance and health care delivery,
- To promote the use of medical savings accounts,
- To improve access to long-term care services and coverage,
- To simplify the administration of health insurance, and for other purposes.

### PENALTIES IF NOT COMPLIANT

- HHS excludes provider from Medicare participation
- Civil fines $100 per violation for each provision violated per day; $25,000 CY cap
- Criminal fines $250,000 or 10 yrs. Imprisonment, or both

### THE HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH (HITECH) ACT

- Enacted as part of the American Recovery and Reinvestment Act (ARRA) of 2009, was
- Signed into law on February 17, 2009, to promote the adoption and meaningful use of health information technology.
- Subtitle D of the HITECH Act addresses the privacy and security concerns associated with the electronic transmission of health information, in part, through several provisions that strengthen the civil and criminal enforcement of the HIPAA rules.

### HITECH ACT 2009

- Four categories of violations that reflect increasing levels of culpability
- Four corresponding tiers of penalty amounts that significantly increase the minimum penalty amount for each violation
- A maximum penalty amount of $1.5 million for all violations of an identical provision

### HIPAA-HITECH RULE

- Breach notification rule
- Defining "breach"
- According to HITECH, the term "breach" means "the unauthorized acquisition, access, use or disclosure of protected health information which compromises the security or privacy of such information, except where the unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information."
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CASE STUDY - PHARMACY

- Pharmacy Chain Enters into Business Associate Agreement with Law Firm
  
  **Covered Entity:** Pharmacy Chain
  
  **Issue:** Impermissible Uses and Disclosures; Business Associates

- A complaint alleged that a law firm working on behalf of a pharmacy chain in an administrative proceeding impermissibly disclosed the PHI of a customer of the pharmacy chain. OCR investigated the allegation and found no evidence that the law firm had impermissibly disclosed the customer's PHI. However, the investigation revealed that the pharmacy chain and the law firm had not entered into a Business Associate Agreement, as required by the Privacy Rule to ensure that PHI is appropriately safeguarded. Without a properly executed agreement, a covered entity may not disclose PHI to its law firm. To resolve the matter, OCR required the pharmacy chain and the law firm to enter into a business associate agreement.

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CASE STUDY

- A pharmacy employee placed a customer's insurance card in another customer's prescription bag. The pharmacy did not consider the customer's insurance card to be protected health information (PHI). OCR clarified that an individual's health insurance card meets the statutory definition of PHI and, as such, needs to be safeguarded. Among other corrective actions to resolve the specific issues in the case, the pharmacy revised its policies regarding PHI and retrained its staff. The revised policies are applicable to all individual stores in the pharmacy chain.

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CASE STUDY

- A chain pharmacy disclosed protected health information to municipal law enforcement officials in a manner that did not conform to the provisions of the Privacy Rule. Among other corrective actions to resolve the specific issues in the case, OCR required this chain to revise its national policy regarding law enforcement's access to patient protected health information to comply with the Privacy Rule requirements, including that disclosures of protected health information to law enforcement only be made in response to written requests from law enforcement officials, unless state law requires otherwise. The revised policy was implemented in the chain's stores nationwide.

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HIPAA/HITECH

- Copies of records

- Individuals now have the right to receive an electronic copy of their personal health information that's stored in an electronic health record (EHR). Healthcare organizations can charge a fee that covers their labor costs for producing the copy.


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PENALTIES

- Tougher fines

- Penalties now can be levied against individuals within a healthcare organization as well as the organization itself. Penalties for breaches of personal healthcare information or other HIPAA violations range up to $1.5 million per violation. This is separate from any criminal penalties that might apply.
TJC- THE JOINT COMMISSION

- Formerly known as JCAHO
- Facts about hospital accreditation - The Joint Commission has accredited hospitals for more than 60 years and today it accredits approximately 4,168 general, children’s, long term acute, psychiatric, rehabilitation and specialty hospitals, and 378 critical access hospitals, through a separate accreditation program.
- Approximately 82 percent of the nation’s hospitals are currently accredited by The Joint Commission.

DEFINITION OF ACCREDITATION

- a process whereby a professional association or nongovernmental agency grants recognition to a school or health care institution for demonstrated ability to meet predetermined criteria for established standards, such as the accreditation of hospitals by the Joint Commission on Accreditation of Healthcare Organizations.

TJC- MEDICATION MANAGEMENT STANDARDS

- Standard MM.01.01.03 The [organization] safely manages high-alert and hazardous medications.
- Standard MM.02.01.01 The [organization] selects and procures medications.
- Standard MM.04.01.01 Medication orders are clear and accurate.

