# RECENT TRENDS IN HEALTH CARE COMPLIANCE

## **Table of Contents**

NON-COMPLIANCE WITH HIPAA REGULATIONS CAN COST YOU	2
RECORD YEAR FOR HIPAA ENFORCEMENT	5
Breach Notification and Data Security:	8
RESPECT HIPAA & LOOK OUT FOR STATE LAWS	8



#### NON-COMPLIANCE WITH HIPAA REGULATIONS CAN COST YOU

The Health Insurance Portability and Accountability Act (HIPAA) mandates that covered entities comply with the HIPAA Privacy Rule, Security Rule and Breach Notification Rule set out by the Department of Health and Human Services (HHS) Office of Civil Rights (OCR). These covered entities include Health Care Providers, Health Care Clearinghouses, and Health Plans who transmit health information in electronic form. In 2013, the regulations were extended to cover *Business Associates* of covered entities and required these Business Associates to comply with HIPAA regulations. Business Associates are entities that create, transmit or maintain protected health information on a covered entity's behalf.

The Privacy Rule governs how protected health information (hereinafter "PHI") shall be used and disclosed. The Security Rule has the same overall purpose of protecting PHI with a specific focus on electronically created, maintained or transmitted PHI. Electronic protected health information (hereinafter "ePHI") is often stored on laptops, flash drives, emails and electronic health records. While the Privacy and Security Rules are set up to protect the confidentiality of a patient's PHI or ePHI, they both offer exceptions for access and disclosures made for the purposes of treatment, payment and health care operations, so as not to hinder a patient's ability to be able to receive or pay for services.

At a minimum, a covered health care entity is required to create and maintain in writing, the following HIPAA infrastructure:

Designate a Privacy Officer;

Designate a Security Officer;

Perform a Risk Analysis with Documented Risk Management Policies and Procedures;

Create and Make Available a Notice of Privacy Practices;

Adopt Necessary Policies and Procedures;

Perform and Document Workforce Training;

Develop and Implement Mitigation Procedures;

Adhere to Administrative, Physical and Technical Safeguards of PHI and ePHI;

Develop and Implement Mechanisms to Receive and Handle Complaints and Breaches; and

Perform Periodic Assessments and Audits.

The HIPAA Breach Notification Rule specifically governs how covered entities and their business associates must handle impermissible uses or disclosures of PHI, also known as breaches. This rule dictates the content of the notice, to whom notice must be given, timeliness of the notice and other appropriate deadlines. Breaches must be assessed to determine the number of individuals affected and the possibility of mitigation, both of which effect how the breach should be ultimately handled. For example, breaches effecting less than 500 people require individual notice, whereas breaches affecting 500 people or more require individual notice, notice to specific news outlets

and notice to the Secretary of HHS. Due to the complexity of the breach notification standards, it is paramount that your Privacy and Security Officers know and understand the breach notification requirements.

#### How much money are we talking?

Not complying with HIPAA regulations can be expensive. The fines can range from \$112 to \$55,910 per violation, with a maximum of \$1,667,299 in a calendar year for repeat violations. The categories of violations are based upon the level of negligence demonstrated by the individual/entity that caused the breach. Penalties are based on the nature of the breach and the extent of harm caused by the breach. These penalty amounts increase annually with inflation.

VIOLATION	AMOUNT PER VIOLATION	VIOLATIONS OF AN IDENTIAL PROVISION IN A CALENDAR YEAR		
Did Not Know	\$112-\$55,910	\$1,667,299		
Reasonable Cause	\$1,118-\$55,910	\$1,667,299		
Willful Neglect - Corrected	\$11,182-\$55,910	\$1,667,299		
Willful Neglect - Not Corrected	\$55,910	\$1,667,299		

The HHS Office of Civil rights has collected tens of millions of dollars in settlements. These settlement funds are then funneled back into the enforcement program to further strengthen their auditing efforts and oversight. This practice makes the program self-sustaining and will continue to grow and develop making it that much more likely that you or a health care provider that you know will be audited.

In addition to steep fines, an equally threatening issue is damage to your business reputation. There is no doubt that media coverage of publicized breaches can have a chilling effect on patients who are already on heightened alert to issues like identity theft. In 2018 alone, OCR has publicized settlements ranging from \$100,000 to \$4.3 million. They also maintain a searchable section on their webpage known to compliance professionals as the "Wall of Shame." Should your entity receive the unpleasant distinction of being highlighted on this website, you should know that it details information on the underlying offense and the required corrective action. As one may imagine, in addition to the monetary burden, placement on this list may also have a chilling effect on whether patients continue to utilize a health care provider. A quick glance at the Wall of Shame contains a searchable list of thousands of entities that may be under investigation, as well as an archive of past non-compliant entities. https://ocrportal.hhs.gov/ocr/breach/breach report.jsf

The covered entities hit the hardest by enforcement action are listed below based on frequency:

• Private Practices:

- General Hospitals;
- Outpatient Facilities;
- Pharmacies; and
- Health Plans.

According to OCR, issues investigated most are, compiled cumulatively in order of frequency:

- Impermissible uses and disclosures of PHI;
- Lack of safeguards of PHI;
- Lack of patient access to their PHI;
- Lack of administrative safeguards of electronic PHI; and
- Use or disclosure of more than the minimum necessary PHI.

#### Show *victims* the money!

HHS OCR has currently issued a Notice of Proposed Rule Making (NPRM) to request comments on how they may allow victims of HIPAA breaches to share in the monetary settlements received for HIPAA non-compliance. Director of the HHS OCR, Roger Severino recently stated, "OCR is interested in hearing from industry advocates and patients about what would be the proper approach for...creating a system for providing compensation to those hurt by breaches and HIPAA violations. He further shared that "a lot of breaches do end up causing significant stress, trauma, and anxiety."

It is in a health care provider's best interest to comply with HIPAA regulations, not only because it is the law but because there is a legitimate interest in protecting PHI. Patients can be harmed by identity theft and embarrassment which can have a chilling effect on health care providers who create breaches. Additionally, no entity wants to incur the expense of large fines and burden of adhering to corrective action plan requirements.

Samarria Dunson (<u>samarria@dunsongroup.com</u>) is attorney/principal of Dunson Group, LLC, a health care compliance consulting and law firm in Montgomery, Alabama. Attorney Dunson is also Of Counsel with the law firm of Balch & Bingham, LLP.

www.dunsongroup.com



#### RECORD YEAR FOR HIPAA ENFORCEMENT

In the current environment of regulation reduction, it is notable that the Department of Health and Human Services (HHS) received a record \$28.6 million dollars in publicized settlements and judgments for HIPAA violations in 2018. These numbers surpass previous years with the closest year on record being 2016 in which HHS collected \$23.5 million dollars. These numbers reflect that HIPAA enforcement actions are on the rise.

There are several factors that are leading to this increase in fines:

- 1. A lack of understanding about what encompasses an adequate HIPAA Risk Assessment;
- 2. Failure to attain Business Associate Agreements when applicable;
- 3. Failure to comply with physical, technical and administrative safeguards to secure protected health information (PHI); and
- 4. Failure to implement encryption solutions or alternative adequate measures.

### 2018 Settlements and Judgments

Date	<b>Covered Entity</b>	Amount	Violation
January	Filefax, Inc.	\$100,000	Impermissible disclosures of paper records and insufficient physical safeguards
January	Fresenius Medical Care North America	\$3,500,000	Lack of adequate Risk Analysis, failure to utilize encryption, impermissible disclosures, inadequate policies
June	MD Anderson	\$4,348,000	Impermissible disclosures of electronic PHI and lack of encryption
August	Boston Medical Center	\$100,000	Filming patients without consent
September	Brigham and Women's Hospital	\$384,000	Filming patients without consent
September	Massachusetts General Hospital	\$515,000	Filming patients without consent

September	Advanced Care Hospitals	\$500,000	Impermissible disclosures and failure to attain Business Associate Agreements, failure to implement an adequate HIPAA compliance program
October	Allergy Associates of Hartford	\$125,000	Impermissible disclosure and failure to sanction employee for HIPAA violation
October	Anthem, Inc.	\$16,000,000	Lack of adequate Risk Analysis, failure to monitor electronic PHI activities, failure to adequately respond to the breach, insufficient safeguards to prevent inappropriate disclosures
November	Pagosa Springs	\$111,400	Failure to terminate employee access and failure to attain Business Associate Agreements
December	Cottage Health	\$3,000,000	Lack of adequate Risk Analysis, failure to implement an adequate compliance program, failure to attain Business Associate Agreements

It is important to note that this record setting total does not encompass all of the enforcement action taken by HHS against covered entities in 2018. These numbers simply represent larger, more notable settlements and judgments. In fact, HHS took corrective action against countless health care providers, health plans and business associates last year and it does not appear that these numbers will decrease in 2019. As of February 22, 2019, HHS has officially begun investigating over 50 entities for large scale breaches. For more information on these investigations of breaches of 500 individuals or more, visit the Wall of Shame on the HHS website. Pursuant to the HITECH Act of 2009, the Secretary of HHS is required to post information about entities who breach the PHI of 500 people or more to demonstrate transparency to health care consumers.

