Medicare TSPD Documentation Requirements

Documentation

The Centers for Medicare and Medicaid Services (CMS) have specific documentation necessary prior to dispensing diabetic footwear.

The Therapeutic Shoes for Persons with Diabetes (TSD) was passed in 1993. The bill was designed to help prevent lower limb ulcers, amputation, and other complications in people who are diagnosed with diabetes.

Acronyms

CERT: Comprehensive Error Rate Testing
DMEPOS: Durable Medical Equipment, Prosthetics, Orthotics and Supplies
DOS: Date of Service
SWO: Standard Written Order
LCD: Local Coverage Determination
MLN: Medicare Learning Network
OIG: Office of Inspector General
POD: Proof of Delivery
POS: Place of Service

The *Certifying Physician* provides the medical care for and manages the beneficiary's systemic diabetic condition.

- The Certifying Physician must be a D.O. or M.D.
- The Certifying Physician may not furnish shoes unless he/she is in a defined rural area or health professional shortage area.
- The Certifying Physician cannot be a podiatrist.

Coverage of Therapeutic Shoes and Inserts

Provided by Nurse Practitioners and Physician Assistants "Incident To"

NPs or PAs providing ancillary services as auxiliary personnel could meet the "incident to" requirements for therapeutic shoes to beneficiaries when ***all*** of the requirements are met:

1. The supervising physician has documented in the medical record the patient is diabetic and has been, and continues to provide, the patient follow-up under a comprehensive management program of that condition; ***and,***
2. The NP or PA certifies that the provision of the therapeutic shoes is part of the comprehensive treatment plan being provided to the patient; ***and,***
3. The supervising physician must review and verify (sign and date) all of the NP or PA notes in the medical record pertaining to the provision of the therapeutic shoes and inserts, acknowledging their agreement with the actions of the NP or PA
   - Practicing ***"incident to"*** the supervising physician

- Joint DME MAC Article
  - "Nurse Practitioners and Physician Assistants as Certifying Physicians for Therapeutic Shoes and Inserts"
    - Jurisdiction B: https://www.cgsmedicare.com/jb/pubs/news/2020/11/cope19409.html
    - Jurisdiction C: https://www.cgsmedicare.com/jc/pubs/news/2020/11/cope19409.html

Revised: February 2021

The *Prescribing Physician* writes the order for the therapeutic shoes, modifications, and inserts.

- May be podiatrist, M.D., D.O., Physician Assistant , Nurse Practitioner, or a Clinical Nurse Specialist.
- Must be knowledgeable in diabetic shoes and inserts
- The Prescribing Physician *can* be the supplier.

The *supplier* is the actual entity that furnishes the shoe, modification, and/or insert and bills Medicare.

- The supplier may be a podiatrist, pedorthist, orthotist, prosthetist or other qualified individual
- The Prescribing Physician may be the supplier
- The Certifying Physician may be the supplier only if he/she is practicing in a defined rural area or a defined health care professional shortage area.

Below is the analysis of claim denials for therapeutic shoes/inserts for diabetic persons HCPCS codes A5500, A5512, and A5513 reviewed between July 1 and September 30, 2022. The error rate for this quarter is 63.76%. The top 10 reasons for claim denials are as follows:

Medical record documentation does not include a clinical foot evaluation that the certifying physician either conducted or approved, initialed, and dated by the certifying physician. Therefore, there is no verification that the beneficiary had 1 of the 6 conditions the Local Coverage Determination (LCD) specifies must be present for coverage.
Documentation did not include a supplier-conducted, in-person evaluation of the patient's feet prior to selection of the specific items.
The medical records do not verify that the certifying physician is managing the patient's diabetes.
The medical record documentation is not authenticated (handwritten or electronic) by the author. Refer to Medicare Program Integrity Manual 100-08, Chapter 3, Section 3.3.2.4.
The in-person evaluation of the patient's feet is missing a description of the abnormalities the shoes/inserts/modifications will need to accommodate.
Medical records do not include a certifying physician clinical evaluation that discusses the management of the beneficiary's systemic diabetes condition within 6 months prior to shoe delivery.
Documentation did not include an in-person supplier visit at the time of delivery that assessed the fit of the shoes and inserts with the patient wearing them.
Documentation did not include a Statement of Certifying Physician.
The patient's medical records do not indicate the presence of 1 or more of the 6 conditions the LCD specifies must be present in order for the patient to meet coverage criteria for therapeutic shoes.
The supplier's delivery evaluation did not document that the supplier assessed, with the beneficiary wearing the shoes and inserts, that the shoes/inserts/modifications fit properly.

