NABP
National Association of Boards of Pharmacy

REPORT OF THE COMMITTEE ON

LAW ENFORCEMENT/LEGISLATION

Members Present

Steven W. “Steve” Schierholt (OH), *chair*; Alexandra Blasi (KS); Sebastian Hamilton (MA); Tony King (MT); Deborah C. “Debbie” Mack (AR); David Rochefort (NH); Kim Tanzer (MA); Lorri Walmsley (AZ); Shauna White (DC); Jennifer “Jenny” Downing Yoakum (TX); and Gayle D. Ziegler (ND).

Others Present

Reginald “Reggie” Dilliard, *Executive Committee liaison;* Lemrey “Al” Carter; Melissa Madigan; Eileen Lewalski; Maureen Schanck; Cameron Orr; and Andrea Busch, *NABP staff*.

Introduction

The committee met virtually on January 13, 2021.

Review of the Task Force Charge

Committee members reviewed their charge and accepted it as follows:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy.
2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association.
3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

Background and Discussion

The committee reviewed and discussed the recommended amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* made by the Task Force on Medication Reuse; the Task Force on Medication-Assisted Treatment; and the Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment (Overview TF). The committee also reviewed and discussed suggested *Model Act* language to reflect Food and Drug Administration (FDA) guidelines and recent updates to pharmacy practice regulation, as well as National Council for Prescription Drug Programs (NCPDP) and Centers for Disease Control and Prevention (CDC) guidelines for oral medication dosing.

The committee began discussions by reviewing the work of the Task Force on Medication Reuse and the background information on that issue. Several members described take-back and/or repository programs that were implemented in their states and reiterated that a vast amount of medications that would otherwise be wasted can be provided to patients in need,

stating that the benefits outweigh the risks involved with reuse. Members agreed with the task force's recommended amendments to the *Model Act* in the Return and Reuse of Prescription Drugs section pertaining to a failed delivery attempt by the pharmacy but thought that the language should be broader and, thus, removed the specification that medications could only be returned to the pharmacy if there was a failed delivery attempt by a common carrier. Members decided to preserve the language that a medication could only be returned provided that it was still in the original, sealed, and tamper-evident bulk, unit-of-use, or unit-dose packaging, or the dispensing pharmacy's original packaging, and that pharmacy staff should evaluate the medications to ensure that their integrity and stability had been maintained. While members had some concern that this evaluation was not foolproof, they believed in trusting pharmacists to use their professional judgment. Additionally, members agreed to remove the language that references United States Pharmacopeia standards because it could cause an unnecessary barrier due to it being difficult for pharmacies to conduct the required quality testing.

Regarding the *Model Act* language in the Prescription Drug Repository Programs section, the committee agreed with the task force that these types of programs should only accept non-controlled medications but added a footnote to clarify that there could be an exception for federally scheduled controlled substance medications that may be prescribed for substance use disorders, provided that they are allowed by federal and state laws and regulations. As the task force did, the committee discussed at length the notification requirement for patients receiving medications from repository programs and ultimately decided to remove the patient acknowledgment provision due to the burden it places on the pharmacist or repository staff. The members concurred that patient notification was necessary but agreed that state boards should individually decide whether a patient acknowledgement and/or waiver would be most appropriate for their programs.

Members then turned their attention to the *Model Act* amendments recommended by the Task Force on Medication-Assisted Treatment. After reviewing the background information and summary of the meeting, the committee unanimously agreed to add the definition of "Medication-assisted Treatment (MAT)," as well as the language in the Pharmacist Care Services section that addresses emergency-use dispensing. The committee agreed with the task force's decision to add language that would allow a pharmacist to use their professional judgment to assess the clinical appropriateness of a patient's request for treatment, as well as determine the appropriate length of treatment, so that the patient is able to obtain long-term treatment from a qualified practitioner. The members also agreed with adding the footnote clarifying that, for long-term treatment, a pharmacist should only prescribe MAT under a collaborative practice agreement. While being cognizant of the fact that the recommended emergency-use dispensing language was unprecedented, members supported a progressive approach that allows pharmacists to initiate MAT for emergency-use dispensing to bridge the gap for opioid use disorder patients who present at the pharmacy suffering from withdrawal and are ready to begin treatment.

The committee then reviewed the recommended *Model Act* amendments made by the Overview TF. One of the members who had served on the 2019 Task Force on Requirements for Pharmacy Technician Education provided background information regarding that task force's creation of the definition of "Advanced-Level Certified Pharmacy Technician," which the Overview TF felt should be added. Another member, who had been serving on the New Hampshire Board of Pharmacy, provided additional information regarding that board's experience in promulgating rules for an advanced-level pharmacy technician. The committee discussed at length the education, training, and experience that must be obtained for an individual to engage in advanced-level practice, as well as the activities that the supervising pharmacist would be comfortable delegating to that category of pharmacy technician. The Executive Committee liaison shared with the members that the Executive Committee had reviewed the Report of the Overview TF, agreed with the concept of an advanced-level pharmacy technician, and were in support of higher-level pharmacy technicians performing certain activities within their scope of certification and as assigned by the pharmacist. However, he shared that the Executive Committee was not in support of creating a new pharmacy technician category due to the increased regulatory and administrative burden that may be placed on the boards. With this in mind, the committee agreed to strike the Overview TF's definition for "Advanced-Level Certified Pharmacy Technician" and the associated registration requirements, and instead, added language to the definitions of "Certified Pharmacy Technician Candidate" and "Certified Pharmacy Technician" to allow those individuals to perform certain activities that are within the scope of certification or education and training but exclude clinical patient care activities such as "Drug Utilization Review," clinical conflict resolution, and "Patient Counseling."

After minimal discussion, the committee also agreed to strike the Overview TF's definition and associated registration requirements for "Ancillary Pharmacy Staff Person," as members believed it would also be too burdensome on boards to create another registration category, particularly one without any education or training requirements. Members did, however, support NABP's efforts in continuing to encourage boards of pharmacy to require a path for all pharmacy technicians to become certified.

While reviewing the pharmacy technician-related *Model Act* language, members noted that the prescription transfer provisions failed to note that federal regulations require that the transfer of information for controlled substance prescriptions in Schedules III-V must be communicated directly between two pharmacists. Thus, the committee requested that a footnote be added that refers to the United States Code of Federal Regulations pertaining to this requirement.

Additionally, there were several recommended amendments to the *Model Act* that were made pursuant to current federal guidance, which were reviewed by the members. As such, they unanimously agreed to add definitions as submitted for "Biological Product," "Biosimilar Product," Interchangeable Product," and "Reference Product" to align with current terminology regarding biologics. The committee also reviewed and agreed to add language to the

Compounded Drug Preparations for Veterinary Use section of the Model Rules for Compounded or Repackaged Pharmaceuticals to be consistent with current FDA Center for Veterinary Medicine guidance.

Regarding the implementation of the FDA "MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION" (MOU), the members agreed to add a definition for the "NABP Information Sharing Network," which is a system being developed by NABP that will assist boards of pharmacy in reporting to FDA the information that is mandated by the MOU. The committee also approved the addition of language to the Notification section of the Model Rules for Compounded or Repackaged Pharmaceuticals to reference the MOU but decided not to prescriptively list all the required information that must be reported, as they believed that specificity was unnecessary.

Lastly, pursuant to recommendations by NCPDP guidelines and the CDC's Medication Safety program, the committee approved the addition of language to the label provisions in the Prescription Drug Order Processing section to require that all oral liquid medication dosages be expressed in milliliters to ensure that patients, especially pediatric patients, are dosed correctly. And pursuant to duplicative information that can be obtained from the original sources, the members agreed to remove the Model Rules for the Privacy of Individually Identifiable Health Information and Appendix D Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs.

The revisions recommended by the task forces and identified in other agenda items are denoted by underlines and ~~strikethroughs~~. The recommended revisions by the committee are denoted by double underlines and ~~double strikethroughs~~.

Task Force on Medication Reuse

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Section 105. Definitions.

…

(f6) "Repository Program" means a program that is established to receive previously dispensed medications and redispense such to qualified individuals and/or to facilitate the proper disposal of unacceptable medications in compliance with state and environmental regulations.

Model Rules for the Practice of Pharmacy

…

Section 10. Return and Reuse of Prescription Drugs.

(a) Prescription Drugs may only be returned and reused providing that the Prescription Drugs~~:~~

~~(1) were removed from the Pharmacy for delivery by Pharmacy staff, or a Pharmacy contracted delivery service and returned because the Prescription Drugs were not deliverable or the patient refused delivery, and such Prescription Drugs did not leave the control of the Pharmacy; and~~

~~(1)~~(2) ~~Prescription Drugs W~~were packaged in:

~~(i)~~

(1) the ~~manufacturer's~~ original, sealed, and tamper-evident bulk, unit-of-use[1], or unit-dose packaging; or

~~(ii)~~

(2) the dispensing pharmacy's original packaging that maintains the Product quality.~~; and~~

~~(iii) returned to the pharmacy immediately after the unsuccessful delivery attempt.~~

~~(2)(3) If a Pharmacy attempts, but is not able, to deliver Prescription Drugs using an approved common carrier, then such Prescription Drugs may be returned and reused by the Pharmacy if packaged in:~~

[1] Unit-of-use is not intended to include co-mingled, multi-medication unit-of-use packages also known as compliance packs.

~~(i) the manufacturer's original, sealed, and tamper-evident bulk, unit-of-use[3], or unit-dose packaging; or~~

~~(ii) the dispensing pharmacy's original, sealed, and tamper-evident packaging that maintains the Product quality as per United States Pharmacopeia (USP) standards~~.

(b) All returned packaging must indicate that the Prescription Drug's integrity and stability has been maintained.

(c) All returned Prescription Drugs ~~must have been returned on the same day as the attempted delivery and~~ must be evaluated by appropriate Pharmacy staff to ensure such Prescription Drugs are not adulterated or misbranded.

(d) A state-licensed Pharmacist must verify compliance with all of the above elements.

Section 11. Prescription Drug Repository Programs.

(a) Repository Programs must have written policies and procedures, which include, at a minimum:

(1) Qualifications of acceptable medications for reuse. Such qualifications must include the following provisions:

(i) only non-controlled medications will be accepted[3]

~~(ii)~~(ii) all medications will be inspected and determined to be:

(A) unadulterated;

(B) unexpired; and

(C) in unopened unit dose or manufacturer's tamper-resistant original packaging, or otherwise approved by the board of pharmacy.

~~(iii)~~(iii) maintenance of a separate physical inventory;

~~(iv)~~(iv) completion of a monthly expiration date review for all medications;

~~(v)~~(v) prohibition of charging or accepting compensation for medications except for administrative or minimal dispensing fees;

~~(vi)~~(vi) dispensing by a pharmacist or a practitioner within the practitioner's scope of practice; and

~~(vii)~~(vii) record keeping, including the source and dispensation of all medication.

(2) A requirement that the patient receives notification ~~acknowledge that he or she understands~~ that the medication is being dispensed by a repository program. ~~and that he or she has been provided with the program's qualifications for acceptable medications for reuse.~~

[3] Except for federally scheduled controlled substance medications that may be prescribed for substance use disorders and as allowed by federal and state laws and regulations.

…

Task Force on Medication-Assisted Treatment

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

…

Section 105. Definitions.

…

(d4) Medication-assisted Treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders. Medications used in MAT are approved by Food and Drug Administration (FDA).[4]

…

(e4) "Pharmacist Care Services" is the provision by a Pharmacist of patient care activities within this State or into this State, as defined by the Rules of the Board, with or without the Dispensing of Drugs or Devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.[5]

…

[4] Substance Abuse and Mental Health Services Administration also refers to MAT as "Medications for Opioid Use Disorder" (MOUD), which are FDA-approved medications for the treatment of opioid use disorders and currently include methadone, naltrexone, and buprenorphine.

[5] Objectives of Pharmacist Care Services include cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process, or prevention of a disease or symptomatology. Pharmacist Care Services should be provided by all Pharmacists within the Standard of Care to the extent of their abilities regardless of the practice setting.

Model Rules for the Practice of Pharmacy

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Section 6. Pharmacist Care Services. [6]

…

(d) Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents

The Collaborative Pharmacy Practice Agreement shall include:

(i) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;

(ii) the types of decisions that the Pharmacist is allowed to make;

(iii) a process for generating any necessary Medical Orders, including prescription orders, required to initiate allowed activities;

(iv) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;

(v) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;

(vi) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;

(vii) a provision that allows either party to cancel the Agreement by written notification;

(viii) an effective date;

(ix) signatures of all collaborating Pharmacists and Practitioners who are party to the Agreement, as well as dates of signing; and

[6] Additional Pharmacist Care Services may include, but are not limited to, Patient assessment and evaluation; assessing health plan and medication eligibility and coverage; Administering Drugs, vaccines, or biologicals; performing Peer Review and peer consultations; reviewing, selecting, and developing formularies or plan /practice guidelines; consulting with other health care professionals; providing patient referrals; performing Medication Therapy Management; ordering lab tests; and performing lab tests as provided by State and Federal law.

(x) a procedure for periodic review and renewal within a time frame that is clinically appropriate.

(3) Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

(4) Documentation of Pharmacist Activities
Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals who are providing care to that patient and who are authorized to receive it. Documentation of allowed activities shall be considered Protected Health Information.

(e) Emergency-Use Dispensing
Prescribing and Dispensing Drugs for emergency-use pursuant to a Pharmacist-issued Prescription[7] and appropriate patient counseling, including but not limited to:

(1) Opioid overdose reversal agents, such as naloxone;
(2) Epinephrine;
(3) Antidote kits; ~~and~~
(4) Short-acting beta agonist inhalers; and~~.~~
(5) Medication-assisted Treatment for the purpose of initiating therapy for opioid use disorder. The Pharmacist must:
(i) obtain a DEA registration and a state controlled substance license or registration, if required; and
(ii) use professional judgment to assess the clinical appropriateness of the patient's request and length of treatment until the patient obtains treatment from an authorized practitioner. [8]

[7] Pharmacist may prescribe pursuant to specific statewide protocols or standing orders.
[8] It is contemplated that for long-term treatment, Pharmacists should be prescribing under a collaborative practice agreement rather than under an emergency-use provision.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Section 105. Definitions.

(e) ~~"Advanced-Level Certified Pharmacy Technician" means personnel who have met the requirements for licensure with the Board as a Certified Pharmacy Technician and who have completed an advanced certification or training program approved by the Board, and under the supervision of a Pharmacist, may perform certain activities involved in the Practice of Pharmacy that are within his or her scope of advanced certification and as assigned by the Pharmacist, but excluding clinical patient care activities such as, but not limited to, patient counseling or Drug Utilization Review.~~[9]

…

~~(g) "Ancillary Pharmacy Staff Person" means pharmacy support staff person who is not involved in the Dispensing process but may serve as support staff and may enter the licensed dispensing area. This role may include, but is not limited to, cashier, clerk, bookkeeper, stock person, and delivery personnel.~~

(n) "Certified Pharmacy Technician"[10] means personnel licensed with the Board who have completed a certification program approved by the Board and may, under the supervision of a Pharmacist, perform certain activities involved in the Practice of Pharmacy that are within their scope of certification and as assigned by the Pharmacist, but excluding clinical patient

~~[9] It is contemplated that the Pharmacist will make the sole determination based on an individual's abilities and competence in deciding which responsibilities they feel comfortable delegating to that individual and not based on any type of corporate directive or rubric.~~

[10] The *Model Act* defines Certified Pharmacy Technician and Certified Pharmacy Technician Candidate separately to distinguish between the activities that can be performed. A Certified Pharmacy Technician is recognized, because of the completion of a Board-approved certification program, as having knowledge and skills that qualify them to assist the Pharmacist in the Practice of Pharmacy with limited patient care tasks that exceed routine Dispensing or Drug storage activities. Certified Pharmacy Technician Candidates are limited to routine Dispensing activities, Drug storage, medical coverage claims processing, and cashiering.

care activities such as, but not limited to: ~~perform certain activities involved in the Practice of Pharmacy, such as:~~

~~(1) receiving new written or electronic Prescription Drug Orders;~~
~~(2) prescription transfer;~~
~~(3) Compounding; and~~
~~(4) assisting in the Dispensing process; and~~
~~(5) performing all functions allowed to be performed by pharmacy technicians~~
~~but excluding:~~

(1) Drug Utilization Review (DUR);
(2) clinical conflict resolution; and
(3) ~~prescriber contact concerning Prescription Drug Order clarification or therapy modification; and~~
(4) Patient Counseling.
~~(5) Dispensing process validation.~~

(o) "Certified Pharmacy Technician Candidate means personnel licensed with the Board who intend to complete a certification program approved by the Board and may, under the supervision of the pharmacist, perform certain activities involved in the Practice of Pharmacy that are within their scope of education and training and as assigned by the Pharmacist, but excluding clinical patient care activities such as, but not limited to:~~assist in the pharmacy and perform such functions as:~~

~~a. assisting in the Dispensing process;~~
~~b. processing of medical coverage claims;~~
~~c. stocking of medications; and~~
~~d. cashiering~~
~~but excluding:~~

(1) Drug Utilization Review (DUR)
(2) clinical conflict resolution; and
~~(3) prescriber contact concerning Prescription Drug Order clarification or therapy modification; and~~
(4) Patient Counseling.~~;~~
~~(5) Dispensing process validation;~~
~~(6) prescription transfer; and~~
~~(7) Receipt of new oral Prescription Drug Orders.~~

…

(r) "Remote Dispensing Site" means a location, other than where a pharmacist is located, where Drugs are maintained and prescriptions are filled by a~~n Advanced Level Certified Pharmacy Technician or~~ Certified Pharmacy Technician and dispensed under the direct, remote supervision of a Pharmacist.

…

Article III

Licensing

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Section 301. Unlawful Practice.

(a) Except as otherwise provided in this Act, it shall be unlawful for any individual, whether located in or outside this State, to engage in the Practice of Pharmacy in this State unless currently licensed to practice under any facet of the provisions of this Act.