Health care providers can take action to reduce their risk by doing the following:

- 1. Performing annual Risk Assessments;
- 2. Identifying Business Associates and entering into adequate Business Associate Agreements;
- 3. Creating and updating HIPAA policies and procedures;
- 4. Ensuring that employees and staff members receive up-to-date training; and
- 5. Proactive monitoring of electronic systems containing PHI.

This uptick in penalties illustrates that HHS is serious about their mandate to protect the privacy and security of PHI. Their record demonstrates that they can be successful at attaining multimillion dollar settlements with health care entities and health plans that don't comply with HIPAA

regulations. This is a good time for health care providers and HIPAA Business Associates to review their compliance programs to ensure that they are meeting the requirements. In HIPAA compliance, the lack of a specific strategy to secure PHI is an actionable failure that could result in a large fine and a loss of goodwill with the entity's customers, its patients. If you are unsure about whether your HIPAA compliance program is adequate or if you know that it is time to update your policies, procedures and training, consult a health care compliance expert.

Samarria Dunson (<u>samarria@dunsongroup.com</u>) is attorney/principal of Dunson Group, LLC, a health care compliance consulting and law firm in Montgomery, Alabama. Attorney Dunson is also Of Counsel with the law firm of Balch & Bingham, LLP.



# Breach Notification and Data Security: Respect HIPAA, Also Look Out for State Laws

All states and the District of Columbia have enacted Unfair and Deceptive Acts and Practices (UDAP) statutes to protect consumers. All of these state breach notification statutes require that notice be given to individuals impacted by data breaches within specific time parameters. Some require notice to the state Attorney General's Office while others require notice to credit reporting agencies. Two states, California and Connecticut, even require the provision of credit monitoring services for individuals impacted by a breach.

As of June 1, 2018, Alabama became the 50<sup>th</sup> state to enact data security and breach notification laws. While the Alabama statute was the last to be adopted, it is worth noting that it is among the most comprehensive. Not only does it require appropriate disposal of sensitive data, it requires entities to perform a good faith investigation of data breaches and notify individuals who may have had their information compromised. It also requires entities to maintain reasonable cybersecurity safeguards.

The Alabama Data Breach Notification Act of 2018 applies specifically to "covered entities." The act broadly defines *covered entities* as "a person, sole proprietorship, partnership, government entity, corporation, nonprofit, trust, estate, cooperative association, or other business entity that acquires or uses sensitive personally identifying information." Under this act, a *breach* is "the unauthorized acquisition of data in electronic form containing sensitive personally identifying information." Sensitive personally identifying information includes an Alabama resident's first name or first initial and last name in conjunction with non-truncated identifiers, including the following:

- (1) Social Security number or tax identification number:
- (2) Driver's license number, passport number, military identification number, or other unique identification number issued on a government document used to verify the identity of a specific individual;
- (3) A financial account number, including a bank account number, credit card number, or debit card number, in combination with any security code, access code, password, expiration date, or PIN, that is necessary to access the financial account or to conduct a transaction that will credit or debit the financial account;
- (4) Any information regarding an individual's medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional;
- (5) An individual's health insurance policy number or subscriber identification number and any unique identifier used by a health insurer to identify the individual; or

<sup>&</sup>lt;sup>1</sup> SB318 Section 2(2)

<sup>&</sup>lt;sup>2</sup> SB318 Section 2(1)

(6) A user name or email address, in combination with a password or security question and answer that would permit access to an online account affiliated with the covered entity that is reasonably likely to contain or is used to obtain sensitive personally identifying information.<sup>3</sup>

This law also applies to third-party agents of covered entities. A third-party agent is "an entity that has been contracted to maintain, store, process, or is otherwise permitted to access sensitive personally identifying information in connection with providing services to a covered entity." Under the Health Insurance Portability and Accountability Act (HIPAA) these entities are referred to as *Business Associates*.

There are a few exceptions. For instance, information that has already been made public by government records would not be considered breached. Additionally, information is not considered breached if it has been de-identified, encrypted with a secured encryption key, or truncated such that the identity of the individual could not be reasonably made known from the information provided.

#### **How Does This Impact Alabama Health Care Providers?**

Entities that are already required under federal law to perform breach notification are exempt from this act as long as they fully comply with the federal requirements. Notwithstanding, Alabama health care providers must be able to demonstrate that they are adhering to the following:

- (1) Maintaining policies and procedures in accordance with the HIPAA Privacy Rule, Security Rule, and Breach Notification Rule;
- (2) Providing notice to patients/clients who may have had their protected health information compromised; and
- (3) Providing notice to the Alabama Attorney General's Office if the number of patients/clients impacted is greater than 1,000 people.

When a health care provider is exempt from Alabama's law based on its compliance with HIPAA, they must be reminded that HIPAA defines breaches slightly differently. HIPAA generally defines a breach as "an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of the protected health information." When a breach occurs, the entity must provide individual notice and notice to the Department of Health and Human Services (HHS). For breaches of 500 people or more, media notice must also be given. The content of the report must be written in plain language and include the following elements:

- (1) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known;
- (2) A description of the types of unsecured protected health information that were involved in the breach (such as full name, social security number, date of birth, home address);

\_

<sup>&</sup>lt;sup>3</sup> SB318 Section 2(6)

<sup>&</sup>lt;sup>4</sup> SB318 Section 2(7)

- (3) The steps individuals should take to protect themselves from potential harm resulting from the breach;
- (4) A brief description of what the covered entity involved is doing to investigate the breach, to mitigate the losses, and to protect against any further breaches; and
- (5) Contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an email address, website, or postal address.<sup>5</sup>

Health care providers, at a minimum, must also ensure that their entities have implemented the following HIPAA requirements:

- (1) Designated Privacy and Security Officers;
- (2) Performed a Risk Assessment;
- (3) Adopted policies and procedures in accordance with the HIPAA Security Rule which requires the implementation of Administrative, Physical, and Technical Safeguards;
- (4) Entered into Business Associate Agreements, when applicable; and
- (5) Implemented and maintained an ongoing HIPAA Security program.

#### **Action by State Attorney General**

State Attorney Generals may file a civil enforcement case in federal court if they believe that a resident or multiple residents of their state were threatened or adversely affected by HIPAA privacy and security violations. When this occurs, the state Attorney General must provide notice to the HHS Secretary so it can be determined whether it is necessary for HHS to intervene in the case. If it is determined that HHS is already pursuing an action based on the underlying data breach, it may preempt the state Attorney General from pursuing the matter as a HIPAA issue while the HHS action is pending. However, certain breaches could result in multiple enforcement actions pending simultaneously. A sound HIPAA Privacy and Security program is the best defense to avoid a breach that could lead to adverse consequences to health care providers.

Samarria Dunson (<u>samarria@dunsongroup.com</u>) is attorney/principal of Dunson Group, LLC, a health care compliance consulting and law firm in Montgomery, Alabama. Attorney Dunson is also Of Counsel with the law firm of Balch & Bingham, LLP.

www.dunsongroup.com

-

<sup>&</sup>lt;sup>5</sup> 42 CFR §164.404(c)

<sup>&</sup>lt;sup>6</sup> 42 U.S. Code § 1320d–5

1	28318
2	192523-5
3	By Senators Orr and Holley

ACT #2018-\_\_\_**396** 

4 RFD: Governmental Affairs

5 First Read: 13-FEB-18



1	SB318
2	
3	
4	ENROLLED, An Act,
5	Relating to consumer protection; to require certain
6	entities to provide notice to certain persons upon a breach of
7	security that results in the unauthorized acquisition of
8	sensitive personally identifying information.
9	BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:
10	Section 1. This act may be cited and shall be known
11	as the Alabama Data Breach Notification Act of 2018.
12	Section 2. For the purposes of this act, the
13	following terms have the following meanings:
14	(1) BREACH OF SECURITY or BREACH. The unauthorized
15	acquisition of data in electronic form containing sensitive
16	personally identifying information. Acquisition occurring over
17	a period of time committed by the same entity constitutes one
18	breach. The term does not include any of the following:
19	a. Good faith acquisition of sensitive personally
20	identifying information by an employee or agent of a covered
21	entity, unless the information is used for a purpose unrelated
22	to the business or subject to further unauthorized use.
23	b. The release of a public record not otherwise
24	subject to confidentiality or nondisclosure requirements.