It is important for suppliers to be familiar with the documentation requirements and utilization parameters as outlined in the Therapeutic Shoes for Persons with Diabetes Local Coverage Determination (LCD) L33369 and Policy Article A52501 [PDF].

Suppliers can also review specific policy resources for Therapeutic Shoes on the DMERC websites. There is information related to proper documentation requirements including a physician letter, documentation checklists, FAQs, and a presentation used during web-based workshops.

Coverage Criteria: Based on 7 Main Documents

SCP
Standard Written Order
Medical Notes
Documentation of initial in-person assessment
Documentation of dispensing
Proof of Delivery/Authorization of Payment
Invoice

For an item to be covered by Medicare a written signed and dated order must be on file with the following criteria:

1) The patient has diabetes mellitus (ICD-10 E-codes); **AND**

(This information is documented on the Statement of Certifying Physician)

2) The patient has one or more of the following conditions:
   a) Previous amputation of the foot or part of either foot, *or*
   b) History of previous foot ulceration, *or*
   c) History of pre-ulcerative calluses of either foot, *or*
   d) Peripheral neuropathy with evidence of callus formation, *or*
   e) Foot deformity, *or*
   f) Poor circulation, **AND**

3) The certifying physician who is managing the patient's systemic diabetes has certified that indications 1) and 2) are met and that he/she is treating the patient under a comprehensive plan of care for his/her diabetes and that the patient needs diabetic shoes.

Standard Written Order:

Certification by the physician managing the patient's systemic diabetic condition, a podiatrist or other qualified physician who is knowledgeable in the fitting of diabetic shoes and inserts may prescribe the particular type of footwear necessary.

The SWO should contain:

Patient Information (Name, DOB, Chart #...)

Current Diagnosis (Diabetes, Neuropathy, Previous amputations…)

Devices being prescribed (Custom/Non-custom Shoes and inserts, and/or toe filler)—including code and/or description

Quantity of items

Physician information (name and contact info, signature and date)

SWO vs Rx

- Standard Written Order
  - All Medicare DME claims require SWO.
  - SWO may be generated and populated by Supplier and signed by Prescriber.
  - Replaces Detailed Written Order (01/01/20)
- Prescription
  - Written order from physician, PA, NP or CN. (Supplier may ***not*** create prescription)
  - View it as an “authorization to begin treatment”.
  - Meaningless for billing Medicare as Medicare does not consider Rx part of a medical record.
  - ABC requires you to have a Rx on file.
  - Still considered *best practice* to have Rx on file.

Medicare requires:

The Statement of Certifying Physician (SCP) must be signed and dated within **3 months** prior to dispensing footwear.

The SWO must be signed and dated within **6 months** prior to dispensing footwear.

The Certifying Physician must conduct a clinical foot assessment within **6 months** and document the foot conditions. Clinical notes should be reflected on the SCP.

Alternatively, the Certifying Physician may also attest to the validity of another clinician's foot exam notes.

Supplier will have clinical notes on file or have access to those notes.

Physician Notes on Qualifying Foot Condition

Progress notes dictated during the clinical examination of the foot.

Notes should include diagnosed qualifying foot condition, observations, follow up, treatment plan, and/or management.

PCP notes are made available to the supplier or allowed access to them. Electronic? Consider printed copies with signature

Notes need to be dated within 6 months of your DOS.

Physician Notes on Diabetes Management

Progress notes dictated during a visit for diabetes management.

Notes should include details of diabetes management plan (mention of condition, relevant medications, most recent HbA1c, etc.

PCP notes are made available to the supplier or allowed access to them. Electronic? Consider printed copies with signature.

Notes need to be dated within 6 months of your DOS.

Documentation Timeline

Activity	Responsible Person	Requirements
Visit to document diabetes management	Certifying MD/DO	Within six (6)months prior to delivery
Visit to document qualifying foot condition	Certifying MD/DO, other MD/DO, Podiatrist, PA, NP, CN	Within six (6) months prior to delivery
Completing the Certification Statement	Certifying MD/DO	▪ Within three (3) months prior to delivery ▪ Signed on or after visit(s) to document diabetes management and foot condition
Providing dispensing order to supplier	Prescribing Physician	After visit with Prescribing Physician
Signing detailed written order	Prescribing Physician	After visit with Prescribing Physician
Selection visit	Supplier	Prior to selecting the specific items that will be provided
Delivery Visit	Supplier	▪ After selection visit ▪ After receiving dispensing order or detailed written order
Claim submission	Supplier	▪ After delivery ▪ After receiving detailed written order ▪ After receiving certification statement

Documentation of Initial In-Person Assessment

Medicare requires an in-person, diagnosis-specific foot assessment to be completed by the supplier annually.