(b) The provision of Pharmacist Care Services to an individual in this State, through the use of Telepharmacy Technologies, regardless of the location of the pharmacist, shall constitute the Practice of Pharmacy and shall be subject to regulation.[11]

(1) Licensed Pharmacies located outside this State that provide Pharmacist Care Services to individuals in this State must be licensed within this State under Article V of this Act.

(2) Pharmacists located outside this State who are providing Pharmacist Care Services outside of a licensed Pharmacy to individuals located in this State must register with this State to engage in the nonresident Practice of Pharmacy.

(c) Licensed Practitioners authorized under the laws of this State to Compound Drugs and to Dispense Drugs to their patients in the practice of their respective professions shall meet the same standards, record keeping requirements, and all other requirements for the Dispensing of Drugs applicable to Pharmacists.

(d) It shall be unlawful for any individual to perform the activities of a~~n Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician~~,~~ or Certified Pharmacy Technician Candidate unless currently licensed to do so under the provisions of this Act.

…

Section 304. Renewal of Licenses.

(a) Each Pharmacist, Pharmacy Intern, ~~Advanced Level Certified Pharmacy Technician,~~ and Certified Pharmacy Technician shall apply for renewal of his or her license annually [or at such interval determined by the Board], no later than the first day of _____. A Pharmacist or Pharmacy Intern who desires to continue in the Practice of Pharmacy in this State shall file with the Board an application in such form and containing such data as the Board may require for renewal of the license. If the Board finds that the applicant has been

[11] NABP recognizes that protection of the public health should extend across State borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy within the scope of the "Practice of Pharmacy" and requires an independently practicing pharmacist located outside this State to obtain full licensure for providing Pharmacist Care Services from outside the State to patients within the State.

licensed, and that such license has not been Revoked or placed under Suspension, that the applicant has attested that he or she has no criminal convictions or arrests, has paid the renewal fee, has continued his or her Pharmacy education in accordance with the rules of the Board, and is entitled to continue in the Practice of Pharmacy, the Board shall issue a license to the applicant.

(b) If a Pharmacist fails to make application to the State Board of Pharmacy for renewal of his or her license within a period of three years from the expiration of his or her license, he or she must pass an examination for license renewal; except that a Person who has been licensed under the laws of this State and after the expiration of his or her license, has continually practiced Pharmacy in another State under a license issued by the authority of such State, may renew his or her license upon payment of the designated fee.

(c) Certified Pharmacy Technician Candidates must complete requirements for Certified Pharmacy Technician licensure within 12 months. For good cause shown, the Board may approve one 12-month extension.

…

~~**Section 306. Registration of Ancillary Pharmacy Staff Persons.**~~

~~(a) In order to be registered as an Ancillary Pharmacy Staff Person in this State, an applicant shall:~~

~~(1) have submitted an application in the form prescribed by the Board of Pharmacy;~~

~~(2) have attained the age of _____;~~

~~(3) have paid the fees, if specified, by the Board.~~

~~(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as an Ancillary Pharmacy Staff Person.[12]~~

~~(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Ancillary Pharmacy Staff Persons.~~

Section 307. Licensure of Certified Pharmacy Technicians.

(a) In order to be licensed as a Certified Pharmacy Technician in this State, an applicant shall:[13]

(1) have submitted an application in the form prescribed by the Board of Pharmacy;

~~[12] The Board may specifically authorize a pharmacist whose license has been disciplined to register as an Ancillary Pharmacy Staff Person, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate, or Advanced Level Certified Pharmacy Technician under terms and conditions deemed appropriate.~~

[13] In 2015, the *Model State Pharmacy Act and Model Rules* was amended to require persons seeking to become Certified Pharmacy Technicians to complete each of the requirements outlined in Sections 307(a)(5)(i), 307(a)(5)(ii), and 307(a)(6).

(2) have attained the age of _____;
(3) have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;
(4) have[14]:
(i) graduated from a site-specific training program or a competency-based pharmacy technician education and training program that includes experiential training approved by the Board of Pharmacy;[15]
(ii) completed a minimum number of pharmacy technician practice experience hours approved by the Board of Pharmacy;[16]
(5) have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the Board of Pharmacy;
(6) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule; and
(7) have paid the fees specified by the Board of Pharmacy for the examination and any related materials, and have paid for the issuance of the license.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be licensed as a Certified Pharmacy Technician.[17]

(c) The Board of Pharmacy shall, by rule, establish requirements for licensure of Certified Pharmacy Technicians.

Section 308. Licensure of Certified Pharmacy Technician Candidates.

(a) In order to be licensed as a Certified Pharmacy Technician Candidate in this State, an applicant shall:

(1) have submitted an application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of _____;

[14] Boards should avoid mention of specific examinations or other contracted services in their practice act and regulations to avoid challenges related to an unconstitutional delegation of authority. It is contemplated that Boards will utilize the Certified Pharmacy Technician Candidate Certification Board examination as part of their assessment of technician competence to assist in the practice of pharmacy.

[15] It is recommended that states adopt this requirement, if not currently required, through a process that incorporates provisions for grandfathering.

[16] It is contemplated that Boards will approve those Certified pharmacy technician Candidate training programs whose standards are at least equivalent to the minimum standards developed by an accrediting organization recognized by state Boards, such as ACPE and ASHP. See Comment to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

[17] The Board may specifically authorize a pharmacist whose license has been disciplined to register as a ~~an Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician~~,~~ or Certified Pharmacy Technician Candidate under terms and conditions deemed appropriate.

(3) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;
(4) have paid the fees specified by the Board; and
(5) have enrolled in a site-specific training program or a competency-based pharmacy technician education and training program that includes experiential training approved by the Board of Pharmacy that includes an objective assessment mechanism prepared in accordance with any rules established by the Board

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be licensed as a Certified Pharmacy Technician.[18]

(c) The Board of Pharmacy shall, by rule, establish requirements for licensure of Certified Pharmacy Technicians.

~~**Section 309. Licensure of Advanced Level Certified Pharmacy Technicians.**~~

~~(a) In order to be licensed as an Advanced Level Certified Pharmacy Technician in this State, an applicant shall:~~

~~(1) have met the requirements for licensure with the Board of Pharmacy as a Certified Pharmacy Technician; and~~
~~(2) have completed an advanced certification or training program approved by the Board of Pharmacy.~~

~~(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be licensed as an Advanced Level Certified Pharmacy Technician.[19]~~

~~(c) The Board of Pharmacy shall, by rule, establish requirements for licensure of Advanced Level Certified Pharmacy Technicians~~

…

[18] The Board may specifically authorize a pharmacist whose license has been disciplined to register as a~~n Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician~~,~~ or Certified Pharmacy Technician Candidate~~, or Ancillary Pharmacy Staff Person~~ under terms and conditions deemed appropriate.

[19] The Board may specifically authorize a pharmacist whose license has been disciplined to register as a~~n Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician~~,~~ or Certified Pharmacy Technician Candidate~~, or an Ancillary Pharmacy Staff Person~~ under terms and conditions deemed appropriate.

Article IV

Discipline

Introductory Comment to Article IV

At the very heart of any Pharmacy Act is the enforcement power of the Board of Pharmacy. The Board must have authority to discipline and/or prohibit Pharmacies, Pharmacists, Pharmacy Interns, ~~Advanced Level Certified Pharmacy Technicians,~~ Certified Pharmacy Technicians~~,~~ or Certified Pharmacy Technician Candidates~~, or Ancillary Pharmacy Staff Persons~~ who violate this Act or Rules from continuing to threaten the public if it is to fulfill its responsibilities. The Board must have the ability to stop wrongdoers, either permanently or temporarily, discipline them, and, where appropriate, to guide and assist errant licensees in rehabilitating themselves.

The Model Act *disciplinary provisions are contained in Article IV. They were drafted with the purpose of granting to the Board the widest possible scope within which to perform its disciplinary functions. Standardized disciplinary action terms and definitions were developed to facilitate the accurate reporting of disciplinary actions taken by Boards of Pharmacy and to avoid confusion associated with state-to-state variations in terms and definitions. The grounds for disciplinary action were developed to ensure protection of the public, while reserving to the Board the power to expand upon them and adapt them to changing or local conditions as necessary. The penalties permitted under the* Model Act *will afford the Board the flexibility to conform and relate discipline to offenses.*

Section 401. Disciplinary Action Terms.

The following is a list of disciplinary actions that may be taken, issued, or assessed by the Board of Pharmacy: Revocation, Summary Suspension, Suspension, Probation, Censure, Reprimand, Warning, Cease and Desist, Fine/Civil Penalty, Costs/Administrative Costs.[20]

Section 402. Grounds, Penalties, and Reinstatement.[21]

(a) The Board of Pharmacy may refuse to issue or renew, or may Revoke, Summarily Suspend, Suspend, place on Probation, Censure, Reprimand, issue a Warning against, or issue a Cease and Desist order against, the licenses or the registration of, or assess a Fine/Civil Penalty or

[20] Guidelines for the imposition of sanctions for certain designated offenses can be found in Appendix C: Guidelines for Disciplinary Sanctions of the *Model Act*.

[21] The penalties provided in Section 402 give the Board wide latitude to make the disciplinary action fit the offense. The "reasonable intervals" in 402(c) would be determined by the Board.

Costs/Administrative Costs against any Person Pursuant to the procedures set forth in Section 403 herein below, upon one or more of the following grounds:

…

(8) knowing or suspecting that a Pharmacist or Pharmacy Intern is incapable of engaging in the Practice of Pharmacy or that a~~n Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician or Certified Pharmacy Technician Candidate~~, or Ancillary Pharmacy Staff Person,~~ is incapable of assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public, and failing to report any relevant information to the Board of Pharmacy;

(9) misrepresentation of a material fact by a licensee in securing the issuance or renewal of a license or registration;

(10) fraud by a licensee in connection with the Practice of Pharmacy;

(11) affiliating with websites that may deceive or defraud patients or that violate Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;

(12) engaging, or aiding and abetting an individual to engage in the Practice of Pharmacy without a license; assisting in the Practice of Pharmacy or aiding and abetting an individual to assist in the Practice of Pharmacy without ~~having~~ being licensed ~~or registered~~ with the Board of Pharmacy; or falsely using the title of Pharmacist, Pharmacy Intern, ~~Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate;

…

Section 403. Procedure.[22]

(a) Notwithstanding any provisions of the State Administrative Procedures Act, the Board may, without a hearing, Summarily Suspend a license for not more than 60 days if the Board finds that a Pharmacist, Pharmacy Intern, ~~Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate~~, or Ancillary Pharmacy Staff Person~~ has violated a law or rule that the Board is empowered to enforce, and if continued practice by the Pharmacist, Pharmacy Intern, ~~Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate~~, or Ancillary Pharmacy Staff Person~~ would create an imminent risk of harm to the public. The Suspension shall take effect upon written notice to the Pharmacist, Pharmacy Intern, ~~Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician~~,~~ or Certified

[22] The procedures which must be followed before disciplinary action can be taken in many of the states are determined by the Administrative Procedures Act. The *Model Act* was drafted on the assumption that such an Act was in effect.

Pharmacy Technician Candidate~~, or Ancillary Pharmacy Staff Person~~ specifying the statute or rule violated. At the time it issues the Suspension notice, the Board shall schedule a disciplinary hearing to be held under the Administrative Procedures Act within 20 days thereafter. The Pharmacist, Pharmacy Intern,~~ Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate~~, or Ancillary Pharmacy Staff Person~~ shall be provided with at least 10 days notice of any hearing held under this subsection.

…

Model Rules for the Practice of Pharmacy

Introductory Comment

The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care Services, the following rules are essential.

…

Section 3. Personnel.

(a) Duties and Responsibilities of the Pharmacist-in-Charge

(1) No Person shall operate a Pharmacy without a Pharmacist-in-Charge. The Pharmacist-in-Charge of a Pharmacy shall be designated in the application of the Pharmacy for license, and in each renewal thereof. A Pharmacist may not serve as Pharmacist-in-Charge unless he or she is physically present in the Pharmacy a sufficient amount of time to provide supervision and control. A Pharmacist may not serve as Pharmacist-in-Charge for more than one Pharmacy at any one time except upon obtaining written permission from the Board.

(2) The Pharmacist-in-Charge has the following responsibilities:

…

(-h-) the duties to be performed by ~~Advanced Level Certified Pharmacy Technicians,~~ Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates. The duties and responsibilities of these personnel shall be consistent with their education, training, and experience and shall address the method and level of necessary supervision specific to the practice site. These policies and procedures shall, at a minimum, specify that ~~Advanced Level Certified Pharmacy~~

~~Technicians,~~ Certified Pharmacy Technicians~~;~~ and Certified Pharmacy Technician Candidates are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Certified Pharmacy Technician Candidates shall not be assigned duties that may be performed only by ~~Advanced-Level Certified Pharmacy Technicians or~~ Certified Pharmacy Technicians.

…

(ii) Ensuring that:

(A) all Pharmacists, ~~and~~ Pharmacy Interns, ~~Advanced-Level Certified Pharmacy Technicians,~~ Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates employed at the Pharmacy are currently licensed ~~and that all Ancillary Pharmacy Staff Persons are currently registered~~ with the Board of Pharmacy.

(iii) Notifying the Board of Pharmacy, immediately and in writing, of any of the following[23] changes:

(A) change of employment or responsibility as the Pharmacist-in-Charge;

(B) the separation of employment of any Pharmacist, Pharmacy Intern, ~~Advanced-Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician Candidate, or Certified Pharmacy Technician~~, or Ancillary Pharmacy Staff Person~~ for any confirmed Drug-related reason, including but not limited to, Adulteration, abuse, theft, or diversion, and shall include in the notice the reason for the termination: if it is the employment of the Pharmacist-in-Charge that is terminated, the owner and/or pharmacy permit holder shall notify the Board of Pharmacy;

…

(3) The Pharmacist-in-Charge shall be assisted by a sufficient number of Pharmacists, ~~Advanced-Level Certified Pharmacy Technicians,~~ Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates~~, and Ancillary Pharmacy Staff Persons~~ as may be required to competently and safely provide Pharmacy services.

[23] If states require the Pharmacist-in-Charge or other Person in charge of the Pharmacy to submit information regarding the separation of employment of licensees, especially in circumstances of suspected or confirmed abuse, theft, or diversion of Drugs, states should also be aware of confidentiality and employment laws that may restrict the release of information and be cautioned that the release of such information may create a liability for the reporting Pharmacy.

In instances where the Pharmacist-in-Charge and the owner and/or pharmacy permit holder are the same person and that person is no longer employed or designated as the Person in charge, then the Board must take action to cease operation of the Pharmacy.

(i) The Pharmacist-in-Charge shall maintain and file with the Board of Pharmacy, on a form provided by the Board, a current list of all ~~Advanced Level Certified Pharmacy Technicians,~~ Certified Pharmacy Technicians~~,~~ and Certified Pharmacy Technician Candidates~~, and Ancillary Pharmacy Staff Persons~~ assisting in the provision of Pharmacy services.

(ii) The Pharmacist-in-Charge shall develop or adopt, implement, and maintain written policies and procedures to specify the duties to be performed by ~~Advanced Level Certified Pharmacy Technicians,~~ Certified Pharmacy Technicians~~,~~ and Certified Pharmacy Technician Candidates. The duties and responsibilities of these personnel shall be consistent with their education, training, and experience and shall address the method and level of necessary supervision specific to the practice site. These policies and procedures shall, at a minimum, specify that ~~Advanced Level Certified Pharmacy Technicians,~~ Certified Pharmacy Technicians~~,~~ and Certified Pharmacy Technician Candidates are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that ~~Certified Pharmacy Technicians or Certified Pharmacy Technician Candidates shall not be assigned duties that may be performed only by Advanced Level Certified Pharmacy Technicians and that~~ Certified Pharmacy Technician Candidates shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.

(iii) The Pharmacist-in-charge shall develop or adopt, implement, and maintain a Certified Pharmacy Technician training program that is site-specific to the practice setting of which he or she is in charge for all individuals employed by the Pharmacy who will assist in the Practice of Pharmacy. The Pharmacist-in-Charge shall utilize a Certified Pharmacy Technician training manual as part of the training program. The Pharmacist-in-Charge shall be responsible for maintaining a record of all Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates successfully completing a site-specific training program and an objective assessment mechanism. The Pharmacist-in-Charge shall attest to the Board of Pharmacy, in a timely manner, those persons who, from time to time, have met the training requirements necessary for licensure ~~registration~~ with the Board.[24]

…

[24]All training programs should be subject to approval by the Board of Pharmacy.

Section 4. Prescription Drug Order Processing.

(a) Prescription Drug Order

…

(b) Manner of Issuance of a Prescription Drug Order

A Prescription Drug Order, to be valid, must be issued for a legitimate medical purpose by a Practitioner acting within the course of legitimate professional practice. The responsibility for the proper prescribing and Dispensing of controlled substances is upon the prescribing Practitioner, but a corresponding responsibility rests with the Pharmacist who fills the prescription.[25]

(1) A Prescription Drug Order must be communicated to a Pharmacist, or when recorded in such a way that the Pharmacist may review the Prescription Drug Order as transmitted, to a Pharmacy Intern~~, Advanced Level Certified Pharmacy Technician~~ or a Certified Pharmacy Technician, in a licensed Pharmacy. This may be accomplished in one of the following ways. A Prescription Drug Order, including that for a controlled substance listed in Schedules II through V, may be communicated in written form. A Prescription Drug Order, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, may be communicated orally (including telephone voice communication) [26] or issued electronically.[27]

(2) The Pharmacist shall not dispense a Prescription Drug if the Pharmacist knows or reasonably should know that the Prescription Drug Order was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid Patient-Practitioner relationship.

(3) If communicated orally, the Prescription Drug Order shall be immediately reduced to a form by the Pharmacist, the Pharmacy Intern, ~~Advanced Level Certified Pharmacy Technician,~~ or the Certified Pharmacy Technician that may be maintained for the time required by laws or rules.