1	c. Any lawful investigative, protective, or
2	intelligence activity of a law enforcement or intelligence
3	agency of the state, or a political subdivision of the state.
4	(2) COVERED ENTITY. A person, sole proprietorship,
5	partnership, government entity, corporation, nonprofit, trust
6	estate, cooperative association, or other business entity tha
7	acquires or uses sensitive personally identifying information
8	(3) DATA IN ELECTRONIC FORM. Any data stored
9	electronically or digitally on any computer system or other
10	database, including, but not limited to, recordable tapes and
11	other mass storage devices.
12	(4) GOVERNMENT ENTITY. The State, a county, or a
13	municipality or any instrumentality of the state, a county, or
14	a municipality.
15	(5) INDIVIDUAL. Any Alabama resident whose sensitive
16	personally identifying information was, or the covered entity
17	reasonably believes to have been, accessed as a result of the
18	breach.
19	(6) SENSITIVE PERSONALLY IDENTIFYING INFORMATION.
20	a. Except as provided in paragraph b., an Alabama
21	resident's first name or first initial and last name in
22	combination with one or more of the following with respect to
23	the same Alabama resident:
24	1. A non-truncated Social Security number or tax

25

identification number.

-	2. A non-truncated driver's license number,
2	state-issued identification card number, passport number,
3	military identification number, or other unique identification
:	number issued on a government document used to verify the
1	identity of a specific individual

- 3. A financial account number, including a bank account number, credit card number, or debit card number, in combination with any security code, access code, password, expiration date, or PIN, that is necessary to access the financial account or to conduct a transaction that will credit or debit the financial account.
- 4. Any information regarding an individual's medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional.
- 5. An individual's health insurance policy number or subscriber identification number and any unique identifier used by a health insurer to identify the individual.
- 6. A user name or email address, in combination with a password or security question and answer that would permit access to an online account affiliated with the covered entity that is reasonably likely to contain or is used to obtain sensitive personally identifying information.
- 23 b. The term does not include either of the following:

L	1. Information about an individual which has been
2	lawfully made public by a federal, state, or local government
3	record or a widely distributed media.
<u>l</u>	2. Information that is truncated, encrypted,
;	secured or modified by any other mathematical and a secured

- secured, or modified by any other method or technology that removes elements that personally identify an individual or that otherwise renders the information unusable, including encryption of the data, document, or device containing the sensitive personally identifying information, unless the covered entity knows or has reason to know that the encryption key or security credential that could render the personally identifying information readable or useable has been breached together with the information.
- (7) THIRD-PARTY AGENT. An entity that has been contracted to maintain, store, process, or is otherwise permitted to access sensitive personally identifying information in connection with providing services to a covered entity.
- Section 3. (a) Each covered entity and third-party agent shall implement and maintain reasonable security measures to protect sensitive personally identifying information against a breach of security.
- (b) Reasonable security measures means security measures practicable for the covered entity subject to

1	subsection	(c),	to	imple	ement	and	maintain,	including
2	considerati	on o	f a]	ll of	the	follo	owing:	

- (1) Designation of an employee or employees to coordinate the covered entity's security measures to protect against a breach of security. An owner or manager may designate himself or herself.
- (2) Identification of internal and external risks of a breach of security.
  - (3) Adoption of appropriate information safeguards to address identified risks of a breach of security and assess the effectiveness of such safeguards.
  - (4) Retention of service providers, if any, that are contractually required to maintain appropriate safeguards for sensitive personally identifying information.
  - (5) Evaluation and adjustment of security measures to account for changes in circumstances affecting the security of sensitive personally identifying information.
  - (6) Keeping the management of the covered entity, including its board of directors, if any, appropriately informed of the overall status of its security measures; provided, however, that the management of a government entity subject to this subdivision may be appropriately informed of the status of its security measures through a properly convened execution session under the Open Meetings Act pursuant to Section 36-25A-7, Code of Alabama 1975.

Ţ	(c) An assessment of a covered entity's security
2	shall be based upon the entity's reasonable security measures
3	as a whole and shall place an emphasis on data security
4	failures that are multiple or systemic, including
5	consideration of all the following:
6	(1) The size of the covered entity.
7	(2) The amount of sensitive personally identifying
8	information and the type of activities for which the sensitive
9	personally identifying information is accessed, acquired,
10	maintained, stored, utilized, or communicated by, or on behalf
11	of, the covered entity.
12	(3) The covered entity's cost to implement and
13	maintain the reasonable security measures to protect against a
14	breach of security relative to its resources.
15	Section 4. (a) If a covered entity determines that a
16	breach of security has or may have occurred in relation to
17	sensitive personally identifying information that is accessed,
18	acquired, maintained, stored, utilized, or communicated by, or
19	on behalf of, the covered entity, the covered entity shall
20	conduct a good faith and prompt investigation that includes
21	all of the following:
22	(1) An assessment of the nature and scope of the
23	breach.

identifying information that may have been involved in the

(2) Identification of any sensitive personally

24

-	breach	and	the	identity	of	any	individuals	to	whom	that
2	informa	ation	re.	lates.						

- (3) A determination of whether the sensitive personally identifying information has been acquired or is reasonably believed to have been acquired by an unauthorized person, and is reasonably likely to cause substantial harm to the individuals to whom the information relates.
- (4) Identification and implementation of measures to restore the security and confidentiality of the systems compromised in the breach.
- (b) In determining whether sensitive personally identifying information has been acquired or is reasonably believed to have been acquired by an unauthorized person without valid authorization, the following factors may be considered:
- (1) Indications that the information is in the physical possession and control of a person without valid authorization, such as a lost or stolen computer or other device containing information.
- (2) Indications that the information has been downloaded or copied.
- (3) Indications that the information was used by an unauthorized person, such as fraudulent accounts opened or instances of identity theft reported.
  - (4) Whether the information has been made public.

Section 5. (a) A covered entity that is not a third-party agent that determines under Section 4 that, as a result of a breach of security, sensitive personally identifying information has been acquired or is reasonably believed to have been acquired by an unauthorized person, and is reasonably likely to cause substantial harm to the individuals to whom the information relates, shall give notice of the breach to each individual.

- (b) Notice to individuals under subsection (a) shall be made as expeditiously as possible and without unreasonable delay, taking into account the time necessary to allow the covered entity to conduct an investigation in accordance with Section 4. Except as provided in subsection (c), the covered entity shall provide notice within 45 days of the covered entity's receipt of notice from a third party agent that a breach has occurred or upon the covered entity's determination that a breach has occurred and is reasonably likely to cause substantial harm to the individuals to whom the information relates.
- (c) If a federal or state law enforcement agency determines that notice to individuals required under this section would interfere with a criminal investigation or national security, the notice shall be delayed upon the receipt of written request of the law enforcement agency for a period that the law enforcement agency determines is

1	necessary. A law enforcement agency, by a subsequent written
2	request, may revoke the delay as of a specified date or extend
3	the period set forth in the original request made under this
4	section if further delay is necessary.

- (d) Except as provided by subsection (e), notice to an affected individual under this section shall be given in writing, sent to the mailing address of the individual in the records of the covered entity, or by email notice sent to the email address of the individual in the records of the covered entity. The notice shall include, at a minimum, all of the following:
- (1) The date, estimated date, or estimated date range of the breach.
  - (2) A description of the sensitive personally identifying information that was acquired by an unauthorized person as part of the breach.
  - (3) A general description of the actions taken by a covered entity to restore the security and confidentiality of the personal information involved in the breach.
  - (4) A general description of steps an affected individual can take to protect himself or herself from identity theft.
  - (5) Information that the individual can use to contact the covered entity to inquire about the breach.