To determine appropriate need for shoes, determine correct size and width, and to select footwear that properly addresses specific issues (e.g., swelling, deformities).

If custom inserts (A5513/A5514) are being ordered, new molds or scans are required each calendar year.

Documentation of Exact Items Dispensed

Footwear must be dispensed IN PERSON; try on shoes, heat mold inserts, assess fit.

An objective assessment of fit and function should be recorded.
(Ex. 3/8-1/2” room from end of the toes to the end of the shoe.)

Keep records of your inventory or orders placed from manufacturer.

Dispensed items match inventoried items match billing.

Authorization of Payment and Warranty (aka Delivery Ticket)

Once footwear is dispensed, patient signs and dates the authorization allowing supplier to bill their Medicare/private insurance.

Warranty information is provided by supplier.

Acknowledges receipt of DMEPOS Supplier Quality Standards, Wear and Care Instructions, Break-In, return policy, etc.

Includes exact items dispensed—shoe style, size, width, color, and type and quantity of inserts.

Review the following patient documents:

1. 30 DMEPOS Supplier Quality Standards
2. Shoe Care Instructions
3. Break-In Procedure
4. Warranty and Return Policy

*Verbally review these documents with the patient.

Patient MUST receive these forms upon dispensing.

The patient’s medical records will reflect the need for the care provided. The documentation must demonstrate both medical necessity and the level of the service provided.

The patient’s medical records may include the physician's office records, hospital records, home health care records, records from other healthcare professional and test reports.

Therapeutic Shoes billed to the DME MAC before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

In addition to the documentation mentioned, the following can also be in the patient's chart:

- Intake Form with Medical History
- Prescription/Order information
- Assessment
- Treatment Plan
- Follow Up
- Progress Notes/Performance Outcomes

Advanced Beneficiary Notice (ABN)

The ABN is used to convey to the beneficiary that Medicare is not likely to provide coverage in a certain case. A verbal review should also take place well in advance, so the beneficiary is able to consider the options and make an informed decision about whether to proceed.

Once signed, the GA modifier can be affixed on the claim to require payment by the patient. If not signed or missing modifier, the patient is NOT financially responsible.

Medicare Beneficiary Complaint Log:

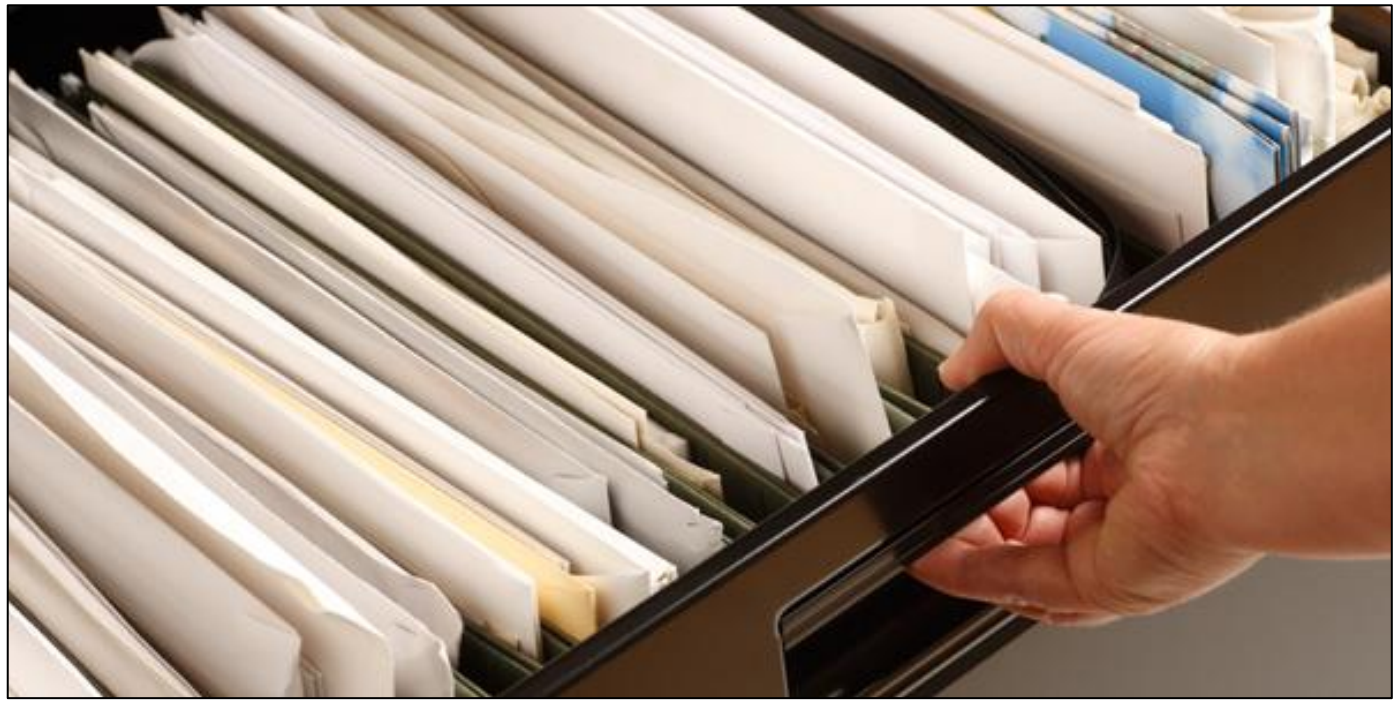
The patient has the right to freely voice grievances and recommend changes in care or services without fear or reprisal or unreasonable interruption of services. Medicare is required by law to investigate all beneficiary complaints.