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[25] While Pharmacists have a corresponding responsibility to ensure that a controlled substance is Dispensed only pursuant to a valid Prescription Drug Order written for a legitimate medical purpose, this should not impede patients from receiving legitimately prescribed controlled substances or non-controlled substances, as patient care should be the primary consideration.

[26] Policies and procedures should also provide guidance for properly identifying agents of the prescribing Practitioner who are trained and competent in communicating Prescription Drug Orders.

[27] Electronically transmitted prescriptions should be transmitted from prescriber to Pharmacy with no intervening Persons making illegal alterations that may be considered as engaging in the Practice of Pharmacy without the authority to do so or without being Licensed to do so to such prescriptions. Evolving technologies and systems have alleviated previous concerns regarding the routes by which electronic prescriptions are transmitted, but any attempts to return to illegal prescription altering practices will be halted.

(4) A Prescription Drug Order for a Schedule II controlled substance may be communicated orally only in the following situations and/or with the following restrictions. Otherwise, a Prescription Drug Order for a Schedule II controlled substance must be communicated in written form or issued electronically.

(i) A Prescription Drug Order for a Schedule II controlled substance may be communicated by the Practitioner or the Practitioner's agent by way of Electronic Transmission, provided the original written, signed Prescription Drug Order is presented to the Pharmacist for review prior to the actual Dispensing of the controlled substance, except as noted in paragraph (ii) or (iii) of this Section 3(b)(3). The original, written Prescription Drug Order shall be maintained in accordance with state and federal recordkeeping requirements.

(ii) In the case of an Emergency Situation, a Prescription Drug Order for a Schedule II controlled substance may be communicated by the Practitioner orally, provided that:

(A) the quantity prescribed and Dispensed is limited to the amount adequate to treat the patient during the emergency period (Dispensing beyond the emergency period must be pursuant to a Prescription Drug Order either written and signed or electronically issued by the prescribing Practitioner);

(B) the orally communicated Prescription Drug Order shall be immediately reduced to writing by the Pharmacist, Pharmacy Intern, ~~Advanced Level Certified Pharmacy Technician,~~ or Certified Pharmacy Technician, if necessary, and shall contain the information required by state and federal law;

(C) if the prescribing Practitioner is not known to the Pharmacist, Pharmacy Intern, ~~Advanced Level Certified Pharmacy Technician,~~ or Certified Pharmacy Technician, he or she must make a reasonable effort to determine that the oral authorization came from a registered Practitioner, which may include a callback to the Practitioner using the Practitioner's phone number as listed in the telephone directory and/or other good faith efforts to ensure his or her identity; and

…

(iii) The prescribing Practitioner may authorize his or her agent to communicate a Prescription Drug Order orally or by way of Electronic Transmission via facsimile to a Pharmacist, Pharmacy Intern, ~~Advanced Level Certified Pharmacy Technician,~~ or Certified Pharmacy Technician in a licensed Pharmacy, provided that the identity of the transmitting agent is included in the order. In an Institutional Facility, the prescribing Practitioner's agent must be authorized by and in

accordance with written policies and procedures of the Facility and applicable state and federal laws.

…

(7) All Prescription Drug Orders for a Schedule III-V controlled substance communicated by way of Electronic Transmission via facsimile shall:

(i) be transmitted to a Pharmacist, Pharmacy Intern, ~~Advanced Level Certified Pharmacy Technician,~~ or Certified Pharmacy Technician in a licensed Pharmacy of the patient's choice;

(ii) identify the transmitter's phone number or any other suitable means to contact the transmitter for verbal and/or written confirmation, the time and date of transmission, and the identity of the Pharmacy intended to receive the transmission, as well as any other information required by federal or state law;

(iii) be transmitted by an authorized Practitioner or his or her designated agent; and

(iv) be deemed the original Prescription Drug Order, provided it meets the requirements of this subsection.

…

(c) Transfer of a Prescription Drug Order

Pharmacies utilizing automated data-processing systems shall satisfy all information requirements of a manual mode for Prescription Drug Order transferal, except as noted below for those pharmacies accessing a common electronic file. The transfer of original Prescription Drug Order information for the purpose of refill Dispensing is permissible between Pharmacies subject to the following requirements:

(1) The information for a prescription, other than for a controlled substance[28], is communicated directly between Pharmacists~~, Advanced Level Certified Pharmacy Technicians,~~ or Certified Pharmacy Technicians and the transferring Pharmacist, ~~Advanced Level Certified Pharmacy Technician,~~ or Certified Pharmacy Technician records the following information:

(i) write the word "VOID" on the face of the invalidated Prescription Drug Order;

(ii) record on the reverse side of the invalidated Prescription Drug Order the name and address of the Pharmacy to which it was transferred and the name of the Pharmacist or Certified Pharmacy Technician receiving the Prescription Drug Order;

(iii) record the date of the transfer and the name of the Pharmacist or Certified Pharmacy Technician transferring the information; and

[28] According to 21 CFR §1306.25 (b)(1), the transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill Dispensing must be communicated directly between two licensed Pharmacists.

(iv) the computer record shall reflect the fact that the original Prescription Drug Order has been voided and shall contain all the other information required above.

(2) The Pharmacist~~, Advanced Level Certified Pharmacy Technician,~~ or Certified Pharmacy Technician receiving the transferred Prescription Drug Order information shall reduce to writing the following:

(i) Write the word "TRANSFER" on the face of the transferred Prescription Drug Order.

(ii) Provide all information required to be on a Prescription Drug Order pursuant to state and federal laws and rules, and include:

(A) date of issuance of original Prescription Drug Order;

(B) original number of refills authorized on original Prescription Drug Order;

(C) date of original Dispensing;

(D) number of valid refills remaining and date of last refill;

(E) Pharmacy's name, address, and original prescription number from which the Prescription Drug Order information was transferred; and

(F) name of transferring Pharmacist or Certified Pharmacy Technician.

(iii) Systems providing for the electronic transfer of information shall not infringe on a patient's freedom of choice as to the provider of Pharmacist Care Services.

…

Section 5. Recordkeeping.

(a) Patient Records[29]

…

(b) Records of Dispensing/Delivery

(1) Records of receipt, Dispensing, Delivery, Distribution, or other disposition of all Drugs or Devices are to be made and kept by Pharmacies for five years[30] and shall include, but not be limited to:

(i) quantity Dispensed for original and refills, if different from original;

(ii) date of receipt, Dispensing, Delivery, Distribution, or other disposition;

(iii) serial number (or equivalent if an institution);

[29] The Pharmacist should have access to clinical and laboratory data concerning each patient, and should monitor each patient's response to his or her Drug therapy. Any unexpected or untoward response should be reported to the prescribing physician. If the Pharmacist is not doing this monitoring, the identity of the health care provider that has assumed this responsibility should be documented in the patient's profile.
It is acceptable for new Prescription Drug Order data to be added to the patient profile, but original entries may not be altered.

[30] States should check federal laws and ensure that the number of years the state requires Dispensing records to be maintained are at least as many as federal requirements.

(iv) the identification of the Pharmacist~~, Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate responsible for Dispensing;
(v) name and Manufacturer of Drug Dispensed if Drug Product selection occurs; and
(vi) records of refills to date.

(2) Pharmacies that ship medications by mail, common carrier, or other type of Delivery service shall implement a mechanism to verify that a patient or caregiver has actually received the Delivered medication.[31]

…

Section 6. Pharmacist Care Services. [32]

…

(b) Patient Counseling[33]

(1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone and shall include appropriate elements of Patient Counseling. Such elements may include the following:
(i) the name and description of the Drug;
(ii) the dosage form, dose, route of Administration, and duration of Drug therapy;
(iii) intended use of the Drug and expected action;
(iv) special directions and precautions for preparation, Administration, and use by the patient;
(v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

---

[31] States that require pharmacies that ship medication by mail, common carrier, or other type of Delivery service to implement a mechanism to verify that the patient or caregiver has actually received the Delivered medication may want to consider allowing the mechanism to include a waiver provision that allows the patient or caregiver to request Delivery without Verification and advises the patient or caregiver of the possible consequences of receiving Delivery without Verification.

[32] Additional Pharmacist Care Services may include, but are not limited to, Patient assessment and evaluation; assessing health plan and medication eligibility and coverage; Administering Drugs, vaccines, or biologicals; performing Peer Review and peer consultations; reviewing, selecting, and developing formularies or plan /practice guidelines; consulting with other health care professionals; providing patient referrals; performing Medication Therapy Management; ordering lab tests; and performing lab tests as provided by State and Federal law.

[33] The intent of this Section is to require that the Pharmacist personally initiate counseling for all new Prescriptions and to exercise his or her professional judgment for refills. Situations may arise, however, where the prescriber specifically indicates that a patient should not be counseled. In such circumstances, it is the responsibility of the Pharmacist to provide the best patient care through appropriate communication with the prescriber and to document the reason(s) for not providing counseling to the patient.

(vi) techniques for self-monitoring Drug therapy;
(vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose; and
(x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(2) An offer for Patient Counseling can be made by a~~n Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician~~,~~ or Certified Pharmacy Technician Candidate when not required by law or deemed necessary by the Pharmacist.

(~~2~~ 3) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(~~3~~4) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to Administer the Drug(s).

(~~4~~5) A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

…

Section 8. Shared Pharmacy Services.

…

(b) Operations

(1) Pharmacies engaging in Shared Pharmacy Services, or a Pharmacist acting independently of a Pharmacy and participating in Shared Pharmacy Services shall:

(i) maintain records identifying, individually, for each Prescription Drug Order processed, the name of each Pharmacist, or Pharmacy Intern who took part in the Drug Utilization Review, refill authorization, or therapeutic intervention functions performed at that Pharmacy and the name of any ~~Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician~~,~~ or Certified Pharmacy Technician Candidate if they assisted in any of those functions;

(ii) maintain records identifying individually, for each Prescription Drug Order filled or dispensed, the name of each Pharmacist or Pharmacy Intern who took part in the filling, dispensing, and counseling functions performed at that Pharmacy and the name of any ~~Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician~~,~~ or Certified Pharmacy Technician Candidate if they assisted in any of those functions;

…

(c) Drug Storage and Security

(1) Drugs shall be stored in compliance with state and federal laws and in accordance with these Rules, including those addressing temperature, proper containers, and the handling of outdated drugs.

(2) Drugs stored at Shared Pharmacy Services Pharmacies shall be stored in an area that is:

(i) separate from any other Drugs used by the health care facility; and

(ii) secured, so as to prevent access by unauthorized personnel.

(3) Access to the area where Drugs are stored at the Shared Pharmacy Services Pharmacy must be limited to:

(i) Pharmacists, ~~Advanced Level Certified Pharmacy Technicians,~~ Certified Pharmacy Technicians, Certified Pharmacy Technician Candidates, or Pharmacy Interns who are employed by the Shared Pharmacy Services Pharmacy; or

(ii) Personnel employed at the Institutional Facility or clinic where the Shared Pharmacy Services Pharmacy is located who:

(A) are licensed health care providers;

(B) are designated in writing by the Pharmacist-in-Charge or the Person responsible for the supervision and on-site operation of the facility where the Automated Pharmacy System is located; and

(C) have completed documented training concerning their duties associated with the Shared Pharmacy Services Pharmacy.

…

(e) Individual Practice

(1) Nothing in this Section shall prohibit an individual Pharmacist licensed in the state, who is an employee of or under contract with a Pharmacy, or a licensed ~~Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern, working under the supervision of the Pharmacy, from accessing that Pharmacy's electronic database from inside or outside the Pharmacy and performing the Prescription Drug Order processing functions permitted by the Pharmacy Act, if both of the following conditions are met:

(i) the Pharmacy establishes controls to protect the confidentiality and integrity of Protected Health Information; and

(ii) no part of the database is duplicated, downloaded, or removed from the Pharmacy's electronic database.

…

Model Rules for Public Health Emergencies

…

Section 5. Temporary Recognition of Nonresident Licensure.

(a) When a State of Emergency is declared due to a Public Health Emergency:

(1) a Pharmacist not licensed in this State, but currently licensed in another state, may Dispense Prescription Drugs in areas affected by the Declared Disaster during the time that the State of Emergency exists if:

(i) the Board can verify current licensure in good standing of the Pharmacist directly with the state or indirectly via a third-party verification system; and[34]

(ii) the Pharmacist is engaged in a legitimate relief effort.

(2) a~~n Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern not ~~registered or~~ licensed in this State, but currently ~~registered or~~ licensed in another state, may assist the Pharmacist in Dispensing Prescription Drugs in affected Disaster Areas during the time that the State of Emergency exists if:

(i) the Board can verify current ~~registration or~~ licensure in good standing of the ~~Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern directly with the state or indirectly via a third-party verification system; and

(ii) the ~~Advanced Level Certified Pharmacy Technician,~~ Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern is engaged in a legitimate relief effort.

…

Appendix G

Model Rules for the Practice of Telepharmacy

…

(b) Remote Dispensing Site Requirements

(1) Shall submit an application to the Board.

(2) The Pharmacist-in-Charge of supervising pharmacy shall be responsible for all operations.

[34] If the information cannot be verified directly by the state Board of Pharmacy in which the nonresident pharmacist is licensed, the NABP Disciplinary Clearinghouse may be utilized to verify that a nonresident pharmacist has not had disciplinary action taken against his or her license.

(3) Shall have a written contract or agreement that outlines the services provided and the responsibilities of each party in complying with federal and state pharmacy laws and rules.
(4) The Pharmacist-in-Charge shall oversee monthly inspections, maintenance and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.
(5) A Pharmacist must be designated to be available within (_) hours, in case of emergency.
(6) Unless staffed by a Pharmacist, a Remote Dispensing Site must be staffed by at least one (1) ~~Advanced-Level Certified Pharmacy Technician or~~ Certified Pharmacy Technician. All ~~Advanced-Level Certified Pharmacy Technicians,~~ Certified Pharmacy Technicians~~;~~ and Certified Pharmacy Technician Candidates shall be under the supervision of a Pharmacist at the supervising Pharmacy at all times that the remote site is operational. The Pharmacist shall supervise Telepharmacy operations electronically from the supervising pharmacy.

…

FDA-Related/Federal Guidance/Code of Federal Regulations-Related Provisions

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

…

Section 105. Definitions.

…

(f) "Bioburden" means the total number of microorganisms associated with a specific item prior to sterilization.

(g) "Biological Product" is:
(1) regulated by Food and Drug Administration (FDA);
(2) used to diagnose, prevent, treat, and cure diseases and medical conditions;
(3) a diverse category of products and generally large, complex molecules;
(4) produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and often more difficult to characterize than small molecule drugs.

(h) “Biosimilar Product" is a Biological Product that is highly similar and has no clinically meaningful differences from an existing FDA-approved Reference Product.

…

(a2) “Digital Signature” means an electronic signature based upon cryptographic methods of originator authentication, and computed by using a set of rules and a set of parameters so that the identity of the signer and the integrity of the data can be verified.[~~35~~]

…

(t2) “Electronic Signature” means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.[36]

…

(c3) “Interchangeable Product” is a Biosimilar Product that meets additional requirements.

…

(n4) “NABP e-Profile ID” means the unique identifier for permittees, licensees, and registrants that is provided by NABP. This unique, unduplicated identifier allows for, but is not limited to, the accurate identification and collection of licensure, disciplinary, and inspection information for permittees, licensees, and registrants, both in-state as well as out of state, in a secure electronic profile that can be utilized for applicant submission, review, and/or Board action.

(o4) “NABP Information Sharing Network”[37] means the information sharing network developed by NABP that collects, assesses, and allows review and sharing of compounding pharmacy and physician information as described in the “MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION”.

…

(d6) “Reference Product” is the single Biological Product, already approved by FDA, against which a proposed Biosimilar Product is compared.

…

~~[35] Public Key Infrastructure (PKI) technology is an example of a system that provides the mechanisms to make digital signatures and encryption of messages possible.~~

[36] The term “Electronic Signature” may have different meanings in various State laws and regulations. It is important to distinguish between “Electronic Signatures” and “Digital Signatures,” which provide a much higher level of security for electronically transmitted information. ~~It is anticipated that federal controlled substance regulations will soon allow for the transmission of controlled substance prescriptions provided that Digital Signatures are used. At that time, states may want to consider requiring Digital signatures as part of all electronically transmitted prescriptions.~~

[37] The information sharing network was built by NABP pursuant to the NABP-FDA Cooperative Agreement to Develop a System for the Collection, Management, and Sharing of Information on Compounding Pharmacies Distributing Interstate.

Model Rules for Compounded or Repackaged Pharmaceuticals

…

Section 2. Notification.

(a) On an annual basis, and within 90 days of the beginning of the calendar year, all licensed Persons shall report to the NABP Information Sharing Network the information required by the "MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION". ~~following:~~

~~a. (1) Whether the licensed Person participates in the following activities during the identified calendar year:~~

~~i. Human drug compounding – sterile~~

~~ii. Human drug compounding – nonsterile~~

~~iii. Patient-specific compounding~~

~~iv. Non-patient-specific compounding~~

~~(2) If a licensed Person is compounding sterile or nonsterile human drug products and is prompted by the NABP Information Sharing Network[38], the licensed Person shall also provide for the identified calendar year the following information[39]:~~

~~(i) Number of prescription orders for compounded human drugs the licensed Person sent out of the facility~~

~~(ii) Number of prescription orders for compounded human drugs dispensed at the facility~~

~~(iii) Total number of prescription orders for compounded human drugs distributed interstate~~

~~(3) If prompted by the NABP Information Sharing Network[40], the licensed Person shall provide the following additional information:~~

~~(i) Number of prescription orders for sterile compounded human drugs distributed interstate~~

~~[38] The Information Sharing Network will prompt the licensed Person for this information if the licensed Person indicates that it is compounding sterile or nonsterile human drug products.~~

~~[39] These three data points will allow the Information Sharing Network to determine whether the licensed Person is distributing inordinate amounts of compounded human drug products interstate, as described in the MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION.~~

~~[40] The Information Sharing Network will prompt the licensed Person for this additional information if it calculates that the licensed Person has distributed inordinate amounts of compounded human drug products interstate as described in the MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION.~~

~~(ii) Names of states into which the licensed Person distributed compounded human drugs during the year~~

~~(iii) Whether compounded human drugs are distributed without patient-specific prescriptions.~~

(b) Upon request from the Board, ~~A~~all licensed Persons shall report to the Board of Pharmacy~~, upon request from the Board~~ the number of Compounded Prescription Drug Orders Dispensed in the State where the Pharmacy is located and ~~(for in-State Pharmacies)~~ out of the State where the Pharmacy is located during a specified time period ~~specified~~, including the Drugs' Active Ingredients, strength, and dosage form(s).