1	(e)(1) A covered entity required to provide notice
2	to any individual under this section may provide substitute
3	notice in lieu of direct notice, if direct notice is not
4	feasible due to any of the following:
5	a. Excessive cost. The term includes either of the
6	following:
7	1. Excessive cost to the covered entity relative to
8	the resources of the covered entity.
9	2. The cost to the covered entity exceeds five
10	hundred thousand dollars (\$500,000).
11	b. Lack of sufficient contact information for the
12	individual required to be notified.
13	c. The affected individuals exceed 100,000 persons.
14	(2) a. Substitute notice shall include both of the
15	following:
16	1. A conspicuous notice on the Internet website of
17	the covered entity, if the covered entity maintains a website,
18	for a period of 30 days.
19	2. Notice in print and in broadcast media, including
20	major media in urban and rural areas where the affected
21	individuals reside.
22	b. An alternative form of substitute notice may be
23	used with the approval of the Attorney General.
24	(f) If a covered entity determines that notice is
25	not required under this section, the entity shall document the

determination in writing and maintain records concerning the determination for no less than five years.

Section 6. (a) If the number of individuals a covered entity is required to notify under Section 5 exceeds 1,000, the entity shall provide written notice of the breach to the Attorney General as expeditiously as possible and without unreasonable delay. Except as provided in subsection (c) of Section 5, the covered entity shall provide the notice within 45 days of the covered entity's receipt of notice from a third party agent that a breach has occurred or upon the entity's determination that a breach has occurred and is reasonably likely to cause substantial harm to the individuals to whom the information relates.

- (b) Written notice to the Attorney General shall include all of the following:
- (1) A synopsis of the events surrounding the breach at the time that notice is provided.
- (2) The approximate number of individuals in the state who were affected by the breach.
- (3) Any services related to the breach being offered or scheduled to be offered, without charge, by the covered entity to individuals, and instructions on how to use the services.

	(4)	The	name,	add	lress,	t€	elepho	ne i	number	c, and	d email
address of	f the	e emj	ployee	or	agent	of	the	COV	ered e	entit	y from
whom addit	iona	al i	nformat	tion	may	be	obtai	ned	about	the	breach.

- (c) A covered entity may provide the Attorney

  General with supplemental or updated information regarding a

  breach at any time.
- (d) Information marked as confidential that is obtained by the Attorney General under this section is not subject to any open records, freedom of information, or other public record disclosure law.

Section 7. If a covered entity discovers circumstances requiring notice under Section 5 of more than 1,000 individuals at a single time, the entity shall also notify, without unreasonable delay, all consumer reporting agencies that compile and maintain files on consumers on a nationwide basis, as defined in the Fair Credit Reporting Act, 15 U.S.C. 1681a, of the timing, distribution, and content of the notices.

Section 8. In the event a third-party agent has experienced a breach of security in the system maintained by the agent, the agent shall notify the covered entity of the breach of security as expeditiously as possible and without unreasonable delay, but no later than 10 days following the determination of the breach of security or reason to believe the breach occurred. After receiving notice from a third-party

1.3

2.4

agent, a covered entity shall provide notices required under Sections 5 and 6. A third-party agent, in cooperation with a covered entity, shall provide information in the possession of the third-party agent so that the covered entity can comply with its notice requirements. A covered entity may enter into a contractual agreement with a third-party agent whereby the third-party agent agrees to handle notifications required under this act.

Section 9. (a) A violation of the notification provisions of this act is an unlawful trade practice under the Alabama Deceptive Trade Practices Act, Chapter 19, Title 8, Code of Alabama 1975, but does not constitute a criminal offense under Section 8-19-12, Code of Alabama 1975. The Attorney General shall have the exclusive authority to bring an action for civil penalties under this act.

- (1) A violation of this act does not establish a private cause of action under Section 8-19-10, Code of Alabama 1975. Nothing in this act may otherwise be construed to affect any right a person may have at common law, by statute, or otherwise.
- (2) Any covered entity or third-party agent who is knowingly engaging in or has knowingly engaged in a violation of the notification provisions of this act will be subject to the penalty provisions set out in Section 8-19-11, Code of Alabama 1975. For the purposes of this act, knowingly shall

mean willfully or with reckless disregard in failing to comply
with the notice requirements of Sections 5 and 6. Civil
penalties assessed under Section 8-19-11, Code of Alabama
1975, shall not exceed five hundred thousand dollars
(\$500,000) per breach.

- (b) (1) Notwithstanding any remedy available under subdivision (2) of subsection (a) of this section, a covered entity that violates the notification provisions of this act shall be liable for a civil penalty of not more than five thousand dollars (\$5,000) per day for each consecutive day that the covered entity fails to take reasonable action to comply with the notice provisions of this act.
- (2) The office of the Attorney General shall have the exclusive authority to bring an action for damages in a representative capacity on behalf of any named individual or individuals. In such an action brought by the office of the Attorney General, recovery shall be limited to actual damages suffered by the person or persons, plus reasonable attorney's fees and costs.
- (3) It is not a violation of this act to refrain from providing any notice required under this act if a court of competent jurisdiction has directed otherwise.
- (4) To the extent that notification is required under this act as the result of a breach experienced by a third-party agent, a failure to inform the covered entity of

1	the breach shall subject the third-party agent to the fine	s
2	and penalties set forth in the act.	

- (5) Government entities shall be subject to the notice requirements of this act. A government entity that acquires and maintains sensitive personally identifying information from a government employer, and which is required to provide notice to any individual under this act, must also notify the employing government entity of any individual to whom the information relates.
- (6) All government entities are exempt from any civil penalty authorized by this act; provided, however, the Attorney General may bring an action against any state, county, or municipal official or employee, in his or her official capacity, who is subject to this act for any of the following:
- a. To compel the performance of his or her duties under this act.
- b. To compel the performance of his or her ministerial acts under this act.
- c. To enjoin him or her from acting in bad faith, fraudulently, beyond his or her authority, or under mistaken interpretation of the law.
- (7) By February 1 of each year, the Attorney General shall submit a report to the Governor, the President Pro
  Tempore of the Senate, and the Speaker of the House of

Representatives describing the nature of any reported breaches of security by government entities or third-party agents of government entities in the preceding calendar year along with recommendations for security improvements. The report shall identify any government entity that has violated any of the applicable requirements in this act in the preceding calendar year.

Section 10. A covered entity or third-party agent shall take reasonable measures to dispose, or arrange for the disposal, of records containing sensitive personally identifying information within its custody or control when the records are no longer to be retained pursuant to applicable law, regulations, or business needs. Disposal shall include shredding, erasing, or otherwise modifying the personal information in the records to make it unreadable or undecipherable through any reasonable means consistent with industry standards.

Section 11. An entity subject to or regulated by federal laws, rules, regulations, procedures, or guidance on data breach notification established or enforced by the federal government is exempt from this act as long as the entity does all of the following:

(1) Maintains procedures pursuant to those laws, rules, regulations, procedures, or guidance.

1	(2) Provides notice to affected individuals pursuant
2	to those laws, rules, regulations, procedures, or guidance.
3	(3) Timely provides a copy of the notice to the
4	Attorney General when the number of individuals the entity
5	notified exceeds 1,000.
6	Section 12. An entity subject to or regulated by
7	state laws, rules, regulations, procedures, or guidance on
8	data breach notification that are established or enforced by
9	state government, and are at least as thorough as the notice
10	requirements provided by this act, is exempt from this act so
11	long as the entity does all of the following:
12	(1) Maintains procedures pursuant to those laws,
13	rules, regulations, procedures, or guidance.
14	(2) Provides notice to affected individuals pursuant
15	to the notice requirements of those laws, rules, regulations,
16	procedures, or guidance.
17	(3) Timely provides a copy of the notice to the
18	Attorney General when the number of individuals the entity
19	notified exceeds 1,000.
20	Section 13. This act shall become effective on the
21	first day of the third month following its passage and
22	approval by the Governor, or its otherwise becoming law.

1	
2	
	<b>*</b>
3	Del Mal
4	President and Presiding Officer of the Senate
5	Mac Mcatchan
6	Speaker of the House of Representatives
7	SB318
8 9 10 11	Senate 01-MAR-18 I hereby certify that the within Act originated in and passed the Senate, as amended.
12 13 14	Patrick Harris, Secretary.
15	
16	
17 18	House of Representatives Amended and passed 22-MAR-18
19	
20	
21	Senate concurred in House amendment 27-MAR-18
22	
23	APPROVED
24	By: Senator OrrTIME 3:37 Pw
	Alabama Secretary Of State
	COVEDNOD Act Num: 2018-396 Bill Num: S-318

Recv'd 03/28/18 04:21pmSLF

# HOUSE ACTION (Continued)

HOUSE OF REPART SENTATIVES.

R. 201 Journal and Despoil Of News.

Mays. Of L. Nays.

Data 3.22-1

Data Among Clark.

このできょう から 水道 自動のなった

**e**Visic<sup>™</sup>

(https://evisit.com/)



# Welcome to the eVisit Resources

A resource for physicians, practice managers, and other healthcare professionals. Join thousands of providers and practice managers.