Complaints need to be documented in the Medicare Beneficiaries Complaint Log.

The log must contain the patient's name, address, telephone number, and health claim number, a summary of the complaint, the date it was received, the name of the person receiving the complaint, and summary of the actions taken to resolve the complaint.

All documentation must be available to the DME MAC upon request.

Keep all documents for at least 10 years.



For patients meeting these criteria, coverage is limited to one of the following within one calendar year (January-December).

One pair of depth shoes (A5500) and 3 pairs of inserts (either A5512 or A5513/A5514).

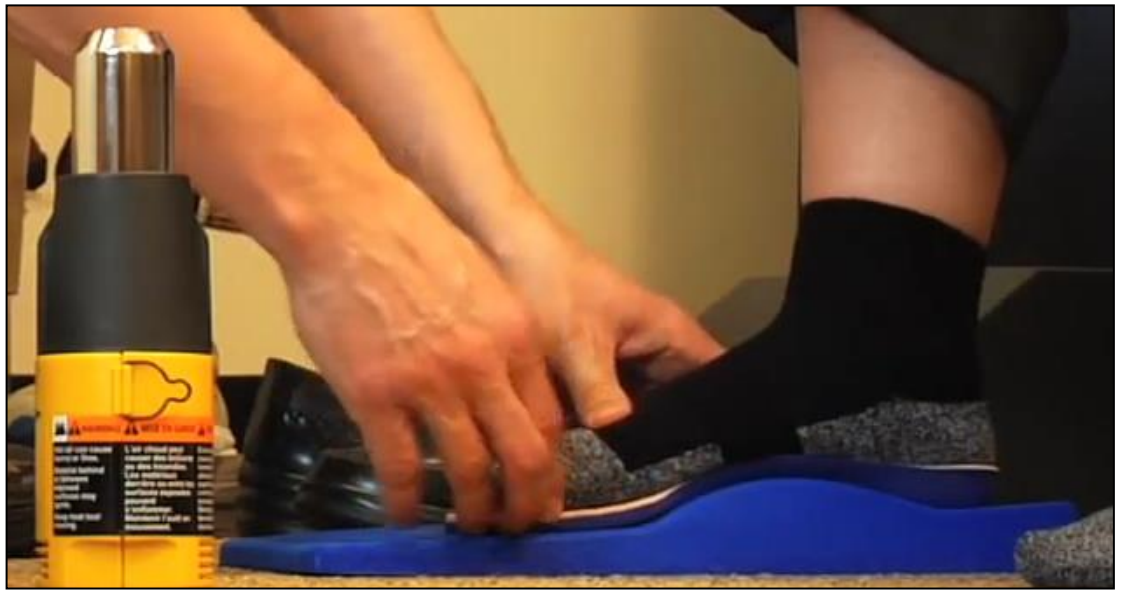
A5500: For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth inlay shoe manufactured to accommodate multi-density inserts