(c) The Pharmacist shall notify patients if they may have received a Product found to have a defect or an out-of-specification result and conduct a recall, if the Board deems necessary.

…

Section 5. Records and Reports.

In addition to standard record keeping and reporting requirements, the following records shall be maintained:

(a) All ~~Distributions of nonsterile Compounded preparations or~~ Dispensing of ~~all~~ Sterile Compounded and nonsterile Compounded preparations.

(b) Any other records required to conform to and demonstrate compliance with USP standards and~~/or~~ Federal law.

…

Section 9. Compounded Drug Preparations for Veterinary Use.~~[41]~~

(a) The use of bulk Drug substances for Compounded Drug preparations is prohibited except when:

(1) Compounding is pursuant to a patient-specific prescription for a non-food-producing animal or as an antidote to prevent animal suffering or death in food-producing animals.

(2) there is no marketed approved, conditionally approved, or Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (indexed) ~~index listed animal~~ Drug that can be used as labeled to treat the condition;

(3) there is no marketed approved animal or human Drug that can be used to treat the condition through off-label Drug use;

(4) the Drug cannot be appropriately Compounded from an approved animal or human Drug;

(5) immediate treatment with the Compounded Drug preparation is necessary to avoid animal suffering or death; and

(6) FDA has not identified a significant veterinary safety concern with the use of the bulk Drug substance for Compounding.

~~[41] This section is intended for non-food-producing animals. For food-producing animals, refer to federal and state laws and rules.~~

(b) It is acceptable for any licensed Pharmacy to Compound veterinary Drug preparations to be used by veterinarians in their office for Administration to clients' animals.

(c) Compounded office use Drug preparations may be Dispensed by a veterinarian to clients only in an urgent or emergency situation for use in a single course of treatment, not to exceed a 120-hour supply.

(d) Prohibition on wholesaling
The Compounded veterinary Drug preparations will not be Distributed by an entity other than the Pharmacy that Compounded such veterinary Drug preparations. This does not prohibit Administration of a Compounded Drug preparation in a veterinary health care setting or Dispensing of a Compounded Drug preparation pursuant to a Prescription Drug Order executed in accordance with federal and state law.

(e) Providing samples of Compounded veterinary Drug preparations is prohibited.

(f) Upon becoming aware of any adverse event or Product defect, the Pharmacy reports the event on the designated FDA form[42] within 15 days and includes the FDA statement about reporting adverse events on the prescription label.

…

Model Rules for the Practice of Pharmacy

…

Section 4. Prescription Drug Order Processing.

…

(e) Labeling

(1) All Drugs Dispensed to ambulatory or outpatients, including Drugs Dispensed by Practitioners shall have a label affixed to the container in which such Drug is Dispensed. The label shall include the following: [43]

(i) Critical Information for Patients – Critical information must appear on the label with emphasis (highlighted or bolded), in a sans serif typeface (such as "arial"), minimum 12-point size, and in "sentence case." Field size and font size may be

[42] FDA Form 1932a or most current version.

[43] Electronically transmitted prescriptions should be transmitted from prescriber to Pharmacy with no intervening Persons making illegal alterations that may be considered as engaging in the Practice of Pharmacy without the authority to do so or without being Licensed to do so to such prescriptions. Evolving technologies and systems have alleviated previous concerns regarding the routes by which electronic prescriptions are transmitted, but any attempts to return to illegal prescription altering practices will be halted.

increased in the best interest of patient care.[44] Critical information text should never be truncated and shall include:

(A) patient name
  (-a-) legal name of the patient; or
  (-b-) if patient is an animal, include the last name of the owner, name of the animal, and animal species.

(B) directions for use
  (-a-) directions for use as indicated by the prescriber and medication purpose/indication if included on prescription drug order[45]; and
  (-b-) language should be simplified, avoiding unfamiliar words and medical jargon; when applicable, use numeric instead of alphabetic characters.[46]

(C) drug name
  (-a-) if written for a brand name and a generic drug is dispensed, include phrase "Generic for [brand name]" or similar wording[47]; and
  (-b-) include drug name suffixes, such as CD, SR, XL, XR, etc.

(D) drug strength, expressed in the metric system whenever possible

(E) oral liquid medication dosage, expressed in milliliters.

(~~E~~F) "use by" date
  (-a-) date after which Drug should not be used; not expiration date of Drug or expiration date of prescription[48]; and
  (-b-) format as – "Use by: MM/DD/YY."

…

[44] Alternative-access methods may be utilized to address visual impairment in patients or caregivers.

[45] Boards of pharmacy and licensees should recognize that "take as directed" may not provide sufficient information for the appropriate use of the medication. "Take as directed" is appropriate when specific directions are included on a unit-of-use package or dispensed package or in situations when directions are not able to be included on the label and the pharmacist presents directions to the patient and documents that such directions were given. "Take as directed" should not be used in lieu of patient counseling.
It is understood that prescription drug orders often do not include the indication for use.

[46] Consider adhering to the universal medication schedule (UMS). The UMS shifts medication-taking into four standardized time periods (morning, noon, evening, bedtime) and uses simplified language and formatting to promote understanding (eg, "take 1 tablet in the morning and 1 tablet at bedtime").

[47] If an Interchangeable Product ~~biologic~~ is dispensed, include the phrase "interchangeable for [Reference Product]."

[48] Boards of Pharmacy may determine that this "use by" date does not apply to all Drugs (for example epinephrine auto-injectors) and may allow the Manufacturer's expiration date to be used if the Drug is kept in the Manufacturer's original, unopened packaging, provided that the Pharmacist uses professional judgement to assess the continued need for the Drug and counsels the patient on proper storage.

~~Model Rules for the~~
~~Privacy of Individually Identifiable Health Information~~

~~(a) Uses and Disclosures of Protected Health Information. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may not use or disclose Protected Health Information, except as permitted or required by this Section.~~

~~(1) Permitted Uses and Disclosures. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board is permitted to use or disclose Protected Health Information as follows:~~

~~(i) to the patient;~~

~~(ii) for the treatment, payment, or health care operations as permitted or required by Paragraph (b) of this Section;~~

~~(iii) incident to a use or disclosure otherwise permitted or required by this Paragraph;~~

~~(iv) pursuant to and in compliance with a valid authorization under Paragraph (c) of this Section;~~

~~(v) pursuant to an agreement under, or as otherwise permitted by, Paragraph (d) of this Section;~~

~~(vi) as permitted by and in compliance with this Paragraph, Paragraph (e), or Paragraph (g).~~

~~(2) Required disclosures. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board is required to disclose Protected Health Information:~~

~~(i) to a patient, when requested under, and required by 45 CFR §164.524 or §164.528; and~~

~~(ii) when required to investigate or determine the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board's compliance with this Section and Federal privacy regulations.~~

~~(See comment list.)~~

~~(b) Uses and Disclosures of Protected Health Information.~~

~~(1) Permitted Uses and Disclosures.~~

~~(i) Except with respect to uses or disclosures that require an authorization under Paragraph (c), a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may use or disclose Protected Health Information for treatment, payment, or health care operations.~~

~~(2) Treatment, Payment, or Health Care Operations~~

~~(i) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may use or disclose Protected Health Information for their treatment, payment, or health care operations.~~

(ii) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may disclose Protected Health Information for treatment activities of a health care provider.

(iii) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may disclose Protected Health Information to a covered entity defined by 45 CFR §160.103 for the payment activities of the entity that receives the information.[49]

(iv) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may disclose Protected Health Information to a covered entity defined by 45 CFR §160.103 for health care operations activities of the entity that receives the information if each Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board has had a relationship with an individual who is the subject of the Protected Health Information being requested, the Protected Health Information pertains to such relationship, and the disclosure is:

(A) for a purpose listed in Paragraph (1) or (2) of the definition of "Health Care Operations"; or

(B) for the purpose of health care fraud and abuse detection or compliance.

(v) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board that participates in an organized health care arrangement may disclose Protected Health Information about a patient to a covered entity defined by 45 CFR §160.103 that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

(c) Uses and Disclosures for which an Authorization is Required.

(1) Authorization for Uses and Disclosures.

(i) Authorization required. General rule. Except as otherwise permitted or required by this section, a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may not use or disclose Protected Health Information without an authorization that is valid under this section. When a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board obtains a valid authorization for its use and disclosure of Protected Health Information, such use or disclosure must be consistent with such authorization.

(ii) Authorization required. Marketing.

(A) A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must obtain authorization for any use or disclosure

[49] 45 CFR §160.103 defines "covered entity" as "(1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter."

of Protected Health Information for marketing, except if the communication is in the form of:

(-a-) a face-to-face communication made by a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board;

(-b-) a promotional gift of nominal value provided by the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board.

(B) If the marketing involves direct or indirect remuneration to the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board from a third party, the authorization must state that such remuneration is involved.

(iii) Valid authorizations. A valid authorization is a document that contains the elements listed in Paragraph (2) of this subsection.

(iv) Prohibition on conditioning of authorizations. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may not condition the provision to a patient of treatment on the provision by a patient of an authorization, except:

(A) a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may condition the provision of research-related treatment on the provision of an authorization for the use or disclosure of Protected Health Information for such research; or

(B) a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may condition the provision of health care that is solely for the purpose of creating Protected Health Information for disclosure to a third party on provision of an authorization for the disclosure of the Protected Health Information to such third party.

(v) Revocation of authorizations. A patient may revoke an authorization at any time, provided that the revocation is in writing, except to the extent that the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board has taken action in reliance thereon.

(vi) An authorization obtained by a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must be retained for a minimum of six years from the date of its creation or the date when it was last in effect, whichever is later.

(2) Authorization: Content Requirements.

(i) Core elements. A valid authorization must contain at least the following elements:

(A) a specific description of the information to be used or disclosed;

(B) the name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;

(C) the name or other specific identification of the person(s), or class of persons, to whom the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may make the requested use or disclosure;

(D) the purpose for the requested use or disclosure. The statement "at the request of the individual" is sufficient when a patient initiates the authorization and does not, or elects not to, provide a statement of the purpose;

(E) an expiration date or an expiration event that relates to the patient or the purpose for the use or disclosure;

(F) signature of the patient and date. If the authorization is signed by a patient's agent, a description of such agent's authority to act for the patient must also be provided.

(ii) Required statements. In addition to the core elements, the authorization must contain statements adequate to place the patient on notice of all of the following:

(A) The patient's right to revoke the authorization in writing, and either:

(a) the exceptions to the right to revoke and a description of how the patient may revoke the authorization; or

(b) a reference to the notice of privacy practices of the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board, that addresses the exceptions to the right to revoke and a description of how to revoke the authorization.

(B) The conditions under which the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may condition treatment or payment on the provision of an authorization or those conditions under which the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board cannot condition treatment or payment on the provision of an authorization, and the consequences of a refusal to provide authorization.

(C) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by these regulations.

(iii) Plain language requirement. The authorization must be written in plain language.

(iv) Copy to the patient. If a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board seeks an authorization from a patient for a use or disclosure of Protected Health Information, the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must provide the patient with a copy of the signed authorization.

(d) Uses And Disclosures Requiring An Opportunity For The Patient To Agree Or To Object. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may use or disclose Protected Health Information provided that the patient is

~~informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this subsection. The Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may orally inform the patient of and obtain the patient's oral agreement or objection to a use or disclosure permitted by this subsection. Uses and disclosures permitted under this subsection are set out in 45 CFR §164.510 (a) and (b).~~

~~(See comment list.)~~

~~(e) Uses And Disclosures For Which An Authorization Or Opportunity To Object Is Not Required. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may use or disclose Protected Health Information without the written authorization of the patient or the opportunity for the patient to agree or object according to the standards set out in 45 CFR §164.512 (a) – (l). When the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board is required by this subsection to inform the patient of, or when the patient may agree to, a use or disclosure permitted by this subsection, the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board's information and the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board's agreement may be given orally.~~

~~(See comment list.)~~

~~(f) Other Requirements Relating To Uses And Disclosures Of Protected Health Information.~~

~~(1) De-identification and Re-identification of Protected Health Information. The de-identification and re-identification of Protected Health Information must conform with the standards and specifications set out in 45 CFR §164.514 (a) – (c).~~

~~(2) Minimum Necessary. Uses and disclosures of Protected Health Information must meet the minimum necessary standards and specifications set out in 45 CFR §164.514 (d).~~

~~(3) Limited Data Set. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board may use or disclose a limited data set as indicated in 45 CFR §164.514(e).~~

~~(4) Verification. Uses and disclosures of Protected Health Information must meet the verification standards and specifications set out in 45 CFR §164.514 (h).~~

~~(See comment list.)~~

~~(g) Notice of Privacy Practices for Protected Health Information. A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must provide each patient with a notice of privacy practices as indicated in 45 CFR §164.520.~~

~~(See comment list.)~~

~~(h) Right to Request Privacy Protection for Protected Health Information.~~

~~A Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must permit a patient to request that the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board restrict the use or disclosure of Protected Health Information as indicated in 45 CFR §164.522.~~

~~(See comment list.)~~

~~(i) Access of Patients to Protected Health Information.~~

~~A patient has a right of access to inspect and obtain a copy of Protected Health Information about the patient in a Designated Record Set, for as long as the Protected Health Information is maintained in the Designated Record Set, as indicated in 45 CFR §164.524.~~

~~(See comment list.)~~

~~(j) Amendment of Protected Health Information.~~

~~A patient has a right to have a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board to amend Protected Health Information about the patient in a Designated Record Set, for as long as the Protected Health Information is maintained in the Designated Record Set, as indicated in 45 CFR §164.526.~~

~~(See comment list.)~~

~~(k) Accounting of Disclosures of Protected Health Information.~~

~~(1) A patient has a right to receive an accounting of disclosures of Protected Health Information made by a Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board in the six years prior to the date on which the accounting is requested, except for the following disclosures:~~

~~(i) to carry out treatment, payment, and health care operations, as provided in Paragraph (b) of this section;~~

~~(ii) to patients, of Protected Health Information about them;~~

~~(iii) incident to a use or disclosure otherwise permitted or required by this Paragraph, as provided in Paragraph (a);~~

~~(iv) pursuant to an authorization, as provided in Paragraph (c);~~

~~(v) for the facility's directory or to persons involved in the patient's care or other notification purposes as provided in Paragraph (d);~~

~~(vi) for national security or intelligence purposes as provided in 45 CFR §164.512(k)(2);~~

~~(vii) To correctional institutions or law enforcement officials as provided in 45 CFR §164.512(k)(5);~~

~~(viii) As part of a limited data set in accordance with 45 CFR §164.514(e); or~~

~~(ix) That occurred prior to the compliance date of April 14, 2003, for the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board.~~

~~(See comment list.)~~

(2) (i) The Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must temporarily suspend a patient's right to receive an accounting of disclosures to a health oversight agency or law enforcement official for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the patient would be reasonably likely to impede the agency's activities and specifying the time for which the suspension is required.

(ii) If the agency or official statement in Paragraph (k)(2)(i) is made orally, the Pharmacy, Pharmacist, Pharmacy Benefits Manager, or Person licensed or registered by the Board must:

(A) Document the statement, including the identity of the agency or official making the statement;

(B) Temporarily suspend the patient's right to an accounting of disclosures subject to the statement; and

(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to Paragraph (k)(2)(i) is submitted during that time.

(3) A patient may request an accounting of disclosures for a period of time less than six years from the date of the request.

(4) The accounting of disclosures of Protected Health Information must conform to the requirements set out in 45 CFR §164.528 (b), (c), and (d).

(See comment list.)

Comments

Section (a)(2)(i). Comment.

45 CFR §164.524 reads:

§164.524 Access of individuals to protected health information.

(a) *Standard: Access to protected health information.*—(1) *Right of access.* Except as otherwise provided in paragraph (a)(2) or (a)(3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:

(i) Psychotherapy notes; and

(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

(2) *Unreviewable grounds for denial.* A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances.

(i) The protected health information is excepted from the right of access by paragraph (a)(1) of this section.

(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.

(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.

(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.

(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

(3) *Reviewable grounds for denial.* A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4) of this section, in the following circumstances:

(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;

(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or

(iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

(4) *Review of a denial of access.* If access is denied on a ground permitted under paragraph (a)(3) of this section, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny. The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (d)(4) of this section.

(b) *Implementation specifications: Requests for access and timely action*—(1) *Individual's request for access.* The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health

information about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.

(2) *Timely action by the covered entity.* (i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than 30 days after receipt of the request as follows.

(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section.

(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section.

(ii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for access.

(c) *Implementation specifications: Provision of access.* If the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Providing the access requested.* The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the protected health information about them in designated record sets. If the same protected health information that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the covered entity need only produce the protected health information once in response to a request for access.

(2) *Form of access requested.* (i) The covered entity must provide the individual with access to the protected health information in the form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable hard copy form or such other form and format as agreed to by the covered entity and the individual.

(ii) Notwithstanding paragraph (c)(2)(i) of this section, if the protected health information that is the subject of a request for access is maintained in one or more designated record sets electronically and if the individual requests an electronic copy of such information, the covered entity must provide the individual with access to the protected health information in the electronic form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual.

(iii) The covered entity may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:

(A) The individual agrees in advance to such a summary or explanation; and

(B) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.

(3) *Time and manner of access.* (i) The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.

(ii) If an individual's request for access directs the covered entity to transmit the copy of protected health information directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual. The individual's request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.

(4) *Fees.* If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

(i) Labor for copying the protected health information requested by the individual, whether in paper or electronic form;

(ii) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media;

(iii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and

(iv) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(iii) of this section.