**Email Address** 

Email must be formatted correctly.

**SUBSCRIBE** 

The Ultimate Telemedicine Guide | What Is Telemedicine? May 25, 2018 in



## What is Telemedicine?

Learn about this rapidly expanding field in our definitive guide.

Telemedicine is a relatively new concept, and in the world of internet, it develops with lightning speed. This article is for those who want to understand all intricacies of this highly dynamic and fascinating field.

#### **Table of Content:**

- 1. History of Telemedicine (https://evisit.com/what-is-telemedicine/#1)
- 2. Telemedicine Today (https://evisit.com/what-is-telemedicine/#2)
- 3. The Difference Between Telemedicine and Telehealth (https://evisit.com/what-is-telemedicine/#3)
- 4. Telemedicine Pros and Cons (https://evisit.com/what-is-telemedicine/#4)
- 5. Top Telemedicine Medical Specialties (https://evisit.com/what-is-telemedicine/#5)
- 6. What services can be provided by telemedicine (https://evisit.com/what-is-telemedicine/#6)
- 7. How Telemedicine Can be Used (https://evisit.com/what-is-telemedicine/#7)
- 8. Types of Telemedicine (https://evisit.com/what-is-telemedicine/#8)
- 9. Telemedicine Clinical Guidelines (https://evisit.com/what-is-telemedicine/#9)

- 10. Telemedicine and Medicare (https://evisit.com/what-is-telemedicine/#10)
- 11. Telemedicine and Medicaid (https://evisit.com/what-is-telemedicine/#11)
- 12. Future of Telemedicine (https://evisit.com/what-is-telemedicine/#12)
- 13. Telemedicine Statistics (https://evisit.com/what-is-telemedicine/#13)
- 14. Telehealth Resource Centers (https://evisit.com/what-is-telemedicine/#14)
- 15. Telemedicine Regulations (https://evisit.com/what-is-telemedicine/#15)
- 16. Barriers to Telemedicine (https://evisit.com/what-is-telemedicine/#16)
- 17. Who Pays for Telemedicine (https://evisit.com/what-is-telemedicine/#17)
- 18. HIPAA and Telemedicine (https://evisit.com/what-is-telemedicine/#18)
- 19. Telemedicine Terms (https://evisit.com/what-is-telemedicine/#19)

#### 1. History of Telemedicine

The field of telemedicine has changed drastically from its inception. It was only about fifty years ago that a few hospitals started experimenting with telemedicine to reach patients in remote locations. But with the rapid changes in <a href="technology">technology</a> (<a href="https://evisit.com/resources/what-is-telemedicine-technology/">https://evisit.com/resources/what-is-telemedicine-technology/</a>) over the last few decades, telemedicine has transformed into a complex integrated service used in hospitals, homes, private physician offices, and other healthcare facilities.

The concept of telemedicine started with the birth of <u>telecommunications technology</u> (<a href="http://evisit.com/telehealth-telemedicine-technology/">http://evisit.com/telehealth-telemedicine-technology/</a>), the means of sending information over a distance in the form of electromagnetic signals. Early forms of telecommunications technology included the telegraph, radio, and telephone. In the la 19th century, the radio and telephone were just starting to emerge as viable communication technologies. Alexander Graham Bell patented the telephone in 1876 and Heinrich Rudolf Hertz performed the first radio transmission in 1887.



But it wasn't until the early 20th century that the general population started to these technologies, and imagine they could be applied to the field of medicine. In 1925, a covillustration of the <u>Science and Invention magazine</u>

(http://www.smithsonianmag.com/history/telemedicine-predicted-in-1925-124140942/no-ist) featured an odd invention by Dr. Hugo Gernsback, called the "teledactyl." The imagined tool would use spindly robot fingers and radio technology to examine a patie from afar, and show the doctor a video feed of the patient. While this invention never past the concept stage, it predicted the popular telemedicine definition we think of too – a remote video consult between doctor and patient.

Several decades later, in the 1950's, a few hospital systems and university-based medic centers experimenting with how to put concept of telemedicine into practice. Medical staff at two different health centers in Pennsylvania about 24 miles apart transmitted radiologic images via telephone. In 1950's, a Canadian doctor built upon this technolog into a Teleradiology system (http://evisit.com/what-is-teleradiology/) that was used in and around Montreal. Then, in 1959, Doctors at the University of Nebraska were able t transmit neurological examinations to medical students across campus via a two-way interactive television. By 1964, they had built a telemedicine link that allowed them to provide health services at Norfolk State Hospital, 112 miles away from campus.

Originally, health professionals developed this technology to reach remote patients liv in the rural areas. But with time, medical staff and the U.S. government saw the big picture – the potential to reach urban populations with healthcare shortages, and to respond to medical emergencies by sharing medical consults and patient health reconwithout delay. In the 1960s, heavy investments from the U.S. Government, including the Public Health Department, NASA, Department of Defense, and the Health and Human Sciences Department drove research and innovation in telemedicine. Sending cardiac rhythms during emergencies started at about this time. For instance, in Miami, the university medical center worked together with the fire rescue department by sending electro-cardiac rhythm signals over the voice radio channels from the rescue sites.



One especially successful telemedicine project funded by the government was called the Space Technology Applied to Rural Papago Advanced Health Care (STARPAHC), and was partnership between NASA and the Indian Health Services. The program funded remormedical services to Native Americans living on the Papago Reservation in Arizona and astronauts in space! Projects like STARPAHC drove research in medical engineering, and helped expand advancements in telemedicine. The next few decades saw continued innovations in telemedicine and wider research at universities, medical centers and research companies.

#### 2. Telemedicine Today

Today the telemedicine field is changing faster than ever before. As technology advance at exponential levels, so does the widespread affordability and accessibility to basic telemedicine tools. For example, not only do we now have the technology for live videoutelemedicine, but much of the U.S. population has experience using online videochat apps (like Skype or Facetime), and access to a computer or mobile device to use them.

Telemedicine was originally created as a way to treat patients who were located in remote places, far away from local health facilities or in areas of with shortages of medical professionals. While telemedicine is still used today to address these problem it's increasingly becoming a tool for convenient medical care. Today's connected patier wants to waste less time in the waiting room at the doctor, and get immediate care for minor but urgent conditions when they need it.

This expectation for more convenient care, combined with the unavailability of many overburdened medical professionals (especially primary care providers) have led to the rise of telemedicine companies. Many offer patients 24/7 access to medical care with a on-call doctor contracted by that company. Others offer hospitals and larger health centers access to extra clinical staff and specialists, for outsourcing of special cases (common model among teleradiology companies). Still others provide a telemedicine platform (http://evisit.com/telemedicine-platform/) for physicians to use to offer virtua visits with their own patients. Increasingly, telemedicine is becoming a way to give medical practices an edge in a competitive healthcare landscape where it's dif to stay independent or maintain a healthy bottom line.

Also impacting the rise of telemedicine today is the growing mobile health field. With t wide variety of mobile health apps and new mobile medical devices that are consumer friendly, patients are starting to use technology to monitor and track their health. Simphome-use medical devices that can take vitals and diagnose ear infections, monitor glucose levels, or measure <u>blood pressure (http://www.well-beingsecrets.com/spirulingbenefits/)</u> let patients gather needed medical information for a doctor's diagnosis, without going into the doctor's office. And again, as more patients get proactive about using technology to manage their health, they also will be more open to alternative wa to get care – through telemedicine!



#### 3. Difference between telemedicine and telehealth

With the interrelated fields of mobile health, digital health, health IT, telemedicine all constantly changing with new developments, it's sometimes difficult to pin down a definition for these terms (http://evisit.com/what-is-the-difference-between-telemedicine-telecare-and-telehealth/). In much of the healthcare industry, the terms "telehealth" and "telemedicine" are often used interchangeably. In fact, even the ATA considers them to be interchangeable terms. This isn't surprising since the telehealth and telemedicine definitions encompass very similar services, including: medical education, e-health patient monitoring, patient consultation via video conferencing, health wireless applications, transmission of image medical reports, and many more.

However, if you want to get technical, telemedicine is really a subset of telehealth. Whereas telehealth is a broad term that includes all health services provided telecommunications technology, telemedicine refers specifically to clinical services.

There's how the California Telehealth Resource Center defines telehealth:

"Telehealth is a collection of means or methods for enhancing health care, public healt and health education delivery and support using telecommunications technologies."

Telehealth may involve more general health services, like public health services, where telemedicine is a specific kind of telehealth that involves a clinician providing some kin of medical services.