TJC ACCREDITATION STANDARDS

- Standard MM.05.01.13 The [organization] safely obtains medications when the pharmacy is closed.
- Standard MM.05.01.17 The [organization] follows a process to retrieve recalled or discontinued medications.
- Standard MM.05.01.01 A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the[organization].

“DO NOT USE” LIST OF ABBREVIATIONS

- Board of Commissioners approved a National Patient Safety Goal requiring organizations to develop and implement a list of abbreviations not to use.
- In 2004, The Joint Commission created its “do not use” list of abbreviations.
- Currently, this requirement does not apply to preprogrammed health information technology systems (for example, electronic medical records or CPOE systems), but remains under consideration for the future.

<table>
<thead>
<tr>
<th>Do not use</th>
<th>Potential Problem</th>
<th>Use instead</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 (zero)</td>
<td>Mistaken for “O”</td>
<td>write “zero”</td>
</tr>
<tr>
<td>IU (international Unit)</td>
<td>Mistaken for IV (intravenous) or the #20 (hem)</td>
<td>Write international unit</td>
</tr>
<tr>
<td>Q.O.D, QD, q.d, qd, q.d</td>
<td>Mistaken for each other Period after “Q” mistaken for “I”</td>
<td>Write “daily”</td>
</tr>
<tr>
<td>Trailing zero (X.0mg)*</td>
<td>Decimal point is missed</td>
<td>Write Xmg</td>
</tr>
<tr>
<td>Lack of leading zero (1mg)</td>
<td>Write 0.X mg</td>
<td></td>
</tr>
<tr>
<td>MS</td>
<td>Can mean morphine sulfate or magnesium sulfate</td>
<td>Write “morphine sulfate” or Write “magnesium sulfate”</td>
</tr>
<tr>
<td>MgSO4, MgS04</td>
<td>Confused for one another</td>
<td></td>
</tr>
</tbody>
</table>
INSTITUTION FOR SAFE MEDICATION PRACTICE (ISMP)

- ISMP List of Error-Prone Abbreviations, Symbols, Dose Designations

Official Do not use list:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Potential Problem</th>
<th>Use Instead</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; (greater than)</td>
<td>Misinterpreted as number or the letter “L” Confused for one another</td>
<td>Write “greater than”</td>
</tr>
<tr>
<td>&lt; (less than)</td>
<td>Misinterpreted due to similar abbreviations for multiple drugs</td>
<td>Write drug names in full</td>
</tr>
<tr>
<td>Apothecary Units</td>
<td>Unfamiliar to many practitioners</td>
<td>Use metric units</td>
</tr>
<tr>
<td>@</td>
<td>Mistaken for the number “2” (two)</td>
<td>Write “at”</td>
</tr>
<tr>
<td>cc</td>
<td>Mistaken for “U” when poorly written</td>
<td>Write “mL” (preferred) or “ml” or “milliliters”</td>
</tr>
<tr>
<td>mg</td>
<td>Misinterpreted for milligrams resulting in thousand-fold overdoses</td>
<td>Write “micrograms”</td>
</tr>
</tbody>
</table>

Abbreviations Intended Meanings Misinterpretations

| AD, AS, AU | Right ear, left ear, each ear | Right eye, left eye, both eye |
| DD, OD, OU | Right eye, left eye, both eyes | Right ear, left ear, both ear |
| D/C | Discontinue in discharge | D/C medications |

Sound Alike/Look alike drugs (http://www.ismp.org/Tools/confuseddrugnames.pdf)

- Serzone (antidepressant) seroquel (antipsychotic)
- HCT (hydrocortisone) HCTZ (hydrochlorothiazide)
- MSO4 (morphine sulfate) MgSO4 (magnesium sulfate)
- HCl (hydrochloric acid) KCl (potassium chloride)
- AcetaZOLAMIDE Aceta HEXAMIDE
- Adderall Inderal
- Allegra Viagra
- Alora Aldara
- Benadryl Benazepril

AMERICAN SOCIETY OF HEALTH SYSTEMS PHARMACISTS (ASHP)

- ASHP is a 35,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care, and other components of health care systems. ASHP is the only national organization of hospital and health-system pharmacists and has a long history of improving medication use and enhancing patient safety.

ASHP Pharmacy Practice Model Initiative (PPMI)

The American Society of Health-System Pharmacists and ASHP Research and Education Foundation have launched a new Web-based assessment tool and set of national goals and measurements to help hospital pharmacists determine how their health systems align with the recommendations of the Pharmacy Practice Model Initiative (PPMI). The goal of this initiative is to significantly advance the health and well being of patients by developing and disseminating a futuristic practice model that supports the most effective use of pharmacists as direct patient care providers. As part of this initiative, advancing the role of pharmacy technicians who assist pharmacists in health systems is examined and discussed. http://www.ashp.org/PPMI/AboutPPMI.aspx
ASHP PPMI OBJECTIVES

× Implement Change - Identify specific actions pharmacy leaders and staff should take to implement practice model change including determination of the necessary staff (pharmacy leaders, pharmacists, and technicians) skills and competencies required to implement this model.