(d) *Implementation specifications: Denial of access.* If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Making other information accessible.* The covered entity must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.

(2) *Denial.* The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain:

(i) The basis for the denial;

(ii) If applicable, a statement of the individual's review rights under paragraph (a)(4) of this section, including a description of how the individual may exercise such review rights; and

(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in §164.530(d) or to the Secretary pursuant to the procedures in §160.306. The description must include the name, or title, and telephone number of the contact person or office designated in §164.530(a)(1)(ii).

(3) *Other responsibility.* If the covered entity does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.

(4) *Review of denial requested.* If the individual has requested a review of a denial under paragraph (a)(4) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.

(e) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by §164.530(j):

(1) The designated record sets that are subject to access by individuals; and

(2) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

[65 FR 82802, Dec. 28, 2000, as amended at 78 FR 5701, Jan. 25, 2013; 78 FR 34266, June 7, 2013; 79 FR 7316, Feb. 6, 2014]

§164.528 Accounting of disclosures of protected health information.

(a) *Standard: Right to an accounting of disclosures of protected health information.* (1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:

(i) To carry out treatment, payment and health care operations as provided in §164.506;

(ii) To individuals of protected health information about them as provided in §164.502;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in §164.502;

(iv) Pursuant to an authorization as provided in §164.508;

(v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in §164.510;

(vi) For national security or intelligence purposes as provided in §164.512(k)(2);

(vii) To correctional institutions or law enforcement officials as provided in §164.512(k)(5);

(viii) As part of a limited data set in accordance with §164.514(e); or

(ix) That occurred prior to the compliance date for the covered entity.

(2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in §164.512(d) or (f), respectively, for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.

(ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:

(A) Document the statement, including the identity of the agency or official making the statement;

(B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and

(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.

(3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.

(b) *Implementation specifications: Content of the accounting.* The covered entity must provide the individual with a written accounting that meets the following requirements.

(1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.

(2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:

(i) The date of the disclosure;

(ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;

(iii) A brief description of the protected health information disclosed; and

(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§164.502(a)(2)(ii) or 164.512, if any.

(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under §§164.502(a)(2)(ii) or 164.512, the accounting may, with respect to such multiple disclosures, provide:

(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;

(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and

(iii) The date of the last such disclosure during the accounting period.

(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with §164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:

(A) The name of the protocol or other research activity;

(B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;

(C) A brief description of the type of protected health information that was disclosed;

(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;

(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and

(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.

(ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

(c) *Implementation specifications: Provision of the accounting.* (1) The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.

(i) The covered entity must provide the individual with the accounting requested; or

(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and

(B) The covered entity may have only one such extension of time for action on a request for an accounting.

(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.

(d) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by §164.530(j):

(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;

(2) The written accounting that is provided to the individual under this section; and

(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals

Section (d). Comment.

45 CFR §164.510(a) and (b) read:

> §164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.
> A covered entity may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section. The covered entity may orally inform the individual of and obtain the individual's oral agreement or objection to a use or disclosure permitted by this section.
> (a) *Standard: Use and disclosure for facility directories.* (1) *Permitted uses and disclosure.* Except when an objection is expressed in accordance with paragraphs (a)(2) or (3) of this section, a covered health care provider may:
> (i) Use the following protected health information to maintain a directory of individuals in its facility:
> (A) The individual's name;
> (B) The individual's location in the covered health care provider's facility;
> (C) The individual's condition described in general terms that does not communicate specific medical information about the individual; and
> (D) The individual's religious affiliation; and
> (ii) Use or disclose for directory purposes such information:
> (A) To members of the clergy; or
> (B) Except for religious affiliation, to other persons who ask for the individual by name.
> (2) *Opportunity to object.* A covered health care provider must inform an individual of the protected health information that it may include in a directory and the persons to whom it may disclose such information (including disclosures to clergy of information regarding religious affiliation) and provide the individual with the opportunity to restrict or prohibit some or all of the uses or disclosures permitted by paragraph (a)(1) of this section.
> (3) *Emergency circumstances.* (i) If the opportunity to object to uses or disclosures required by paragraph (a)(2) of this section cannot practicably be provided because of the individual's incapacity or an emergency

~~treatment circumstance, a covered health care provider may use or disclose some or all of the protected health information permitted by paragraph (a)(1) of this section for the facility's directory, if such disclosure is:~~
~~(A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and~~
~~(B) In the individual's best interest as determined by the covered health care provider, in the exercise of professional judgment.~~
~~(ii) The covered health care provider must inform the individual and provide an opportunity to object to uses or disclosures for directory purposes as required by paragraph (a)(2) of this section when it becomes practicable to do so.~~
~~(b) *Standard: Uses and disclosures for involvement in the individual's care and notification purposes —*~~
~~(1) *Permitted uses and disclosures.* (i) A covered entity may, in accordance with paragraphs (b)(2), (b)(3), or (b)(5) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's health care or payment related to the individual's health care.~~
~~(ii) A covered entity may use or disclose protected health information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, as applicable.~~
~~(2) *Uses and disclosures with the individual present.* If the individual is present for, or otherwise available prior to, a use or disclosure permitted by paragraph (b)(1) of this section and has the capacity to make health care decisions, the covered entity may use or disclose the protected health information if it:~~
~~(i) Obtains the individual's agreement;~~
~~(ii) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or~~
~~(iii) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.~~
~~(3) *Limited uses and disclosures when the individual is not present.* If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's care or payment related to the individual's health care or needed for notification purposes. A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.~~
~~(4) *Uses and disclosures for disaster relief purposes.* A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2), (b)(3), or (b)(5) of this section apply to such uses and disclosures to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.~~
~~(5) *Uses and disclosures when the individual is deceased.* If the individual is deceased, a covered entity may disclose to a family member, or other persons identified in paragraph (b)(1) of this section who were involved in the individual's care or payment for health care prior to the individual's death, protected health information of the individual that is relevant to such person's involvement, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity.~~

Section (e). Comment.

45 CFR §164.512(a) – (l) read:

§164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required. A covered entity may use or disclose protected health information without the written authorization of the individual, as described in §164.508, or the opportunity for the individual to agree or object as described in §164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.* (1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) *Standard: Uses and disclosures for public health activities.* (1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products;

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance;

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or

(v) An employer, about an individual who is a member of the workforce of the employer, if:

(A) The covered entity is a covered health care provider who provides health care to the individual at the request of the employer:

(*1*) To conduct an evaluation relating to medical surveillance of the workplace; or

(*2*) To evaluate whether the individual has a work-related illness or injury;

(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;

(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and
(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:
(*1*) By giving a copy of the notice to the individual at the time the health care is provided; or
(*2*) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.
(vi) A school, about an individual who is a student or prospective student of the school, if:
(A) The protected health information that is disclosed is limited to proof of immunization;
(B) The school is required by State or other law to have such proof of immunization prior to admitting the individual; and
(C) The covered entity obtains and documents the agreement to the disclosure from either:
(*1*) A parent, guardian, or other person acting *in loco parentis* of the individual, if the individual is an unemancipated minor; or
(*2*) The individual, if the individual is an adult or emancipated minor.
(2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.
(c) *Standard: Disclosures about victims of abuse, neglect or domestic violence.* (1) *Permitted disclosures.* Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:
(i) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;
(ii) If the individual agrees to the disclosure; or
(iii) To the extent the disclosure is expressly authorized by statute or regulation and:
(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or
(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.
(2) *Informing the individual.* A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:
(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or
(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.
(d) *Standard: Uses and disclosures for health oversight activities.* (1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary

actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:
(i) The health care system;
(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;
(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or
(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.
(2) *Exception to health oversight activities.* For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:
(i) The receipt of health care;
(ii) A claim for public benefits related to health; or
(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.
(3) *Joint activities or investigations.* Nothwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.
(4) *Permitted uses.* If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.
(e) *Standard: Disclosures for judicial and administrative proceedings*—(1) *Permitted disclosures.* A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:
(i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order; or
(ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:
(A) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iii) of this section, from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or
(B) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section.
(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:
(A) The party requesting such information has made a good faith attempt to provide written notice to the individual (or, if the individual's location is unknown, to mail a notice to the individual's last known address);
(B) The notice included sufficient information about the litigation or proceeding in which the protected health information is requested to permit the individual to raise an objection to the court or administrative tribunal; and
(C) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:
(*1*) No objections were filed; or
(*2*) All objections filed by the individual have been resolved by the court or the administrative tribunal and the disclosures being sought are consistent with such resolution.

(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information, if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:
(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or
(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.
(v) For purposes of paragraph (e)(1) of this section, a qualified protective order means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:
(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and
(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.
(vi) Notwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered entity makes reasonable efforts to provide notice to the individual sufficient to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(v) of this section.
(2) *Other uses and disclosures under this section.* The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information.
(f) *Standard: Disclosures for law enforcement purposes.* A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.
(1) *Permitted disclosures: Pursuant to process and as otherwise required by law.* A covered entity may disclose protected health information:
(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or
(ii) In compliance with and as limited by the relevant requirements of:
(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;
(B) A grand jury subpoena; or
(C) An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:
(*1*) The information sought is relevant and material to a legitimate law enforcement inquiry;
(*2*) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and
(*3*) De-identified information could not reasonably be used.
(2) *Permitted disclosures: Limited information for identification and location purposes.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:
(i) The covered entity may disclose only the following information:
(A) Name and address;
(B) Date and place of birth;
(C) Social security number;
(D) ABO blood type and rh factor;
(E) Type of injury;

(F) Date and time of treatment;
(G) Date and time of death, if applicable; and
(H) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.
(ii) Except as permitted by paragraph (f)(2)(i) of this section, the covered entity may not disclose for the purposes of identification or location under paragraph (f)(2) of this section any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.
(3) *Permitted disclosure: Victims of a crime.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures that are subject to paragraph (b) or (c) of this section, if:
(i) The individual agrees to the disclosure; or
(ii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:
(A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;
(B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and
(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.
(4) *Permitted disclosure: Decedents.* A covered entity may disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct.
(5) *Permitted disclosure: Crime on premises.* A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.
(6) *Permitted disclosure: Reporting crime in emergencies.* (i) A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:
(A) The commission and nature of a crime;
(B) The location of such crime or of the victim(s) of such crime; and
(C) The identity, description, and location of the perpetrator of such crime.
(ii) If a covered health care provider believes that the medical emergency described in paragraph (f)(6)(i) of this section is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care, paragraph (f)(6)(i) of this section does not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to paragraph (c) of this section.
(g) *Standard: Uses and disclosures about decedents.* (1) *Coroners and medical examiners.* A covered entity may disclose protected health information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. A covered entity that also performs the duties of a coroner or medical examiner may use protected health information for the purposes described in this paragraph.
(2) *Funeral directors.* A covered entity may disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. If necessary

for funeral directors to carry out their duties, the covered entity may disclose the protected health information prior to, and in reasonable anticipation of, the individual's death.

(h) *Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes.* A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.

(i) *Standard: Uses and disclosures for research purposes.* (1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:

(i) *Board approval of a waiver of authorization.* The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use or disclosure of protected health information has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with 7 CFR lc.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or

(B) A privacy board that:

(*1*) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;

(*2*) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and

(*3*) Does not have any member participating in a review of any project in which the member has a conflict of interest.

(ii) *Reviews preparatory to research.* The covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

(iii) *Research on decedent's information.* The covered entity obtains from the researcher:

(A) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

(2) *Documentation of waiver approval.* For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

(i) *Identification and date of action.* A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

(ii) *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(*1*) An adequate plan to protect the identifiers from improper use and disclosure;

(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
(B) The research could not practicably be conducted without the waiver or alteration; and
(C) The research could not practicably be conducted without access to and use of the protected health information.
(iii) *Protected health information needed.* A brief description of the protected health information for which use or access has been determined to be necessary by the institutional review board or privacy board, pursuant to paragraph (i)(2)(ii)(C) of this section;
(iv) *Review and approval procedures.* A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:
(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);
(B) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (i)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (i)(2)(iv)(C) of this section;
(C) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and
(v) *Required signature.* The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.
(j) *Standard: Uses and disclosures to avert a serious threat to health or safety.* (1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:
(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and
(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or
(ii) Is necessary for law enforcement authorities to identify or apprehend an individual:
(A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or
(B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in §164.501.
(2) *Use or disclosure not permitted.* A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:

(i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or
(ii) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy described in paragraph (j)(2)(i) of this section.
(3) *Limit on information that may be disclosed.* A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.
(4) *Presumption of good faith belief.* A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.
(k) *Standard: Uses and disclosures for specialized government functions.* (1) *Military and veterans activities.* (i)*Armed Forces personnel.* A covered entity may use and disclose the protected health information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the Federal Register the following information:
(A) Appropriate military command authorities; and
(B) The purposes for which the protected health information may be used or disclosed.
(ii) *Separation or discharge from military service.* A covered entity that is a component of the Departments of Defense or Homeland Security may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.
(iii) *Veterans.* A covered entity that is a component of the Department of Veterans Affairs may use and disclose protected health information to components of the Department that determine eligibility for or entitlement to, or that provide, benefits under the laws administered by the Secretary of Veterans Affairs.
(iv) *Foreign military personnel.* A covered entity may use and disclose the protected health information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel under the notice published in the Federal Register pursuant to paragraph (k)(1)(i) of this section.
(2) *National security and intelligence activities.* A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, *et seq.*) and implementing authority (*e.g.*, Executive Order 12333).
(3) *Protective services for the President and others.* A covered entity may disclose protected health information to authorized Federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056 or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or for the conduct of investigations authorized by 18 U.S.C. 871 and 879.
(4) *Medical suitability determinations.* A covered entity that is a component of the Department of State may use protected health information to make medical suitability determinations and may disclose whether or not the individual was determined to be medically suitable to the officials in the Department of State who need access to such information for the following purposes:
(i) For the purpose of a required security clearance conducted pursuant to Executive Orders 10450 and 12968;
(ii) As necessary to determine worldwide availability or availability for mandatory service abroad under sections 101(a)(4) and 504 of the Foreign Service Act; or
(iii) For a family to accompany a Foreign Service member abroad, consistent with section 101(b)(5) and 904 of the Foreign Service Act.

(5) *Correctional institutions and other law enforcement custodial situations.* (i) *Permitted disclosures.* A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:
(A) The provision of health care to such individuals;
(B) The health and safety of such individual or other inmates;
(C) The health and safety of the officers or employees of or others at the correctional institution;
(D) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;
(E) Law enforcement on the premises of the correctional institution; or
(F) The Administration and maintenance of the safety, security, and good order of the correctional institution.
(ii) *Permitted uses.* A covered entity that is a correctional institution may use protected health information of individuals who are inmates for any purpose for which such protected health information may be disclosed.
(iii) *No application after release.* For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.
(6) *Covered entities that are government programs providing public benefits.* (i) A health plan that is a government program providing public benefits may disclose protected health information relating to eligibility for or enrollment in the health plan to another agency administering a government program providing public benefits if the sharing of eligibility or enrollment information among such government agencies or the maintenance of such information in a single or combined data system accessible to all such government agencies is required or expressly authorized by statute or regulation.
(ii) A covered entity that is a government agency administering a government program providing public benefits may disclose protected health information relating to the program to another covered entity that is a government agency administering a government program providing public benefits if the programs serve the same or similar populations and the disclosure of protected health information is necessary to coordinate the covered functions of such programs or to improve Administration and management relating to the covered functions of such programs.
(l) *Standard: Disclosures for workers' compensation.* A covered entity may disclose protected health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault

Section (f). Comment.

45 CFR §164.514(a) - (c), (d), (e), and (h) read:

§164.514 Other requirements relating to uses and disclosures of protected health information.
(a) *Standard: De-identification of protected health information.* Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.
(b) *Implementation specifications: Requirements for de-identification of protected health information.* A covered entity may determine that health information is not individually identifiable health information only if:
(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
(ii) Documents the methods and results of the analysis that justify such determination; or

(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:
(A) Names;
(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
(*1*) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
(*2*) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
(D) Telephone numbers;
(E) Fax numbers;
(F) Electronic mail addresses;
(G) Social security numbers;
(H) Medical record numbers;
(I) Health plan beneficiary numbers;
(J) Account numbers;
(K) Certificate/license numbers;
(L) Vehicle identifiers and serial numbers, including license plate numbers;
(M) Device identifiers and serial numbers;
(N) Web Universal Resource Locators (URLs);
(O) Internet Protocol (IP) address numbers;
(P) Biometric identifiers, including finger and voice prints;
(Q) Full face photographic images and any comparable images; and
(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and
(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.
(c) *Implementation specifications: Re-identification.* A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:
(1) *Derivation.* The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
(2) *Security.* The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.
(d)(1) *Standard: minimum necessary requirements.* In order to comply with §164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for, or the use and disclosure of, protected health information.
(2) *Implementation specifications: Minimum necessary uses of protected health information.* (i) A covered entity must identify:
(A) Those persons or classes of persons, as appropriate, in its workforce who need access to protected health information to carry out their duties; and
(B) For each such person or class of persons, the category or categories of protected health information to which access is needed and any conditions appropriate to such access.