Here are a couple quick examples:

Telehealth (https://evisit.com/resources/what-is-telehealth-services/):

A public health app that alerts the public of a disease outbreak A video-conferencing platform for medical education

### Telemedicine:

A mobile app that lets physicians treat their patients remotely via video-chat A software solution that lets primary care providers send patient photos of a rash or mole to a dermatologist at another location for quick diagnosis

As the field of telehealth continues to expand and change, these terms are likely to change and encompass even more health services.

## 4. Telemedicine Pros and Cons

In most cases, telemedicine is a net benefit. It expands access to quality patient care, especially to regions and underserved populations that need it the most. It provides a way to cut down on healthcare spending and engage today's connected patient. It has the potential to change the healthcare delivery model for the better.

However, telemedicine also has a few downsides — by nature of its virtual interaction, and because of societal and technological barriers that could change in the future. The good news is, with the growing popularity and widespread acceptance of telemedicine resolve themselves. With new technological

advancements and shifting policy that increasingly supports telemedicine, we're continuously finding ways to improve telemedicine and make it a viable, even advantageous form of healthcare delivery for many medical scenarios.

Here's a quick overview of the top pros and cons of telemedicine:

Pros of Telemedicine

More convenient, accessible care for patients

More accessible, convenient healthcare for patients is the driving force behind the telemedicine field. Telemedicine was originally developed in the U.S. as a way to addre care shortages, especially in remote rural areas. Now telemedicine is used around the world, whether it's to provide basic healthcare in third-world countries or allow an elderly patient with mobility issues to see the doctor from home. Telemedicine has the power not only to break down typical geographical barriers to care access, but to make the entire healthcare delivery model more convenient to patients.



Saves on Healthcare costs

The U.S. spends over <u>\$2.9 trillion (https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-</u>

Reports/NationalHealthExpendData/downloads/highlights.pdf) on healthcare every ye more than any other developed nation. On top of that, an estimated \$200 billion (http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aadc 75 71ad8c22a/?vgnextoid=bb321cbfa3401410VgnVCM10000076192ca2RCRD) of co

are avoidable, unnecessary spending. Telemedicine has the power to cut our healthcal spending by reducing problems like medication non-adherence and unnecessary ER visits, and making typical doctor visits more efficient.

Extends access to consults from specialists

With telemedicine, a medical practice or hospital system can immediately expand acce to niche medical specialists. This makes it easy for primary care doctors to consult medical specialists on a patient case, and for patients to see a needed specialist on a rare form of cancer, no matter their location. As another example, small hospitals without adequate radiology specialist on-staff can outsource evaluation of x-rays via telemedicine.

Increasing patient engagement

Today's patient lives in an increasingly connected world and expects a different kind of care experience. Telemedicine engages patients by allowing them to connect with thei doctor more frequently, in a convenient way. That means more questions asked and answered, a stronger doctor-patient relationship, and patients who feel empowered to manage their care.

Better quality patient care

Telemedicine makes it easier for providers to follow-up with patients and make sure everything is going well. Whether they're using a more extensive remote patient monitoring system to watch the patient's heart, or doing a videochat to answer medication questions after a hospital discharge – telemedicine leads to better care outcomes.

For a longer list of the benefits of telemedicine, see Why Telemedicine (http://evisit.com/why-telemedicine/)

Cons

Requires technical training and equipment



Like most technology solutions, telemedicine platforms usually require some training and equipment purchases. How much is really dependent on the solution – a more extensive inpatient telemedicine platform that will be used between primary doctors a consulting specialist may require more training and the purchase of a telemedicine can and various mobile health devices. A secure videochat app like eVisit, requires much le staff training and usually only requires purchase of a webcam.

Some telemedicine models may reduce care continuity

Telemedicine companies that are consumer-facing offer the huge benefit of on-demar care for patients. A sick patient can simply login online and request a visit with one of t telemedicine company's doctors and get treatment. But this model, similar to the retain health movement, leads to a breakdown in care continuity. A random doctor who does know the patient, doesn't know their whole medical history. The best approach to telemedicine? Providing tools to providers to easily connect with their own patients.

May reduce in-person interactions with doctors

Some critics of telemedicine argue that online interactions are impersonal, and physical exams are often necessary to make a full diagnosis. If more patients are resorting to online interactions in place of in-person visits, what effects will that have?

In-person patient-doctor visits are clearly valuable and necessary in many circumstanc Telemedicine is best used to supplement these visits – to do simple check-ins with patients and make sure everything is going well. For minor acute conditions (like infections), an in-person visit with an established patient is often not needed. In those cases, telemedicine can save the patient, the doctor, and the healthcare system time a money.

Navigating the changing policy and reimbursement landscape can be tricky

Telemedicine reimbursement is a difficult topic, especially with the constantly <a href="mailto:changin;">changin;</a>
<a href="mailto:state-policies">state policies (http://evisit.com/state-policy-landscape/)</a>. Many states now have parity laws which require <a href="private-payers">private payers to reimburse for telemedicine visits</a>

(http://evisit.com/telemedicine-private-payers-issues/) the same way as in-person visits

The best way to navigate reimbursement is to call up your top payers and ask their policies. You can also check out our guide to telemedicine reimbursement and this helpful matrix from ATA (http://www.americantelemed.org/docs/default-source/policy/2015-ata-state-legislation-matrix.pdf?sfvrsn=4) on state policy.

It's also important to note that many doctors using telemedicine will charge the patien convenience fee, ranging from \$35 – \$125 per visit. This fee is direct from the patient a is on top of (or in place of) any reimbursement through a payer. While that means patients are paying out-of-pocket, many of eVisit's clients have found patients don't mind, and in fact are happy to pay the additional fee for the convenience.

# 5. Top Telemedicine Medical Specialties

Telemedicine is used in many different medical fields, throughout ambulatory and hospital settings. Almost every medical field has some use for consulting a patient or another provider (usually a specialist) remotely. Because of shortages of care, limited access to specialists in some areas, and remote locations of patients (especially in rura or sparsely populated areas), telemedicine is incredibly useful to any healthcare provic trying to expand access to quality patient care.

Some medical specialties were early adopters of telemedicine and have pushed development of solutions specifically for their specialty. As a result, there are several k niche telemedicine specialties. Here are some of the most popular telemedicine solutions specialties:

<u>Teleradiology (https://evisit.com/resources/what-is-telepsychiatry/)</u> – Teleradiology is actua one of the earliest fields of telemedicine, beginning in the 1960s. Teleradiology solutio were developed to expand access to diagnosticians of x-rays. Smaller hospitals arounc the U.S. may not always have a radiologist on staff, or may not have access to one around the clock. That means patients coming into the ER, especially during off-hours, will have to wait for diagnosis. Teleradiology solutions now offer providers at one location to send a patient's x-rays and records securely to a qualified radiologist at another location, and get a quick consult on the patient's condition.

**Telepsychiatry** – Telepsychiatry allows qualified psychiatrists to provide treatment to patients remotely, expanding access to behavioral health services. <u>Telepsychiatry</u> (<a href="http://evisit.com/telepsychiatry-software-solutions/">http://evisit.com/telepsychiatry-software-solutions/</a>) is incredibly popular, in part because of the nation-wide shortage of available psychiatrists, and because psychiatry often does not require the same physical exams of the medical field.

Teledermatology (https://evisit.com/resources/what-is-teledermatology/) – Teledermatology solutions are usually store-and-forward technologies that allow a general healthcare provider to send a patient photo of a rash, a mole, or another skin anomaly, for remot diagnosis. As frontline providers of care, primary care practitioners are often the first medical professionals to spot a potential problem. Teledermatology solutions lets PCP continue to coordinate a patient's care, and offer a quick answer on whether further examination is needed from a dermatologist.

**Teleophthalmology** – Teleophthalmology solutions allow opthamologists to examine patients' eyes, or check-in about treatments from a distance. A common example is an opthamologist diagnosing and treating an eye infection. These solutions are usually either live or store-and-forward telemedicine.

<u>Telenephrology (https://evisit.com/resources/what-is-telenephrology/)</u> – telenephrology is nephrology practiced at a distance. Telenephrology solutions are most commonly used interprofessionally, when a family physician needs to consult a nephrologist about a patient with kidney disease.

**Teleobstetrics** – teleobstetrics allow obstetricians to provide prenatal care from afar. Th could mean, for example, recording a baby's heart at one location and forwarding it to an obstetrician for diagnosis at another facility.