A5501: Shoe molded from cast (s) of patient's foot (custom molded shoe), per shoe

A5503-A5506: Modification of off-the-shelf depth-inlay shoe or custom-molded shoe with additional features

A5510: Direct-formed, compression molded to patient's foot *without* external heat source, multi-density insert(s), prefabricated, per shoe *(Not a reimbursable code)*

A5512: Multiple-density insert, direct-formed, molded to foot after external heat source of 230°F, or higher, total contact with patient's foot, including arch, base layer minimum of 1/4" material of Shore A 35 Durometer or 3/16" material of Shore A 40 Durometer (or higher), prefabricated, each



A5513: Multiple-density insert, custom-molded from **model of patient's foot**, total contact with patient's foot, including arch, base layer, minimum of 3/16" material of Shore A 35 Durometer (or higher), including arch filler and other shaping material, custom fabricated, each

A5514: Multiple-density insert, made by **direct carving** with CAM technology from a rectified CAD model created from a digitized scan of the patient total contact with patient's foot, including arch, base layer, minimum of 3/16" material of Shore A 35 Durometer (or higher), and other shaping material, custom fabricated, each

L5000: Partial foot, shoe insert with longitudinal arch, toe filler; for beneficiaries missing digits, particularly the hallux (great toe), or the forefoot, designed to provide standing balance and toe off support for improved gait. The biomechanical control differs from the foot-protective function provided by inserts used as part of diabetes management.

Modifiers:

KX-Specific required documentation on file

**Must be appended to all claims for diabetic footwear

LT -Left Side

RT -Right Side

EY-No physician or other licensed health care provider order for this item or service. Use if there is not a completed order

GA-Properly completed ABN on file (when applicable)

A modification of a custom molded or depth shoe will be covered as a **substitute for an insert**.

A5503: Rigid rocker bottoms or roller bottoms
A5504: Wedges
A5505: Metatarsal bars
A5507: Not otherwise specified modification of off-the-shelf depth inlay shoe or custom-molded shoe, per shoe
A5508: Deluxe feature of off-the-shelf depth inlay shoe or custom-molded shoe, per shoe *(Not a reimbursable code)*

Medicare Benefit Policy Manual
Publication 100-02 Chapter 15 Section 20.3

“If a custom-made item was ordered but not furnished to a beneficiary because the individual died, or because the order was canceled by the beneficiary, or because the beneficiary’s condition changed and the item was no longer reasonable and necessary or appropriate, ***payment can be made*** based on the supplier’s expenses.”

- Custom or customized items only
- Reimbursement is invoiced amount
- DOS will be date of cancellation/death
- You will need to produce the invoice if asked

Medically Necessary Upgrades

“An upgrade may be from one item to another within a single Health Insurance Common Procedure Coding System (HCPCS) code or may be from one HCPCS code to another. When an upgrade is within a single code, the upgraded item must include features that exceed the official code descriptor for that item.”

While boots achieve the same medical benefit, they are more expensive and have additional features that can be considered an upgrade. The provider can bill the boot as an upgrade for the difference. A signed ABN is required in this instance.

When suppliers know that an item will not be paid in full because it does not meet the coverage criteria stated in the LCD, the supplier can still obtain partial payment at the time of initial determination if the claim is billed using one of the upgrade modifiers, GK or GL.

GK - Reasonable and necessary item/service associated with a GA or GZ modifier

GL - Medically unnecessary upgrade provided instead of non-upgraded item, no charge, no ABN

ABN must be obtained.

On one claim line the supplier bills with a GA modifier the HCPCS code that describes the item that was provided.

On the next claim line, the supplier bills with a GK modifier the HCPCS code that describes the item that is covered based on the LCD. **(Note: The codes must be billed in this specific order on the claim.)**

Claim line with the GA modifier will be denied as not medically necessary with a "patient responsibility" (PR) message.

The supplier may charge their "usual and customary" fee for the upgraded item that is provided.

The Audit Proof Chart

Measuring Documentation:

The in-person evaluation of the beneficiary by the supplier at the time of selecting the items that will be provided (refer to Non-Medical Necessity Coverage and Payment Rules, criterion 4) must include at least the following:

1. An examination of the beneficiary's feet with a description of the abnormalities that will need to be accommodated by the shoes/inserts/modifications.