(ii) A covered entity must make reasonable efforts to limit the access of such persons or classes identified in paragraph (d)(2)(i)(A) of this section to protected health information consistent with paragraph (d)(2)(i)(B) of this section.
(3) *Implementation specification: Minimum necessary disclosures of protected health information.* (i) For any type of disclosure that it makes on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information disclosed to the amount reasonably necessary to achieve the purpose of the disclosure.
(ii) For all other disclosures, a covered entity must:
(A) Develop criteria designed to limit the protected health information disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought; and
(B) Review requests for disclosure on an individual basis in accordance with such criteria.
(iii) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:
(A) Making disclosures to public officials that are permitted under §164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s);
(B) The information is requested by another covered entity;
(C) The information is requested by a professional who is a member of its workforce or is a business associate of the covered entity for the purpose of providing professional services to the covered entity, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or
(D) Documentation or representations that comply with the applicable requirements of §164.512(i) have been provided by a person requesting the information for research purposes.
(4) *Implementation specifications: Minimum necessary requests for protected health information.* (i) A covered entity must limit any request for protected health information to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.
(ii) For a request that is made on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information requested to the amount reasonably necessary to accomplish the purpose for which the request is made.
(iii) For all other requests, a covered entity must:
(A) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and
(B) Review requests for disclosure on an individual basis in accordance with such criteria.
(5) *Implementation specification: Other content requirement.* For all uses, disclosures, or requests to which the requirements in paragraph (d) of this section apply, a covered entity may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.
(e)(1) *Standard: Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.
(2) *Implementation specification: Limited data set:* A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:
(i) Names;
(ii) Postal address information, other than town or city, State, and zip code;
(iii) Telephone numbers;
(iv) Fax numbers;
(v) Electronic mail addresses;
(vi) Social security numbers;

(vii) Medical record numbers;
(viii) Health plan beneficiary numbers;
(ix) Account numbers;
(x) Certificate/license numbers;
(xi) Vehicle identifiers and serial numbers, including license plate numbers;
(xii) Device identifiers and serial numbers;
(xiii) Web Universal Resource Locators (URLs);
(xiv) Internet Protocol (IP) address numbers;
(xv) Biometric identifiers, including finger and voice prints; and
(xvi) Full face photographic images and any comparable images.
(3) *Implementation specification: Permitted purposes for uses and disclosures.* (i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.
(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.
(4) *Implementation specifications: Data use agreement* — (i) *Agreement required.* A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.
(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:
(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;
(B) Establish who is permitted to use or receive the limited data set; and
(C) Provide that the limited data set recipient will:
(*1*) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
(*2*) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
(*3*) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
(*4*) Ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
(*5*) Not identify the information or contact the individuals.
(iii) *Compliance.* (A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:
(1) Discontinued disclosure of protected health information to the recipient; and
(2) Reported the problem to the Secretary.
(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.
. . .
(h)(1) *Standard: Verification requirements.* Prior to any disclosure permitted by this subpart, a covered entity must:

(i) Except with respect to disclosures under §164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and
(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.
(2) *Implementation specifications: Verification.* (i) *Conditions on disclosures.* If a disclosure is conditioned by this subpart on particular documentation, statements, or representations from the person requesting the protected health information, a covered entity may rely, if such reliance is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements.
(A) The conditions in §164.512(f)(1)(ii)(C) may be satisfied by the administrative subpoena or similar process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.
(B) The documentation required by §164.512(i)(2) may be satisfied by one or more written statements, provided that each is appropriately dated and signed in accordance with §164.512(i)(2)(i) and (v).
(ii) *Identity of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:
(A) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;
(B) If the request is in writing, the request is on the appropriate government letterhead; or
(C) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.
(iii) *Authority of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:
(A) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;
(B) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.
(iv) *Exercise of professional judgment.* The verification requirements of this paragraph are met if the covered entity relies on the exercise of professional judgment in making a use or disclosure in accordance with §164.510 or acts on a good faith belief in making a disclosure in accordance with §164.512(j).

Section (g). Comment.

45 CFR §164.520 reads:

§164.520 Notice of privacy practices for protected health information.
(a) *Standard: Notice of privacy practices.* (1) *Right to notice.* Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.
(2) *Exception for group health plans.* (i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or
(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.
(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in §164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:
(A) Maintain a notice under this section; and
(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.
(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in §164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.
(3) *Exception for inmates.* An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.
(b) *Implementation specifications: Content of notice*—(1) *Required elements.* The covered entity must provide a notice that is written in plain language and that contains the elements required by this paragraph.
(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed: "THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY."
(ii) *Uses and disclosures.* The notice must contain:
(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.
(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written authorization.
(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law as defined in §160.202 of this subchapter.
(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law.
(E) A description of the types of uses and disclosures that require an authorization under §164.508(a)(2) (a)(4), a statement that other uses and disclosures not described in the notice will be made only with the individual's written authorization, and a statement that the individual may revoke an authorization as provided by §164.508(b)(5).
(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement informing the individual of such activities, as applicable:
(A) In accordance with §164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications; (B) In accordance with §164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan; or

(C) If a covered entity that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan*, intends to use or disclose protected health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes.
(iv) *Individual rights.* The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:
(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by §164.522(a), including a statement that the covered entity is not required to agree to a requested restriction, except in case of a disclosure restricted under §164.522(a)(1)
(B) The right to receive confidential communications of protected health information as provided by §164.522(b), as applicable;
(C) The right to inspect and copy protected health information as provided by §164.524;
(D) The right to amend protected health information as provided by §164.526;
(E) The right to receive an accounting of disclosures of protected health information as provided by §164.528; and
(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.
(v) *Covered entity's duties.* The notice must contain:
(A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices with respect to protected health information, and to notify affected individuals following a breach of unsecured protected health information;
(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and
(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.
(vi) *Complaints.* The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.
(vii) *Contact.* The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by §164.530(a)(1)(ii).
(viii) *Effective date.* The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.
(2) *Optional elements.* (i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by §164.512(j)(1)(i).
(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.
(3) *Revisions to the notice.* The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other

privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.
(c) *Implementation specifications: Provision of notice.* A covered entity must make the notice required by this section available on request to any person and to individuals as specified in paragraphs (c)(1) through (c)(3) of this section, as applicable.
(1) *Specific requirements for health plans.* (i) A health plan must provide the notice:
(A) No later than the compliance date for the health plan, to individuals then covered by the plan;
(B) Thereafter, at the time of enrollment, to individuals who are new enrollees.
(ii) No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.
(iii) The health plan satisfies the requirements of paragraph (c)(1) of this section if notice is provided to the named insured of a policy under which coverage is provided to the named insured and one or more dependents.
(iv) If a health plan has more than one notice, it satisfies the requirements of paragraph (c)(1) of this section by providing the notice that is relevant to the individual or other person requesting the notice.
(v) If there is a material change to the notice:
(A) A health plan that posts its notice on its web site in accordance with paragraph (c)(3)(i) of this section must prominently post the change or its revised notice on its web site by the effective date of the material change to the notice, and provide the revised notice, or information about the material change and how to obtain the revised notice, in its next annual mailing to individuals then covered by the plan.
(B) A health plan that does not post its notice on a web site pursuant to paragraph (c)(3)(i) of this section must provide the revised notice, or information about the material change and how to obtain the revised notice, to individuals then covered by the plan within 60 days of the material revision to the notice.
(2) *Specific requirements for certain covered health care providers.* A covered health care provider that has a direct treatment relationship with an individual must:
(i) Provide the notice:
(A) No later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider; or
(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.
(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;
(iii) If the covered health care provider maintains a physical service delivery site:
(A) Have the notice available at the service delivery site for individuals to request to take with them; and
(B) Post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered health care provider to be able to read the notice; and
(iv) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(iii) of this section, if applicable.
(3) *Specific requirements for electronic notice.* (i) A covered entity that maintains a web site that provides information about the covered entity's customer services or benefits must prominently post its notice on the web site and make the notice available electronically through the web site.
(ii) A covered entity may provide the notice required by this section to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the covered entity knows that the e-mail transmission has failed, a paper copy of the notice must be provided to the individual. Provision of electronic notice by the covered entity will satisfy the provision requirements of paragraph (c) of this section when timely made in accordance with paragraph (c)(1) or (2) of this section.

(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service. The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.
(iv) The individual who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a covered entity upon request.
(d) *Implementation specifications: Joint notice by separate covered entities.* Covered entities that participate in organized health care arrangements may comply with this section by a joint notice, provided that:
(1) The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;
(2) The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and
(i) Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;
(ii) Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and
(iii) If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.
(3) The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.
(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by §164.530(j), by retaining copies of the notices issued by the covered entity and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.

Section (h). Comment.

45 CFR §164.522 reads:

§164.522 Rights to request privacy protection for protected health information.
(a)(1) *Standard: Right of an individual to request restriction of uses and disclosures.* (i) A covered entity must permit an individual to request that the covered entity restrict:
(A) Uses or disclosures of protected health information about the individual to carry out treatment, payment, or health care operations; and
(B) Disclosures permitted under §164.510(b).
(ii) Except as provided in paragraph (a)(1)(vi) of this section, a covered entity is not required to agree to a restriction.
(iii) A covered entity that agrees to a restriction under paragraph (a)(1)(i) of this section may not use or disclose protected health information in violation of such restriction, except that, if the individual who requested the restriction is in need of emergency treatment and the restricted protected health information is needed to provide the emergency treatment, the covered entity may use the restricted protected health information, or may disclose such information to a health care provider, to provide such treatment to the individual.

(iv) If restricted protected health information is disclosed to a health care provider for emergency treatment under paragraph (a)(1)(iii) of this section, the covered entity must request that such health care provider not further use or disclose the information.
(v) A restriction agreed to by a covered entity under paragraph (a) of this section, is not effective under this subpart to prevent uses or disclosures permitted or required under §§164.502(a)(2)(ii), 164.510(a) or 164.512.
(vi) A covered entity must agree to the request of an individual to restrict disclosure of protected health information about the individual to a health plan if:
(A) The disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law; and
(B) The protected health information pertains solely to a health care item or service for which the individual, or person other than the health plan on behalf of the individual, has paid the covered entity in full.
(2) *Implementation specifications: Terminating a restriction.* A covered entity may terminate a restriction, if:
(i) The individual agrees to or requests the termination in writing;
(ii) The individual orally agrees to the termination and the oral agreement is documented; or
(iii) The covered entity informs the individual that it is terminating its agreement to a restriction, except that such termination is:
(A) Not effective for protected health information restricted under paragraph (a)(1)(vi) of this section; and
(B) Only effective with respect to protected health information created or received after it has so informed the individual.
(3) *Implementation specification: Documentation.* A covered entity must document a restriction in accordance with §160.530(j) of this subchapter.
(b)(1) *Standard: Confidential communications requirements.* (i) A covered health care provider must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the covered health care provider by alternative means or at alternative locations.
(ii) A health plan must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the health plan by alternative means or at alternative locations, if the individual clearly states that the disclosure of all or part of that information could endanger the individual.
(2) *Implementation specifications: Conditions on providing confidential communications.* (i) A covered entity may require the individual to make a request for a confidential communication described in paragraph (b)(1) of this section in writing.
(ii) A covered entity may condition the provision of a reasonable accommodation on:
(A) When appropriate, information as to how payment, if any, will be handled; and
(B) Specification of an alternative address or other method of contact.
(iii) A covered health care provider may not require an explanation from the individual as to the basis for the request as a condition of providing communications on a confidential basis.
(iv) A health plan may require that a request contain a statement that disclosure of all or part of the information to which the request pertains could endanger the individual.

Section (i). Comment.

45 CFR §164.524 reads:

§164.524 Access of individuals to protected health information.
(a) *Standard: Access to protected health information.* (1) *Right of access.* Except as otherwise provided in paragraph (a)(2) or (a)(3) of this section, an individual has a right of access to inspect and obtain a copy of

protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:
(i) Psychotherapy notes; and
(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.
(2) *Unreviewable grounds for denial.* A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances.
(i) The protected health information is excepted from the right of access by paragraph (a)(1) of this section.
(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.
(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.
(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.
(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.
(3) *Reviewable grounds for denial.* A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4) of this section, in the following circumstances:
(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;
(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or
(iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.
(4) *Review of a denial of access.* If access is denied on a ground permitted under paragraph (a)(3) of this section, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny. The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (d)(4) of this section.
(b) *Implementation specifications: Requests for access and timely action*—(1) *Individual's request for access.* The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.
(2) *Timely action by the covered entity.* (i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than 30 days after receipt of the request as follows.

(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section.
(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section.
(ii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:
(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and
(B) The covered entity may have only one such extension of time for action on a request for access.
(c) *Implementation specifications: Provision of access.* If the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.
(1) *Providing the access requested.* The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the protected health information about them in designated record sets. If the same protected health information that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the covered entity need only produce the protected health information once in response to a request for access.
(2) *Form of access requested.* (i) The covered entity must provide the individual with access to the protected health information in the form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable hard copy form or such other form and format as agreed to by the covered entity and the individual.
(ii) Notwithstanding paragraph (c)(2)(i) of this section, if the protected health information that is the subject of a request for access is maintained in one or more designated record sets electronically and if the individual requests an electronic copy of such information, the covered entity must provide the individual with access to the protected health information in the electronic form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual.
(iii) The covered entity may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:
(A) The individual agrees in advance to such a summary or explanation; and
(B) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.
(3) *Time and manner of access.* (i) The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.
(ii) If an individual's request for access directs the covered entity to transmit the copy of protected health information directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual. The individual's request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.
(4) *Fees.* If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

(i) Labor for copying the protected health information requested by the individual, whether in paper or electronic form;
(ii) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media;
(iii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and
(iv) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(iii) of this section.
(d) *Implementation specifications: Denial of access.* If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.
(1) *Making other information accessible.* The covered entity must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.
(2) *Denial.* The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain:
(i) The basis for the denial;
(ii) If applicable, a statement of the individual's review rights under paragraph (a)(4) of this section, including a description of how the individual may exercise such review rights; and
(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in §164.530(d) or to the Secretary pursuant to the procedures in §160.306. The description must include the name, or title, and telephone number of the contact person or office designated in §164.530(a)(1)(ii).
(3) *Other responsibility.* If the covered entity does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.
(4) *Review of denial requested.* If the individual has requested a review of a denial under paragraph (a)(4) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.
(e) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by §164.530(j):
(1) The designated record sets that are subject to access by individuals; and
(2) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

Section (j). Comment.

45 CFR §164.526 reads:

§164.526 Amendment of protected health information.
(a) Standard: right to amend.
(1) Right to amend. An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.

(2) Denial of amendment. A covered entity may deny an individual's request for amendment, if it determines that the protected health information or record that is the subject of the request:
(i) Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of protected health information is no longer available to act on the requested amendment;
(ii) Is not part of the designated record set;
(iii) Would not be available for inspection under §164.524; or
(iv) Is accurate and complete.
(b) Implementation specifications: requests for amendment and timely action.
(1) Individual's request for amendment. The covered entity must permit an individual to request that the covered entity amend the protected health information maintained in the designated record set. The covered entity may require individuals to make requests for amendment in writing and to provide a reason to support a requested amendment, provided that it informs individuals in advance of such requirements.
(2) Timely action by the covered entity. (i) The covered entity must act on the individual's request for an amendment no later than 60 days after receipt of such a request, as follows.
(A) If the covered entity grants the requested amendment, in whole or in part, it must take the actions required by paragraphs (c)(1) and (2) of this section.
(B) If the covered entity denies the requested amendment, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d)(1) of this section.
(ii) If the covered entity is unable to act on the amendment within the time required by paragraph (b)(2)(i) of this section, the covered entity may extend the time for such action by no more than 30 days, provided that:
(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and
(B) The covered entity may have only one such extension of time for action on a request for an amendment.
(c) Implementation specifications: accepting the amendment. If the covered entity accepts the requested amendment, in whole or in part, the covered entity must comply with the following requirements.
(1) Making the amendment. The covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by, at a minimum, identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment.
(2) Informing the individual. In accordance with paragraph (b) of this section, the covered entity must timely inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to have the covered entity notify the relevant persons with which the amendment needs to be shared in accordance with paragraph (c)(3) of this section.
(3) Informing others. The covered entity must make reasonable efforts to inform and provide the amendment within a reasonable time to:
(i) Persons identified by the individual as having received protected health information about the individual and needing the amendment; and
(ii) Persons, including business associates, that the covered entity knows have the protected health information that is the subject of the amendment and that may have relied, or could foreseeably rely, on such information to the detriment of the individual.
(d) Implementation specifications: denying the amendment. If the covered entity denies the requested amendment, in whole or in part, the covered entity must comply with the following requirements.
(1) Denial. The covered entity must provide the individual with a timely, written denial, in accordance with paragraph (b)(2) of this section. The denial must use plain language and contain:
(i) The basis for the denial, in accordance with paragraph (a)(2) of this section;
(ii) The individual's right to submit a written statement disagreeing with the denial and how the individual may file such a statement;

(iii) A statement that, if the individual does not submit a statement of disagreement, the individual may request that the covered entity provide the individual's request for amendment and the denial with any future disclosures of the protected health information that is the subject of the amendment; and
(iv) A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in §164.530(d) or to the Secretary pursuant to the procedures established in §160.306. The description must include the name, or title, and telephone number of the contact person or office designated in §164.530(a)(1)(ii).
(2) Statement of disagreement. The covered entity must permit the individual to submit to the covered entity a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement. The covered entity may reasonably limit the length of a statement of disagreement.
(3) Rebuttal statement. The covered entity may prepare a written rebuttal to the individual's statement of disagreement. Whenever such a rebuttal is prepared, the covered entity must provide a copy to the individual who submitted the statement of disagreement.
(4) Recordkeeping. The covered entity must, as appropriate, identify the record or protected health information in the designated record set that is the subject of the disputed amendment and append or otherwise link the individual's request for an amendment, the covered entity's denial of the request, the individual's statement of disagreement, if any, and the covered entity's rebuttal, if any, to the designated record set.
(5) Future disclosures. (i) If a statement of disagreement has been submitted by the individual, the covered entity must include the material appended in accordance with paragraph (d)(4) of this section, or, at the election of the covered entity, an accurate summary of any such information, with any subsequent disclosure of the protected health information to which the disagreement relates.
(ii) If the individual has not submitted a written statement of disagreement, the covered entity must include the individual's request for amendment and its denial, or an accurate summary of such information, with any subsequent disclosure of the protected health information only if the individual has requested such action in accordance with paragraph (d)(1)(iii) of this section.
(iii) When a subsequent disclosure described in paragraph (d)(5)(i) or (ii) of this section is made using a standard transaction under part 162 of this subchapter that does not permit the additional material to be included with the disclosure, the covered entity may separately transmit the material required by paragraph (d)(5)(i) or (ii) of this section, as applicable, to the recipient of the standard transaction.
(e) Implementation specification: actions on notices of amendment. A covered entity that is informed by another covered entity of an amendment to an individual's protected health information, in accordance with paragraph (e)(3) of this section, must amend the protected health information in designated record sets as provided by paragraph (e)(1) of this section.
(f) Implementation specification: documentation. A covered entity must document the titles of the persons or offices responsible for receiving and processing requests for amendments by individuals and retain the documentation as required by §164.530(j).