**Teleoncology** – the teleoncology field has quickly expanded in the last few years, to provide more accessible and convenient care to patients with cancer. While some teleoncology solutions offer store-and-forward tools to forward images for diagnosis, others are live video platforms to allow patient consults with the oncologist.

<u>Telepathology (https://evisit.com/resources/what-is-telepathology/)</u> – telepathology solutio let pathologists share pathology at a distance for diagnosis, research, and education. Most telepathology tools are store-and-forward solutions, allowing pathologists to sha and forward high-resolution images and videos.

**Telerehabilitation** – telerehabilitation allow medical professionals to deliver re' (such as physical therapy) remotely.

Vic

# 6. What services can be provided by telemedicine

Telemedicine can be used for a wide variety of health services. Here's a short list of common conditions a primary care doctor may treat via telemedicine:

Allergies (http://www.webmd.com/allergies/)

Arthritic Pain (http://www.arthritis.org/living-with-arthritis/pain-management/)

Asthma (http://www.nhlbi.nih.gov/health/health-topics/topics/asthma)

Bronchitis (http://www.mayoclinic.org/diseases-

conditions/bronchitis/basics/definition/con-20014956)

Colds and Flu

Diarrhea

Infections

**Insect Bites** 

Pharyngitis

Conjunctivitis

Rashes

**Respiratory Infections** 

**Sinusitis** 

Skin Inflammations

Cellulitis

Sore Throats

**Sprains & Strains** 

**Bladder Infections** 

**UTIs** 

**Sports Injuries** 

Vomiting

Telemedicine services can range widely by specialty. A surgeon might use telemedicine to do post-operation check-ins with patients, to make sure their wound is not infected. gynecologist might use a live telemedicine solution to provide birth control counseling An endocrinologist may do live videochats with patients to discuss recent lab results an answer questions.

The list goes on. If you're still curious about what services telemedicine is best used for review this list of Medicare-reimbursed telemedicine services

(http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf) below. It's by no means a complete list, but it shows you the wide range of health services via telemedicine that a already reimbursable.

7. How does telemedicine work/How can it be used/Types of telemedicine

So by now you know what telemedicine is. But how are <u>telemedicine systems</u> (<a href="http://evisit.com/telehealth-systems/">http://evisit.com/telehealth-systems/</a>) actually delivered? What kinds of technology allows digital connections between a provider at a large hospital and a patient in a remote, rural home?

With the expansion of the internet, much of how telemedicine is delivered has change. Now, with a simple internet connection, many patients in remote areas can participate at least some <u>types of telemedicine</u> (<a href="http://evisit.com/what-are-the-types-of-telemedicine/">http://evisit.com/what-are-the-types-of-telemedicine/</a>). Here are a few examples of telemedicine connections.

# Networked Programs

Networked connections (like high speed internet lines) are typically used to link remote health clinics to larger health facilities like metropolitan hospitals. According to the AT/ there are about 200 networked telemedicine programs in the U.S., granting telemedici access to more than 3000 rural sites.

# Point-to-point Connections

Point-to-point connections link small remote health centers to one, large, central healt facility via high speed internet. This type of telemedicine connection lets smaller or understaffed clinics outsource medical care to specialists at other locations within the same health system. Point-to-point connections are especially common for telepsychiatry, teleradiology, and urgent care services.

## Monitoring Center Links

Monitoring center links are used for one type of telemedicine – remote patient monitoring. This type of telemedicine link creates a digital connection between a patient's house and a remote monitoring facility, so that a patient's medical data can b measured at home and transmitted electronically to a distant medical monitoring facil These links usually take the form of internet, SMS, or telephone connections. They're most commonly used for monitoring of pulmonary, cardiac, or fetal medical data.

# 8. Types of Telemedicine

What do you envision when someone says "telemedicine"? The most popular image is probably a doctor consulting a patient via a videochat platform. Two-way video conferencing is quickly becoming a popular virtual alternative to in-person doctor visits.

A telemedicine definition encompasses a much broader range of healthcare services than just real-time medical consultations over video. Telemedicine includes any clinica services provided via telecommunications technology. Here's a summary of the main types of telemedicine.

### Store-and-forward telemedicine solutions

Sometimes called asynchronous telemedicine, store-and-forward solutions enable healthcare providers to forward and share patient medical data (lab results, images, videos, records) with a provider at a different location. These platforms offer a kind of sophisticated, secure, email platform – a way to share private patient data online in a secure way.

The asynchronous term refers to the fact that the consulting specialist, patient, and primary doctor don't need to all be communicating at the same time. As a parallel, thir about a telephone call versus an email exchange. A telephone call (synchronous) requires all parties to be communicating in real-time – an email exchange does not.

Store-and-forward telemedicine works best for interprofessional medical services – where a provider needs to outsource diagnosis to a specialist. For instance, teleradiolc relies heavily on store-and-forward technology to allow technicians and health

professionals at smaller hospitals to share patient x-rays for diagnosis by a specialist a another location. Asynchronous telemedicine is also commonly used for teledermatology and teleophthalmology.

Store-and-forward telemedicine is a great way to increase <a href="http://www.well-beingsecrets.com/lose-20-pounds-one-month/">heterore-month/</a>) efficiency since a provider, patient, and specialist don't need to be in the same place, at the same time. It also facilitates faster diagnosis, especially for patients located in underserved settings that may not have the necessary specialist on staff. Overall, this adds up to lower patient wait times, more accessible healthcare, better patient outcomes, and a more optimized schedule for physicians.

## Remote patient monitoring

Telemedicine solutions that fall into the remote patient monitoring (RPM) allow healthcare providers to track a patient's vital signs and other health data from a distan This makes it easy to watch for warning signs and quickly intervene in patients who are at health-risk or are recovering from a recent surgery, for example. This type of telemedicine is sometimes also called telemonitoring or home telehealth.

RPM telemedicine is quickly rising in popularity as more health professionals realize its potential effects on chronic care management. For instance, a patient with diabetes whas a glucose tracker in their home can measure their glucose levels at regular interva and transmit them to their doctor. If all is well, those results are simply recorded. If something looks off, the physician may flag it and call in the patient for a consult.

Like most telemedicine tools, remote patient monitoring solutions make it easier for patients and physicians to maintain close communication. Many RPM solutions record and transmit a patient's medical data automatically, generating a regular report for the physician. In some cases, this medical data is transmitted to a team of health monitori professionals who are responsible for flagging any warning signs and sending them or to the physician, if needed.

The key to successful remote patient monitoring telemedicine is having the right healtl tracking tools in the patient's home. With the recent growth of wearables and mobile medical devices, this is getting easier. Patients have better, cheaper, more accessible tools at their disposal for tracking their health signs and reporting medical data.

#### Real-time telehealth

Real-time telemedicine (also called "synchronous telemedicine") is probably what most people first think of when they hear "telemedicine." Real-time telemedicine requires a live interaction between either a health professional and patient, or between health professionals, using audio and video communication. Think videochat. While most rea time telemedicine software (http://evisit.com/telemedicine-software/) is much more sophisticated than a simple videochat platform, the basic goal is to both see and talk to the patient from afar. This type of telemedicine is meant to offer a virtual alternative to the in-person doctor's visit.

The popularity of real-time telemedicine solutions has increased rapidly in the past fev years, as companies like Teladoc and DoctoronDemand have offered an affordable, ea way for patients to connect with a doctor from anywhere and get immediate treatmen Doctors are also starting to adopt real-time telemedicine solutions to give their patient the added convenience of virtual doctor visits, improve their care outcomes, boost wollife balance, and reap the many other benefits. With simply a compatible device, interr connection, microphone, and webcam – a patient can now get medical treatment. That the beauty of real-time telemedicine.

#### 9. Telemedicine Clinical Guidelines

While the industry is still a long way from a standard set of established guidelines for telemedicine, the American Telemedicine Association has put together guidelines for a <u>range of specialties (http://www.americantelemed.org/resources/telemedicine-practice-guidelines/telemedicine-practice-guidelines#.VckQYvlViko)</u> based on a survey hundreds of research study. What are the clinical, technical, and administrative guidelines a medical practice needs to put in place when they're adopting telemedicine Beyond the minimal legal requirements of that state, what are telemedicine is practices?

Based on over 600 studies, the AMA has put together a comprehensive set of guideling for professionals using telemedicine in primary and urgent care – a field that is quickly adopting telemedicine to expand basic healthcare access. Here are some of the basic protocols and rules a primary care or urgent care facility should put into place when starting their telemedicine program.