2. For all shoes, taking measurements of the beneficiary's feet.

3. For custom molded shoes (A5501) and inserts (A5513/A5514), taking impressions, making casts, or obtaining CAD-CAM images of the beneficiary's feet that will be used in creating positive models of the feet.

The Audit Proof Chart

Delivery Documentation:

At the time of in-person delivery to the beneficiary of the items selected, the supplier must conduct an **objective assessment** of the fit of the shoe and inserts and document the results. **A beneficiary's subjective statements regarding fit as the sole documentation of the in-person delivery does not meet this criterion.**

If criteria 1-5 are not met, the therapeutic shoes, inserts and/or modifications will be denied as noncovered. When codes are billed without a KX modifier, they will be denied as noncovered.

The in-person evaluation of the beneficiary by the supplier at the time of delivery (refer to Non-Medical Necessity Coverage and Payment Rules, criterion 5) must be conducted with the beneficiary wearing the shoes and inserts and must document that the shoes/inserts/modifications fit properly.

Effective March 2019

According to Noridian Medicare, there are changes required when reporting the RT and LT modifier(s). Changes apply to HCPCS codes for Therapeutic Shoes for Persons with Diabetes (TSD).

"Effective for claims with dates of service (DOS) on or after 3/1/2019, suppliers must bill each item on two separate claim lines using the RT and LT modifiers and 1 UOS on each claim line. Do not use the combination RTLT modifier on the same claim line and bill with 2 units of service (UOS). Claim lines for HCPCS codes requiring the use of the RT and LT modifiers billed without the RT and/or LT modifiers or with the RT LT on a single claim line, will be rejected as incorrect coding."

Proper Medicare Claim

DOS	POS	CODE	MOD 1	MOD 2	MOD 3	CHARGES	QTY	TOTAL
1/13/23	12	A5500	KX	RT		87.85	1	87.85
1/13/23	12	A5500	KX	LT		87.85	1	87.85
1/13/23	12	A5514	KX	RT		53.47	1	$53.47
1/13/23	12	A5514	KX	LT		53.47	1	$53.47
1/13/23	12	A5514	KX	RT		53.47	1	$53.47
1/13/23	12	A5514	KX	LT		53.47	1	$53.47
1/13/23	12	A5514	KX	RT		53.47	1	$53.47
1/13/23	12	A5514	KX	LT		53.47	1	$53.47

A provider of DMEPOS products must possess the following:

DMEPOS Supplier Number—855S form is the application to enroll in the Medicare program
Facility Accreditation—organization which establishes and enforces standards (not required in a podiatry office)
Professional Liability—this is liability insurance for the services which are rendered
Product Liability – the liability for the devices or products dispensed from the office/clinic
Property/Casualty—the protection of the storefront

HIPAA- Health Insurance Portability and Accountability Act of 1996, mandates the use of standards for the exchange of health care data.

What is it?
It is protection for the privacy and security of Protected Health Information (PHI). It is also the standardization of electronic data interchange in health care transactions.

HIPAA

Covered entities may use PHI for the purposes of Treatment, Payment and Health Care Operations (TPO) *without any special permission* from the patient.

Special permission, called an authorization, must be obtained for uses and disclosures other than for TPO.

HIPAA (continued)

The purpose of HIPAA is to:

- Limit the unauthorized use and disclosure of PHI
- Give patients new rights to access their medical records and to know who else has accessed them
- Restrict most disclosure of health information to the minimum needed for the intended purpose
- Establish new criminal and civil sanctions for proper use or disclosure
- Establish new requirements for access to records by researchers and others

HIPAA (continued)

In a healthcare setting, the patient has the:

- Right to a notice of the covered entity privacy practices
- Right to request restrictions and confidential communications concerning PHI
- Right to obtain access to protected health information for inspection and copying
- Right to obtain an accounting of certain disclosures
- Right to request amendment of PHI

HIPAA (continued)

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HIPAA COMPLIANCE

It's NOT a suggestion...it's the law!

10-STEP

HIPAA CHECKLIST

Create a Security and Privacy Policy

Name a Privacy and Security Officer

Perform Periodic Vulnerability Reviews

Create a Specific Policy for Email

Create a Specific Mobile Policy

Train Your Staff

Develop a Privacy Notice

Solidify Business Associate Relationships

Establish a Protocol for Possible Breaches

Make Sure the Privacy and Security Policies are Followed

The End