Section (k)(1)(vi) and (vii). Comment.

45 CFR §164.512(k)(2) and (5) read:

(k) Standard: uses and disclosures for specialized government functions.
. . .
(2) National security and intelligence activities. A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, et seq.) and implementing authority (e.g., Executive Order 12333).
. . .

(5) *Correctional institutions and other law enforcement custodial situations.* (i) *Permitted disclosures.* A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:
(A) The provision of health care to such individuals;
(B) The health and safety of such individual or other inmates;
(C) The health and safety of the officers or employees of or others at the correctional institution;
(D) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;
(E) Law enforcement on the premises of the correctional institution; or
(F) The Administration and maintenance of the safety, security, and good order of the correctional institution.
(ii) *Permitted uses.* A covered entity that is a correctional institution may use protected health information of individuals who are inmates for any purpose for which such protected health information may be disclosed.
(iii) *No application after release*. For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.

Section (k)(1)(viii). Comment.

45 CFR §164.514(e) reads:

§164.514 Other requirements relating to uses and disclosures of protected health information.
. . .
(e)(1) *Standard: Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.
(2) *Implementation specification: Limited data set:* A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:
(i) Names;
(ii) Postal address information, other than town or city, State, and zip code;
(iii) Telephone numbers;
(iv) Fax numbers;
(v) Electronic mail addresses;
(vi) Social security numbers;
(vii) Medical record numbers;
(viii) Health plan beneficiary numbers;
(ix) Account numbers;
(x) Certificate/license numbers;
(xi) Vehicle identifiers and serial numbers, including license plate numbers;
(xii) Device identifiers and serial numbers;
(xiii) Web Universal Resource Locators (URLs);
(xiv) Internet Protocol (IP) address numbers;
(xv) Biometric identifiers, including finger and voice prints; and
(xvi) Full face photographic images and any comparable images.
(3) *Implementation specification: Permitted purposes for uses and disclosures.* (i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.

(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.
(4) *Implementation specifications: Data use agreement*—(i) *Agreement required.* A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.
(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:
(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;
(B) Establish who is permitted to use or receive the limited data set; and
(C) Provide that the limited data set recipient will:
(*1*) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
(*2*) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
(*3*) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
(*4*) Ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
(*5*) Not identify the information or contact the individuals.
(iii) *Compliance.* (A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:
(1) Discontinued disclosure of protected health information to the recipient; and
(2) Reported the problem to the Secretary.
(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.
. . .

Section (k)(4). Comment.

45 CFR §164.528 reads:

§164.528—Accounting of disclosures of protected health information.
(a) Standard: right to an accounting of disclosures of protected health information.
(1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:
(i) To carry out treatment, payment and health care operations as provided in §164.506;
(ii) To individuals of protected health information about them as provided in §164.502;
(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in §164.502;
(iv) Pursuant to an authorization as provided in §164.508;

(v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in §164.510;
(vi) For national security or intelligence purposes as provided in §164.512(k)(2);
(vii) To correctional institutions or law enforcement officials as provided in §164.512(k)(5);
(viii) As part of a limited data set in accordance with §164.514(e); or
(ix) That occurred prior to the compliance date for the covered entity.
(2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in §164.512(d) or (f), respectively, for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.
(ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:
(A) Document the statement, including the identity of the agency or official making the statement;
(B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and
(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.
(3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.
(b) Implementation specifications: content of the accounting. The covered entity must provide the individual with a written accounting that meets the following requirements.
(1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.
(2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:
(i) The date of the disclosure;
(ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;
(iii) A brief description of the protected health information disclosed; and
(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§164.502(a)(2)(ii) or 164.512, if any.
(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under §§164.502(a)(2)(ii) or 164.512, the accounting may, with respect to such multiple disclosures, provide:
(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;
(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and
(iii) The date of the last such disclosure during the accounting period.
(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with §164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:
(A) The name of the protocol or other research activity;
(B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;

(C) A brief description of the type of protected health information that was disclosed;
(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;
(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.
(ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.
(c) Implementation specifications: provision of the accounting.
(1) The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.
(i) The covered entity must provide the individual with the accounting requested; or
(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:
(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and
(B) The covered entity may have only one such extension of time for action on a request for an accounting.
(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.
(d) Implementation specification: documentation. A covered entity must document the following and retain the documentation as required by §164.530(j):
(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;
(2) The written accounting that is provided to the individual under this section; and
(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.

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Appendix D

Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs

Section 1. Purpose.

The purpose of these Guidelines is to provide Pharmacists and patients with appropriate direction and information for the design, implementation, and participation in Medication Adherence Monitoring Services and Patient Intervention Programs. Such Guidelines are needed in the interest of public health

to protect the confidentiality of patient health care information and prohibit inappropriate and potentially detrimental contact with the patient.

Medication Adherence Monitoring Services and Patient Intervention Programs are those that promote improved medication use behaviors, such as medication regimen adherence and appropriate self-monitoring and self-reporting, through such efforts as refill reminder programs and patient medication, disease state, and Drug therapy option education.

It shall be contrary to these Guidelines for any Person (including, but not limited to, health insurance carriers, health benefit management companies, and health care marketing enterprises) to attempt to or cause a switch of a patient's medication, or direct a patient away from a course of therapy, solely for economic or financial gains or incentives.

Nothing in these Guidelines supersedes existing State Drug Product selection laws or procedures for Drug recalls, nor prevents access to Nonconfidential Health Care Information for research purposes.

The privacy standards found in the NABP's Model Rules for the Privacy of Individually Identifiable Patient Information should be carefully considered when conducting adherence and patient intervention programs.

Section 2. Definitions.

(a) "Affiliated Entity" means legally separate covered entities that are affiliated and that designate themselves as a single covered entity for the purposes of this section.

(b) "De-identified Health Information" means Health Information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. De-identified health information must meet the specifications of the de-identified health information described in the Health Insurance Portability and Accountability Act (HIPAA) privacy rules (45 CFR §164.514(b)).

(c) "External Entities" means those organizations that exist outside of the pharmacist-patient relationship and that participate in the implementation of Patient Compliance and Patient Intervention Programs. External Entities include, but are not limited to, health insurance carriers, health benefit management companies, and health care marketing enterprises.[50]

(d) "Health Information" means any information, whether oral or recorded in any form or medium, that:

(1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse.

(2) relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual.

[50] Depending on the activities conducted by External Entities, they may be construed as "business associates" as defined under HIPAA and its related privacy rules (45 CFR Part 160). If so, HIPAA and its privacy rules that apply to those External Entities acting as business associates shall take precedence over contrary state law. In addition, "business associate agreements," as defined under HIPAA and its privacy rules, shall be required between a Pharmacist or Pharmacy and the External Entity acting as a business associate so as to prevent the unauthorized use or disclosure of Protected Health Information.

(e) "HIPAA" is the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) and any amendments thereof.

(f) "Individually Identifiable Health Information" is information that is a subset of health information, including demographic information collected from an individual and

(1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) that identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(g) "Medication Adherence Monitoring Service" is defined as any structured activity that complements or supplements the existing responsibilities regarding the Dispensing of prescriptions and associated Patient Counseling, and that uses Protected Health Information to contact the patient or caregiver via phone, print, electronic media, or other means of communication, in order to improve patient compliance with and adherence to prescribed medication therapy and that involves the collection and analysis of data related to patient medication use. Medication Adherence Monitoring Services may incorporate such efforts as refill reminder and patient education programs.

(h) "Patient Intervention Program" is defined as any structured activity that complements or supplements the existing responsibilities regarding the Dispensing of prescriptions and associated Patient Counseling, and that uses Protected Health Information to contact the patient or caregiver via phone, print, electronic media, or other means of communication, to discuss, inform, and/or affect patient therapy or choice of medications.

(i) "Protected Health Information" means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is

(i) transmitted by electronic media;

(ii) maintained in any medium described in the definition of electronic media at §162.103 of the HIPAA privacy rules (45 CFR Part 160);

(iii) transmitted or maintained in any other form or medium.

(2) Protected health information excludes individually identifiable health information in

(i) education records covered by the Family Educational Right and Privacy Act, as amended 20 USC 1232(g);

(ii) records described at 20 USC 1232(g)(4)(B)(iv); and

(iii) employment records held by a licensee in its role as an employer.

Section 3. Protection Against Illegal Use or Disclosure of Protected Health Information

Medication Adherence Monitoring Services and Patient Intervention Programs shall be conducted in a manner to protect against the illegal use or disclosure of Protected Health Information. The illegal use or

disclosure of Protected Health Information constitutes a violation of HIPAA and its related privacy rules (45 CFR Part 160) and may constitute a violation of state pharmacy practice acts or rules or other State laws or rules.

The following minimal safeguards shall be in place for Medication Adherence Monitoring Services and Patient Intervention Programs:

(a) Appropriate notice shall be given to patients regarding participation in Medication Adherence Monitoring Services and Patient Intervention Programs;

(b) Protected Health Information shall be maintained in a manner to protect against the illegal use or disclosure of such information;

(c) Protected Health Information shall be accessed only by the pharmacist or by individuals under the direct supervision of the pharmacist, or by an affiliated entity of that pharmacist and may be released or disclosed to an External Entity pursuant to the notice of privacy practices required by 45 CFR §164.520 and the Model Rules for the Privacy of Individually Identifiable Patient Information of this *Model Act*;

(d) Protected Health Information used to implement a Medication Adherence Monitoring Service or Patient Intervention Program shall not be released or disclosed to any External Entity other than the External Entity implementing the program with, or on behalf of, the pharmacy;

(e) All personnel with access to Protected Health Information shall sign and their employer shall retain on file current confidentiality and non-disclosure agreements;

(f) If the Medication Adherence Monitoring Service or Patient Intervention Program information is mailed, delivery systems that (1) ensure the information will be delivered to the designated patient or caregiver and will remain confidential; and (2) allow for the return of the information if not deliverable, shall be utilized. For example, if the contact is via the US Postal Service, the information should be mailed first class in a sealed security envelope;

(g) Methods to access, transmit, store, analyze, or purge Protected Health Information shall be implemented using procedures generally recognized as secure by experts qualified by training and experience;

(h) External Entities maintaining Protected Health Information outside the pharmacy's internal system shall adhere to the same security requirements adhered to by the pharmacy in regard to its internal system, including but not limited to, those requirements addressing information access, storage, auditability, and release;

(i) Procedures shall be in place to ensure that purged Protected Health Information cannot be misused or placed into active operation without appropriate authorization; and

(j) Internet connectivity or remote access tied directly to systems containing Protected Health Information must be secure.

~~Section 4. Patient Participation.~~

~~Medication Adherence Monitoring Services and Patient Intervention Programs shall be conducted in the best interest of the patient and shall inform patients about the program's purpose and use of Protected Health Information. The patient shall have the option to withdraw from any such program at any time. Patients shall be provided with a notice of privacy practices, which includes a description of the Medication Adherence Monitoring Service or Patient Intervention Program;~~

~~Programs designed to change a patient's medication or medication therapy solely for economic or financial gains or incentives without the consent of the patient and prescribing practitioner are contrary to these Guidelines and may violate state pharmacy practice acts and rules and/or other state and federal laws or regulations.~~

~~Nothing in these Guidelines supersedes existing State Drug Product selection laws or procedures for Drug recalls, nor prevents access to De-identified Health Information for research purposes.~~

~~Section 5. Pharmacist Participation.~~

~~A pharmacist shall oversee and approve all Medication Adherence Monitoring Services and Patient Intervention Programs and shall be responsible for: (1) the accuracy of the list of participating patients; and (2) the accuracy and appropriateness of the information being presented to the patients during the life of the program. Pharmacists involved in Medication Adherence Monitoring Services and Patient Intervention Programs, whether through contact with patients or caregivers or through the design, implementation, management, and analysis of the programs, shall be educated about such programs and their objectives. Results of the programs shall be communicated to all participating pharmacists.~~

~~Section 6. Utilization of De-identified and Protected Health Information for Research Purposes.~~

~~Notwithstanding any other provision of law, nothing in these Guidelines shall be interpreted to prohibit the release of:~~

~~(a) Protected Health Information for research that is subject to the requirements of federal laws and regulations protecting the rights and welfare of research participants;~~
~~(b) De-identified Health Information; or~~
~~(c) A limited data set for purposes of research, public health, or health care operations.~~

~~Section 7. Measurement and Analysis of Program.~~

~~Medication Adherence Monitoring Services and Patient Intervention Programs may include methodologies to measure the outcomes of the program in relation to patient care and the~~

performance of the pharmacy/pharmacist. The following minimum guidelines shall be observed when measuring and analyzing the program outcomes:

(a) Analysis and aggregate data reports shall not contain Protected Health Information;
(b) Study design, measurement, and analysis shall adhere to accepted research and study designs; and
(c) Reports prepared or published shall provide accurate and statistically correct information.

Comments

Section 2. Comment.

45 CFR §164.514(b) reads:

(b) *Implementation specifications: Requirements for de-identification of protected health information.* A covered entity may determine that health information is not individually identifiable health information only if:
(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
(ii) Documents the methods and results of the analysis that justify such determination; or
(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:
(A) Names;
(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
(*1*) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
(*2*) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
(D) Telephone numbers;
(E) Fax numbers;
(F) Electronic mail addresses;
(G) Social security numbers;
(H) Medical record numbers;
(I) Health plan beneficiary numbers;
(J) Account numbers;
(K) Certificate/license numbers;
(L) Vehicle identifiers and serial numbers, including license plate numbers;
(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);
(O) Internet Protocol (IP) address numbers;
(P) Biometric identifiers, including finger and voice prints;
(Q) Full face photographic images and any comparable images; and
(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and
(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

20 USC 1232g reads:

Sec. 1232g. Family educational and privacy rights
(a) Conditions for availability of funds to educational agencies or institutions; inspection and review of education records; specific information to be made available; procedure for access to education records; reasonableness of time for such access; hearings; written explanations by parents; definitions
(1)(A) No funds shall be made available under any applicable program to any educational agency or institution which has a policy of denying, or which effectively prevents, the parents of students who are or have been in attendance at a school of such agency or at such institution, as the case may be, the right to inspect and review the education records of their children. If any material or document in the education record of a student includes information on more than one student, the parents of one of such students shall have the right to inspect and review only such part of such material or document as relates to such student or to be informed of the specific information contained in such part of such material. Each educational agency or institution shall establish appropriate procedures for the granting of a request by parents for access to the education records of their children within a reasonable period of time, but in no case more than forty-five days after the request has been made.
(B) No funds under any applicable program shall be made available to any State educational agency (whether or not that agency is an educational agency or institution under this section) that has a policy of denying, or effectively prevents, the parents of students the right to inspect and review the education records maintained by the State educational agency on their children who are or have been in attendance at any school of an educational agency or institution that is subject to the provisions of this section.
(C) The first sentence of subparagraph (A) shall not operate to make available to students in institutions of postsecondary education the following materials:
(i) financial records of the parents of the student or any information contained therein;
(ii) confidential letters and statements of recommendation, which were placed in the education records prior to January 1, 1975, if such letters or statements are not used for purposes other than those for which they were specifically intended;
(iii) if the student has signed a waiver of the student's right of access under this subsection in accordance with subparagraph (D), confidential recommendations —
(I) respecting admission to any educational agency or institution,
(II) respecting an application for employment, and
(III) respecting the receipt of an honor or honorary recognition.

(D) A student or a person applying for admission may waive his right of access to confidential statements described in clause (iii) of subparagraph (C), except that such waiver shall apply to recommendations only if (i) the student is, upon request, notified of the names of all persons making confidential recommendations and (ii) such recommendations are used solely for the purpose for which they were specifically intended. Such waivers may not be required as a condition for admission to, receipt of financial aid from, or receipt of any other services or benefits from such agency or institution.

(2) No funds shall be made available under any applicable program to any educational agency or institution unless the parents of students who are or have been in attendance at a school of such agency or at such institution are provided an opportunity for a hearing by such agency or institution, in accordance with regulations of the Secretary, to challenge the content of such student's education records, in order to insure that the records are not inaccurate, misleading, or otherwise in violation of the privacy rights of students, and to provide an opportunity for the correction or deletion of any such inaccurate, misleading or otherwise inappropriate data contained therein and to insert into such records a written explanation of the parents respecting the content of such records.
(3) For the purposes of this section the term "educational agency or institution" means any public or private agency or institution which is the recipient of funds under any applicable program.
(4)(A) For the purposes of this section, the term "education records" means, except as may be provided otherwise in subparagraph (B), those records, files, documents, and other materials which—
(i) contain information directly related to a student; and
(ii) are maintained by an educational agency or institution or by a person acting for such agency or institution.

(B) The term "education records" does not include—
(i) records of instructional, supervisory, and administrative personnel and educational personnel ancillary thereto which are in the sole possession of the maker thereof and which are not accessible or revealed to any other person except a substitute;
(ii) records maintained by a law enforcement unit of the educational agency or institution that were created by that law enforcement unit for the purpose of law enforcement;
(iii) in the case of persons who are employed by an educational agency or institution but who are not in attendance at such agency or institution, records made and maintained in the normal course of business which relate exclusively to such person in that person's capacity as an employee and are not available for use for any other purpose; or
(iv) records on a student who is eighteen years of age or older, or is attending an institution of postsecondary education, which are made or maintained by a physician, psychiatrist, psychologist, or other recognized professional or paraprofessional acting in his professional or paraprofessional capacity, or assisting in that capacity, and which are made, maintained, or used only in connection with the provision of treatment to the student, and are not available to anyone other than persons providing such treatment, except that such records can be personally reviewed by a physician or other appropriate professional of the student's choice.