This practice model must be futuristic and reflect the evolution of numerous aspects of pharmacy practice in hospitals and health systems over the last 50 years including:

1. medication-use policy and product selection;
2. medication distribution;
3. clinical pharmacy practice;
4. pharmacy technician roles;
5. pharmacists’ roles as organizational leaders;
6. adherence to standards-based practice;
7. response to the medication-use safety quality and safety movements in the U.S.; and
8. impact of technology.

WHAT SERVICES HAVE YOU DETERMINED TO BE ESSENTIAL TO SUPPORT YOUR PHARMACY PRACTICE MODEL?

• Our certified, registered, and highly trained pharmacy technicians are utilized in expanded roles in support of the pharmacist.
• This allows the pharmacy department to provide valuable services to the hospital and supports the pharmacist to focus on clinical patient care.
• Our technicians are trained to participate in several advanced services:
  • Decentralized Service. This technician team provides deliveries, responds to missing drug inquiries, inspects nursing units and medication rooms daily, and tracks the use and quantity of non-formulary medications and patient’s medications brought into the hospital.
  • Medication Reconciliation. This team collects and documents medication histories for emergency department admissions, as part of the medication reconciliation process. They conduct patient interviews and call doctor’s offices, nursing homes, and community pharmacies to obtain complete and accurate information.
  • Anticoagulation Program. This team serves the ambulatory care anticoagulation program by scheduling, registering, and escorting patients. They are specially trained to perform finger-stick blood collection and administer patient questionnaires. They also assure that each patient’s plan of care is sent to the primary care physician.
  • Antimicrobial Stewardship. These technicians conduct a preliminary screen of laboratory reports and medication profiles for bug-drug mismatches.

Chris Fortier - PPMI presentation focusing on technology and technicians [3.58min]

ASHP RESOURCES FOR TECHNICIANS

× http://www.ashp.org/menu/InformationForTechnicians.aspx

× CPE Monitor is a national, collaborative effort by NABP and the Accreditation Council for Pharmacy Education (ACPE) to provide an electronic system for pharmacists and pharmacy technicians to track their completed continuing pharmacy education (CPE) credits. It will also offer state boards of pharmacy the opportunity to electronically authenticate the CPE units completed by their licensees, rather than requiring pharmacists and technicians to submit their proof of completion statements upon request or for random audits.
In the latter part of 2011, through the collaborative efforts of NABP and ACPE, you will be able to start keeping track of your ACPE-accredited CPE credits through CPE Monitor. To prepare for the process, you are encouraged to obtain your NABP e-Profile ID now to ensure your e-Profile is set up properly.

http://www.nabp.net/programs/cpe-monitor/cpe-monitor-service/technicians/

Pharmacy Technician™ means personnel registered with the Board who may, under the supervision of the pharmacist, assist in the pharmacy and perform such functions as:
- (1) assisting in the Dispensing process;
- (2) processing of medical coverage claims;
- (3) stocking of medications; and
- (4) cashiering but excluding:
- (1) Drug Utilization Review (DUR);
- (2) clinical conflict resolution;
- (3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
- (4) Patient Counseling;
- (5) Dispensing process validation;
- (6) prescription transfer; and
- (7) receipt of new Prescription Drug Orders.

Pharmacy Technician™

NABP
ACPE

CPE Monitor

Innovative roles for pharmacy technicians within their work environments with the implementation of the Joint Commission of Pharmacy Practitioners (JCPP) Future Vision of Pharmacy Practice in 2015.

Participants agreed that patient safety should be the cornerstone of advocacy efforts to create a single standard encompassing the education, training, certification, and regulatory oversight of pharmacy technicians.

Education & Testing Requirements
- Participants and survey findings support modifications to the current PTCB certification prerequisites and recertification requirements.
- PTCB now requires a high school diploma or its equivalent; no felony, drug, or pharmacy related convictions; and no denial, suspension, revocation, or restriction of registration or licensure by any State Board of Pharmacy in order to be eligible to take the Pharmacy Technician Certification Exam.
- For recertification, PTCB requires 20 hours of Continuing Pharmacy Education (CPE) every two years; at least one of those credits is required to be in law CPE.
- Summit participants recommended additional certification and recertification requirements. These are under current consideration.

PTCB C.R.E.S.T SUMMIT

Consumer Awareness & State Policy
Survey results identified innovative roles for pharmacy technicians within their work environments with the implementation of the Joint Commission of Pharmacy Practitioners (JCPP) Future Vision of Pharmacy Practice in 2015.