(5)(A) For the purposes of this section the term "directory information" relating to a student includes the following: the student's name, address, telephone listing, date and place of birth, major field of study, participation in officially recognized activities and sports, weight and height of members of athletic teams, dates of attendance, degrees and awards received, and the most recent previous educational agency or institution attended by the student.
(B) Any educational agency or institution making public directory information shall give public notice of the categories of information which it has designated as such information with respect to each student attending the institution or agency and shall allow a reasonable period of time after such notice has been given for a parent to inform the institution or agency that any or all of the information designated should not be released without the parent's prior consent.
(6) For the purposes of this section, the term "student" includes any person with respect to whom an educational agency or institution maintains education records or personally identifiable information, but does not include a person who has not been in attendance at such agency or institution.

(b) Release of education records; parental consent requirement; exceptions; compliance with judicial orders and subpoenas; audit and evaluation of federally-supported education programs; recordkeeping
(1) No funds shall be made available under any applicable program to any educational agency or institution which has a policy or practice of permitting the release of education records (or personally identifiable information contained therein other than directory information, as defined in paragraph (5) of subsection (a) of this section) of students without the written consent of their parents to any individual, agency, or organization, other than to the following—
(A) other school officials, including teachers within the educational institution or local educational agency, who have been determined by such agency or institution to have legitimate educational interests, including the educational interests of the child for whom consent would otherwise be required;
(B) officials of other schools or school systems in which the student seeks or intends to enroll, upon condition that the student's parents be notified of the transfer, receive a copy of the record if desired, and have an opportunity for a hearing to challenge the content of the record;
(C)(i) authorized representatives of (I) the Comptroller General of the United States, (II) the Secretary, or (III) State educational authorities, under the conditions set forth in paragraph (3), or (ii) authorized representatives of the Attorney General for law enforcement purposes under the same conditions as apply to the Secretary under paragraph (3);
(D) in connection with a student's application for, or receipt of, financial aid;
(E) State and local officials or authorities to whom such information is specifically allowed to be reported or disclosed pursuant to State statute adopted—
(i) before November 19, 1974, if the allowed reporting or disclosure concerns the juvenile justice system and such system's ability to effectively serve the student whose records are released, or
(ii) after November 19, 1974, if—
(I) the allowed reporting or disclosure concerns the juvenile justice system and such system's ability to effectively serve, prior to adjudication, the student whose records are released; and
(II) the officials and authorities to whom such information is disclosed certify in writing to the educational agency or institution that the information will not be disclosed to any other party except as provided under State law without the prior written consent of the parent of the student.[1]

(F) organizations conducting studies for, or on behalf of, educational agencies or institutions for the purpose of developing, validating, or administering predictive tests, administering student aid programs, and improving instruction, if such studies are conducted in such a manner as will not permit the personal identification of students and their parents by persons other than representatives of such organizations and such information will be destroyed when no longer needed for the purpose for which it is conducted;
(G) accrediting organizations in order to carry out their accrediting functions;
(H) parents of a dependent student of such parents, as defined in section 152 of title 26;
(I) subject to regulations of the Secretary, in connection with an emergency, appropriate persons if the knowledge of such information is necessary to protect the health or safety of the student or other persons;
(J)(i) the entity or persons designated in a Federal grand jury subpoena, in which case the court shall order, for good cause shown, the educational agency or institution (and any officer, director, employee, agent, or attorney for such agency or institution) on which the subpoena is served, to not disclose to any person the existence or contents of the subpoena or any information furnished to the grand jury in response to the subpoena; and
(ii) the entity or persons designated in any other subpoena issued for a law enforcement purpose, in which case the court or other issuing agency may order, for good cause shown, the educational agency or institution (and any officer, director, employee, agent, or attorney for such agency or institution) on which the subpoena is served, to not disclose to any person the existence or contents of the subpoena or any information furnished in response to the subpoena;

(K) the Secretary of Agriculture, or authorized representative from the Food and Nutrition Service or contractors acting on behalf of the Food and Nutrition Service, for the purposes of conducting program monitoring, evaluations, and performance measurements of State and local educational and other agencies and institutions receiving funding or providing benefits of 1 or more programs authorized under the Richard B. Russell National School Lunch Act (42 U.S.C. 1751 et seq.) or the Child Nutrition Act of 1966 (42 U.S.C. 1771 et seq.) for which the results will be reported in an aggregate form that does not identify any individual, on the conditions that —
(i) any data collected under this subparagraph shall be protected in a manner that will not permit the personal identification of students and their parents by other than the authorized representatives of the Secretary; and
(ii) any personally identifiable data shall be destroyed when the data are no longer needed for program monitoring, evaluations, and performance measurements; and

(L) an agency caseworker or other representative of a State or local child welfare agency, or tribal organization (as defined in section 450b of title 25), who has the right to access a student's case plan, as defined and determined by the State or tribal organization, when such agency or organization is legally responsible, in accordance with State or tribal law, for the care and protection of the student, provided that the education records, or the personally identifiable information contained in such records, of the student will not be disclosed by such agency or organization, except to an individual or entity engaged in addressing the student's education needs and authorized by such agency or organization to receive such disclosure and such disclosure is consistent with the State or tribal laws applicable to protecting the confidentiality of a student's education records.

Nothing in subparagraph (E) of this paragraph shall prevent a State from further limiting the number or type of State or local officials who will continue to have access thereunder.
(2) No funds shall be made available under any applicable program to any educational agency or institution which has a policy or practice of releasing, or providing access to, any personally identifiable information in education records other than directory information, or as is permitted under paragraph (1) of this subsection, unless —
(A) there is written consent from the student's parents specifying records to be released, the reasons for such release, and to whom, and with a copy of the records to be released to the student's parents and the student if desired by the parents, or
(B) except as provided in paragraph (1)(J), such information is furnished in compliance with judicial order, or pursuant to any lawfully issued subpoena, upon condition that parents and the students are notified of all such orders or subpoenas in advance of the compliance therewith by the educational institution or agency, except when a parent is a party to a court proceeding involving child abuse and neglect (as defined in section 3 of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 note)) or dependency matters, and the order is issued in the context of that proceeding, additional notice to the parent by the educational agency or institution is not required.

(3) Nothing contained in this section shall preclude authorized representatives of (A) the Comptroller General of the United States, (B) the Secretary, or (C) State educational authorities from having access to student or other records which may be necessary in connection with the audit and evaluation of Federally-supported education programs, or in connection with the enforcement of the Federal legal requirements which relate to such programs: *Provided*, That except when collection of personally identifiable information is specifically authorized by Federal law, any data collected by such officials shall be protected in a manner which will not

permit the personal identification of students and their parents by other than those officials, and such personally identifiable data shall be destroyed when no longer needed for such audit, evaluation, and enforcement of Federal legal requirements.

(4)(A) Each educational agency or institution shall maintain a record, kept with the education records of each student, which will indicate all individuals (other than those specified in paragraph (1)(A) of this subsection), agencies, or organizations which have requested or obtained access to a student's education records maintained by such educational agency or institution, and which will indicate specifically the legitimate interest that each such person, agency, or organization has in obtaining this information. Such record of access shall be available only to parents, to the school official and his assistants who are responsible for the custody of such records, and to persons or organizations authorized in, and under the conditions of, clauses (A) and (C) of paragraph (1) as a means of auditing the operation of the system.

(B) With respect to this subsection, personal information shall only be transferred to a third party on the condition that such party will not permit any other party to have access to such information without the written consent of the parents of the student. If a third party outside the educational agency or institution permits access to information in violation of paragraph (2)(A), or fails to destroy information in violation of paragraph (1)(F), the educational agency or institution shall be prohibited from permitting access to information from education records to that third party for a period of not less than five years.

(5) Nothing in this section shall be construed to prohibit State and local educational officials from having access to student or other records which may be necessary in connection with the audit and evaluation of any federally or State supported education program or in connection with the enforcement of the Federal legal requirements which relate to any such program, subject to the conditions specified in the proviso in paragraph (3).

(6)(A) Nothing in this section shall be construed to prohibit an institution of postsecondary education from disclosing, to an alleged victim of any crime of violence (as that term is defined in section 16 of title 18), or a nonforcible sex offense, the final results of any disciplinary proceeding conducted by such institution against the alleged perpetrator of such crime or offense with respect to such crime or offense.

(B) Nothing in this section shall be construed to prohibit an institution of postsecondary education from disclosing the final results of any disciplinary proceeding conducted by such institution against a student who is an alleged perpetrator of any crime of violence (as that term is defined in section 16 of title 18), or a nonforcible sex offense, if the institution determines as a result of that disciplinary proceeding that the student committed a violation of the institution's rules or policies with respect to such crime or offense.

(C) For the purpose of this paragraph, the final results of any disciplinary proceeding —

(i) shall include only the name of the student, the violation committed, and any sanction imposed by the institution on that student; and

(ii) may include the name of any other student, such as a victim or witness, only with the written consent of that other student.

(7)(A) Nothing in this section may be construed to prohibit an educational institution from disclosing information provided to the institution under section 14071 [2] of title 42 concerning registered sex offenders who are required to register under such section.

(B) The Secretary shall take appropriate steps to notify educational institutions that disclosure of information described in subparagraph (A) is permitted.

(c) Surveys or data-gathering activities; regulations

Not later than 240 days after October 20, 1994, the Secretary shall adopt appropriate regulations or procedures, or identify existing regulations or procedures, which protect the rights of privacy of students and their families in connection with any surveys or data-gathering activities conducted, assisted, or authorized by the Secretary or an administrative head of an education agency. Regulations established under this subsection shall include

provisions controlling the use, dissemination, and protection of such data. No survey or data-gathering activities shall be conducted by the Secretary, or an administrative head of an education agency under an applicable program, unless such activities are authorized by law.

(d) Students' rather than parents' permission or consent

For the purposes of this section, whenever a student has attained eighteen years of age, or is attending an institution of postsecondary education, the permission or consent required of and the rights accorded to the parents of the student shall thereafter only be required of and accorded to the student.

(e) Informing parents or students of rights under this section

No funds shall be made available under any applicable program to any educational agency or institution unless such agency or institution effectively informs the parents of students, or the students, if they are eighteen years of age or older, or are attending an institution of postsecondary education, of the rights accorded them by this section.

(f) Enforcement; termination of assistance

The Secretary shall take appropriate actions to enforce this section and to deal with violations of this section, in accordance with this chapter, except that action to terminate assistance may be taken only if the Secretary finds there has been a failure to comply with this section, and he has determined that compliance cannot be secured by voluntary means.

(g) Office and review board; creation; functions

The Secretary shall establish or designate an office and review board within the Department for the purpose of investigating, processing, reviewing, and adjudicating violations of this section and complaints which may be filed concerning alleged violations of this section. Except for the conduct of hearings, none of the functions of the Secretary under this section shall be carried out in any of the regional offices of such Department.

(h) Disciplinary records; disclosure

Nothing in this section shall prohibit an educational agency or institution from—

(1) including appropriate information in the education record of any student concerning disciplinary action taken against such student for conduct that posed a significant risk to the safety or well-being of that student, other students, or other members of the school community; or

(2) disclosing such information to teachers and school officials, including teachers and school officials in other schools, who have legitimate educational interests in the behavior of the student.

(i) Drug and alcohol violation disclosures

(1) In general

Nothing in this Act or the Higher Education Act of 1965 [20 U.S.C. 1001 et seq., 42 U.S.C. 2751 et seq.] shall be construed to prohibit an institution of higher education from disclosing, to a parent or legal guardian of a student, information regarding any violation of any Federal, State, or local law, or of any rule or policy of the institution, governing the use or possession of alcohol or a controlled substance, regardless of whether that information is contained in the student's education records, if—

(A) the student is under the age of 21; and

(B) the institution determines that the student has committed a disciplinary violation with respect to such use or possession.

(2) State law regarding disclosure

Nothing in paragraph (1) shall be construed to supersede any provision of State law that prohibits an institution of higher education from making the disclosure described in subsection (a) of this section.

(j) Investigation and prosecution of terrorism

(1) In general

Notwithstanding subsections (a) through (i) of this section or any provision of State law, the Attorney General (or any Federal officer or employee, in a position not lower than an Assistant Attorney General, designated by the Attorney General) may submit a written application to a court of competent jurisdiction for an ex parte order requiring an educational agency or institution to permit the Attorney General (or his designee) to—

(A) collect education records in the possession of the educational agency or institution that are relevant to an authorized investigation or prosecution of an offense listed in section 2332b(g)(5)(B) of title 18, or an act of domestic or international terrorism as defined in section 2331 of that title; and
(B) for official purposes related to the investigation or prosecution of an offense described in paragraph (1)(A), retain, disseminate, and use (including as evidence at trial or in other administrative or judicial proceedings) such records, consistent with such guidelines as the Attorney General, after consultation with the Secretary, shall issue to protect confidentiality.
(2) Application and approval
(A) In general.—An application under paragraph (1) shall certify that there are specific and articulable facts giving reason to believe that the education records are likely to contain information described in paragraph (1)(A).
(B) The court shall issue an order described in paragraph (1) if the court finds that the application for the order includes the certification described in subparagraph (A).
(3) Protection of educational agency or institution
An educational agency or institution that, in good faith, produces education records in accordance with an order issued under this subsection shall not be liable to any person for that production.
(4) Record keeping
Subsection (b)(4) of this section does not apply to education records subject to a court order under this subsection.

Section 3. Comment.

45 CFR §164.520 reads:

§164.520 Notice of privacy practices for protected health information.
(a) *Standard: Notice of privacy practices.* (1) *Right to notice.* Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.
(2) *Exception for group health plans.* (i) An individual enrolled in a group health plan has a right to notice:
(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or
(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.
(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in §164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:
(A) Maintain a notice under this section; and
(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.
(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in §164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.

(3) *Exception for inmates.* An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.
(b) *Implementation specifications: Content of notice*—(1) *Required elements.* The covered entity must provide a notice that is written in plain language and that contains the elements required by this paragraph.
(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed: "THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY."
(ii) *Uses and disclosures.* The notice must contain:
(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.
(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written authorization.
(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law as defined in §160.202 of this subchapter.
(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law.
(E) A description of the types of uses and disclosures that require an authorization under §164.508(a)(2) (a)(4), a statement that other uses and disclosures not described in the notice will be made only with the individual's written authorization, and a statement that the individual may revoke an authorization as provided by §164.508(b)(5).
(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement informing the individual of such activities, as applicable:
(A) In accordance with §164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications; (B) In accordance with §164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan; or
(C) If a covered entity that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan*, intends to use or disclose protected health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes.
(iv) *Individual rights.* The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:
(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by §164.522(a), including a statement that the covered entity is not required to agree to a requested restriction, except in case of a disclosure restricted under §164.522(a)(1)
(B) The right to receive confidential communications of protected health information as provided by §164.522(b), as applicable;
(C) The right to inspect and copy protected health information as provided by §164.524;
(D) The right to amend protected health information as provided by §164.526;
(E) The right to receive an accounting of disclosures of protected health information as provided by §164.528; and

(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.
(v) *Covered entity's duties.* The notice must contain:
(A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices with respect to protected health information, and to notify affected individuals following a breach of unsecured protected health information;
(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and
(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.
(vi) *Complaints.* The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.
(vii) *Contact.* The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by §164.530(a)(1)(ii).
(viii) *Effective date.* The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.
(2) *Optional elements.* (i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by §164.512(j)(1)(i).
(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.
(3) *Revisions to the notice.* The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.
(c) *Implementation specifications: Provision of notice.* A covered entity must make the notice required by this section available on request to any person and to individuals as specified in paragraphs (c)(1) through (c)(3) of this section, as applicable.
(1) *Specific requirements for health plans.* (i) A health plan must provide the notice:
(A) No later than the compliance date for the health plan, to individuals then covered by the plan;
(B) Thereafter, at the time of enrollment, to individuals who are new enrollees.
(ii) No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.
(iii) The health plan satisfies the requirements of paragraph (c)(1) of this section if notice is provided to the named insured of a policy under which coverage is provided to the named insured and one or more dependents.
(iv) If a health plan has more than one notice, it satisfies the requirements of paragraph (c)(1) of this section by providing the notice that is relevant to the individual or other person requesting the notice.
(v) If there is a material change to the notice:

(A) A health plan that posts its notice on its web site in accordance with paragraph (c)(3)(i) of this section must prominently post the change or its revised notice on its web site by the effective date of the material change to the notice, and provide the revised notice, or information about the material change and how to obtain the revised notice, in its next annual mailing to individuals then covered by the plan.
(B) A health plan that does not post its notice on a web site pursuant to paragraph (c)(3)(i) of this section must provide the revised notice, or information about the material change and how to obtain the revised notice, to individuals then covered by the plan within 60 days of the material revision to the notice.
(2) *Specific requirements for certain covered health care providers.* A covered health care provider that has a direct treatment relationship with an individual must:
(i) Provide the notice:
(A) No later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider; or
(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.
(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;
(iii) If the covered health care provider maintains a physical service delivery site:
(A) Have the notice available at the service delivery site for individuals to request to take with them; and
(B) Post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered health care provider to be able to read the notice; and
(iv) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(iii) of this section, if applicable.
(3) *Specific requirements for electronic notice.* (i) A covered entity that maintains a web site that provides information about the covered entity's customer services or benefits must prominently post its notice on the web site and make the notice available electronically through the web site.
(ii) A covered entity may provide the notice required by this section to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the covered entity knows that the e-mail transmission has failed, a paper copy of the notice must be provided to the individual. Provision of electronic notice by the covered entity will satisfy the provision requirements of paragraph (c) of this section when timely made in accordance with paragraph (c)(1) or (2) of this section.
(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service. The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.
(iv) The individual who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a covered entity upon request.
(d) *Implementation specifications: Joint notice by separate covered entities.* Covered entities that participate in organized health care arrangements may comply with this section by a joint notice, provided that:
(1) The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;
(2) The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and
(i) Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;

~~(ii) Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and~~

~~(iii) If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.~~

~~(3) The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.~~

~~(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by §164.530(j), by retaining copies of the notices issued by the covered entity and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.~~

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