Results also indicate a strong need for stakeholders within the pharmacy profession to work together to improve regulatory and statutory requirements pertaining to pharmacy technicians.

TECH
Day and Night we do MEDS right!
SCBOP - DEFINITION OF A PHT

(42) "Pharmacy technician" means an individual other than an intern or extern, who assists in preparing, compounding, and dispensing medicines under the personal supervision of a licensed pharmacist and who is required to register as a pharmacy technician.

SCBOP - PHARMACY PRACTICE

SECTION 40-43-82. Pharmacy technicians; registration; approval of training programs; minimum requirements; pharmacists previously disciplined not eligible to be technicians; volunteers at free medical clinics.

SCBOP APPLICATION & FORMS

- Pharmacy Technician Forms
- Pharmacy Technician Renewal Form 2011-2012
- Pharmacy Technician Reinstatement
- Application Pharmacy Technician Registration Application
- Pharmacy Technician Affidavit of Experience
- Pharmacy Technician Certification of Clinical Experience
- Approved Pharmacy Technician Duties-Policy
- Change of Address Notification
- Change of Employment Notification

PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

- What is a prescription drug monitoring program (PDMP)?
- According to the National Alliance for Model State Drug Laws (NAMSDL), a PDMP is a statewide electronic database which collects designated data on substances dispensed in the state. The PDMP is housed by a specified statewide regulatory, administrative or law enforcement agency. The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession.

ALLIANCE OF STATES WITH PRESCRIPTION MONITORING PROGRAMS

- The Alliance of States with Prescription Monitoring Programs provides a forum for information sharing on prescription monitoring programs (PMPs) among state and federal agencies seeking to curtail drug diversion and abuse while ensuring patient care.
SC STATE PROFILE

- Name of Program: SCRIPTS
- South Carolina Reporting & Identification Prescription Tracking System
  http://www.scdhec.gov/administration/drugcontrol/pmp-fact-sheet.htm

PDMP- SOUTH CAROLINA

- Contact Cheryl A. Anderson, R.Ph Director, Prescription Monitoring Program/South Carolina Department of Health and Environmental Control, Bureau of Drug Control (803) 896-0688 andersc2@dhec.sc.gov

SCRIPTS

- The purpose of the S.C. Reporting & Identification Prescription Tracking System (SCRIPTS) is to collect data on all Schedule II, III, and IV controlled substances dispensed in and/or into the state of South Carolina.
- The program is intended to improve the state’s ability to identify and stop diversion of prescription drugs in an efficient and cost-effective manner that will not impede the appropriate medical use of legal controlled substances.

SCRIPTS

- All dispensers of Schedule II, III, and IV controlled substances are required to collect and report the following information to the data repository managed by Health Information Designs Inc. (HID) of Auburn, Alabama:
  - http://www.scdhec.gov/administration/drugcontrol/pmp.htm

SCRIPTS

- In 2006, the S. C. General Assembly authorized DHEC’s Bureau of Drug Control (BDC) to establish and maintain SCRIPTS. Through the program the BDC monitors the prescribing and dispensing of all Schedule II, III, and IV controlled substances by professionals licensed to prescribe or dispense the substances in South Carolina.

- Dispenser DEA number
- Date dispensed
- Prescription number
- Status - whether prescription is new or a refill
- NDC code for drug dispensed
- Quantity dispensed
- Approximate number of days supplied
- Patient name
- Patient address (including city, state and zip code)
- Patient date of birth
- Prescriber’s DEA number
- Date prescription was issued by prescriber
**SCRIPTS & HIPAA**

- The South Carolina Prescription Monitoring Program (PMP) will require dispensers of controlled substances, i.e., pharmacies and practitioners who dispense directly to patients, to report monthly controlled substance dispensing information for each prescription dispensed, including patient name, prescriber name, dose and quantity of the controlled substance prescribed, and the pharmacy that dispensed the prescription.

**CONCLUSION**

- Stay informed of governmental agencies changes toward Pharmacy Technicians on a state and national scale.

**WHICH DRUGS ARE INCLUDED IN THE TRACKING SYSTEM?**

- Controlled Substances Schedules II, III & IV (i.e., OxyContin®, Percocet®, Vicodin®, Klonopin®, Xanax®, and Valium®)

- What can occur to those who do not report or disclose confidential information? Dispensers who fail to report will be subject to a two thousand ($2,000) dollars fine and/or two (2) years imprisonment. Authorized users who knowingly disclose their account user information or breach confidentiality of the information will be subject to a ten thousand ($10,000) dollars fine and/or ten (10) years imprisonment.