#### When to use telemedicine

While many conditions not on this list can be treated via telemedicine, these condition are an especially good fit for telemedicine: <u>Allergies</u>

(<a href="http://www.webmd.com/allergies/">http://www.webmd.com/allergies/</a>) and <a href="http://www.aaaai.org/conditions-and-treatments/asthma">asthma</a> (<a href="http://www.aaaai.org/conditions-and-treatments/asthma">http://www.aaaai.org/conditions-and-treatments/asthma</a>), <a href="http://www.aaaai.org/conditions-and-treatments/asthma">Chronic bronchitis</a>

(<a href="http://www.medicinenet.com/chronic\_bronchitis/article.htm">http://www.medicinenet.com/chronic\_bronchitis/article.htm</a>), Conjunctivitis
(<a href="http://www.webmd.com/eye-health/eye-health-conjunctivitis">http://www.webmd.com/eye-health/eye-health-conjunctivitis</a>), UTIs, <a href="http://www.webmd.com/eye-health-conjunctivitis">Low back pain</a>
(<a href="http://www.webmd.com/eye-health-conjunctivitis">http://www.webmd.com/eye-health/eye-health-conjunctivitis</a>), UTIs, <a href="http://www.webmd.com/eye-health-conjunctivitis">Low back pain</a>
(<a href="http://www.webmd.com/eye-health-conjunctivitis">http://www.webmd.com/eye-health/eye-health-conjunctivitis</a>), Otitis media, Rashes, <a href="http://www.webmd.com/eye-health-conjunctivitis">UTIs, Low back pain</a>
(<a href="http://www.webmd.com/eye-health-conjunctivitis">http://www.webmd.com/eye-health/eye-health-conjunctivitis</a>), Otitis media, Rashes, <a href="http://www.webmd.com/eye-health-conjunctivitis">Utilis</a>

(http://www.medicinenet.com/upper\_respiratory\_infection/article.htm),
Diabetes, Hypertension (http://www.well-beingsecrets.com/detox-of-your-body-35-natural-ways/), Mental illness/behavioral health (http://www.well-beingsecrets.com/health-benefits-of-coconut-oil/), Prevention and wellness (http://www.well-beingsecrets.com/fatty-liver-diet/) services.

Telemedicine should not be used for any condition where an in-person exam is require because of severe symptoms, certain protocol-driven procedures, or aggressive interventions. Also, for a medical emergency patients should go to the ER or call 911.

Healthcare providers should use their professional judgement to decide when telemedicine is appropriate.

### When to prescribe

Prescribing is acceptable for live-video telemedicine sessions, where the visit cassubstitute for an in-person exam. Prescribing is also ok for telephone consult as long as the provider has a pre-existing relationship with the patient.

Informing the patient

Only some states have actually regulations requiring healthcare providers to get patier informed consent to use telemedicine. However, this is always good practice, whether not your state requires it. Before the first telemedicine visit, providers should explain t patients how telemedicine works (when service is available, scheduling, privacy etc), ar limits on confidentiality, possibility for technical failure, protocols for contact between virtual visits, prescribing policies, and coordinating care with other health professional Everything should be explained in simple, clear language.

Set-up the right space for telemedicine visits

Healthcare providers should create a dedicated space for telemedicine visits to ensure privacy, proper lighting and audio, and avoid interruptions. When possible, providers should place their camera on a level stand and position the camera at eye-level.

Create a contingency plan for emergencies and referrals

Establish a plan for emergencies and communicate it to the patient before the visit. Make sure to have all information on hand for referrals and request transfers.

Patient Management and Evaluation

Always interact with the patient in a culturally competent way, in the language familiar that patient. If the patient cannot understand because of language barrier, telemedicir should not be used.

It is up to the healthcare provider to use professional judgment to determine when telemedicine is appropriate for the patient case, and when it is not. Also, the patient evaluation should be based on the patient's medical history and access to their medical record whenever possible.

To guide these decisions, the provider should create clinical protocols which include the condition to be treated (with ICD code), scope of that condition that can be treated using telemedicine, guidelines required to diagnose (when is telephone sufficient, video), documentation needed to properly assess the patient's condition, parameters for the provider of the provider of the provider should create clinical protocols which include the condition to be treated (with ICD code), scope of that condition that can be treated using the provider of the provi

when the condition can be treated and cannot be treated, and guidelines for when prescription can be done. While this section provides basic, overall guidelines for practicing telemedicine, it's best practices for the <a href="healthcare">healthcare</a>

(<a href="http://www.atlassteak.com/health-benefits-of-steak/">http://www.atlassteak.com/health-benefits-of-steak/</a>) provider to create more detailed protocols for each condition they intend to treat.

Needed information to diagnose includes:

Identifying information
source of the history
chief complaint
history of present illness
associated signs & symptoms
past medical history
family history
personal and social history
medication review
allergies
detailed review of symptoms
provider-directed patient self-examination (including mobile medical devices if needec

# Quality Assurance

Healthcare providers should do regular quality checks on telemedicine services to identify any potential risks and failures (such as with equipment or connectivity, and patient or provider complaints).

Billing

Providers should inform patients of their cost for service before the visit, whenever possible.

In general, follow the same standards as in-person medical services



Providers should continue to follow the standards they would for any in-person medic visit. For instance, they should practice by the same code of ethics, comply with securit guidelines of HIPAA, provide proper documentation to the patient's primary care provider, follow their licensing and credentialing guidelines.

For more details on guidelines for practicing telemedicine, visit the <u>ATA website</u> (<a href="http://www.americantelemed.org/resources/telemedicine-practice-guidelines/telemedicine-practice-guidelines/practice-guidelines-for-live-on-demand-primary-and-urgent-care#.VckQkflViko">http://www.americantelemed.org/resources/telemedicine-practice-guidelines-for-live-on-demand-guidelines/telemedicine-practice-guidelines-for-live-on-demand-primary-and-urgent-care#.VckQkflViko</a>).

### 10. Telemedicine and Medicare

Initially, <u>Medicare only reimbursed providers (http://evisit.com/medicare-telemedicine reimbursement/)</u> for very specific health services provided via telemedicine, often with strict requirements. In the past few years with the rapid growth in the telemedicine industry, Medicare has expanded the list of reimbursable telemedicine services but st imposes many restrictions on how the service is provided.

Here are a few things you should know about Medicare and Telemedicine.

**Defining the Originating and Distant Sites.** Medicare reimburses for <u>telehealth servic</u> (<a href="http://evisit.com/telehealth-systems/">http://evisit.com/telehealth-systems/</a>) offered by a healthcare provider at a distant site to a Medicare beneficiary (the patient) at an Originating Site. The originating site must in a HPSA (Health Professional Shortage Area). The types of originating sites authorize by law are:

physicians or practitioner offices

Hospitals

Critical Access Hospitals (CAH)

**Rural Health Clinics** 

Federally Qualified Health Centers



Hospital-based or CAH-based Renal Dialysis Centers

Skilled Nursing Facilities (SNF)

Community Mental Health Centers (CMHC).

Note: Independent Renal Dialysis Facilities are not eligible originating sites.

The patient must be in a HPSA. In order to be eligible for Medicare reimbursement, the patient (Medicare beneficiary) needs to be receiving virtual care at one of the clinical settings mentioned above, that is also located within a Health Professional Shortage Al (HPSA). To see if the health facility is in a HPSA, use <a href="this://datawarehouse.hrsa.gov/GeoAdvisor/ShortageDesignationAdvisor.aspx">this: CMS tool</a> (<a href="http://datawarehouse.hrsa.gov/GeoAdvisor/ShortageDesignationAdvisor.aspx">http://datawarehouse.hrsa.gov/GeoAdvisor/ShortageDesignationAdvisor.aspx</a>)

**Facility Fees.** In addition to reimbursement for the telemedicine service, Medicare will pay the originating site a facility fee. For example, if you're a primary care provider with patient in your office and you do a telemedicine visit to consult a physician in another location, you could bill for two separate things – the telemedicine service, and a facility fee for using your practice to "host" of the patient visit. Check HCPCS code Q3014 for a full description on facility fees.

**Eligible Providers.** Under Medicare, the following healthcare providers can use telemedicine:

Physicians

**Nurse Practitioners** 

Physician Assistants

**Nurse Midwives** 

Clinical nurse specialists

Clinical Psychologists

Clinical Social Workers

Registered dietitians or nutrition professionals

**Type of telehealth.** Medicare primarily only reimburses for live telemedicine, the physician and patient are interacting in real-time through secure, videochat. This type

telemedicine visit is meant to substitute a face-to-face in-person visit. The only exception is in Hawaii and Alaska, where Medicare reimburses for store-and-forward telemedicinas well.

Only certain CPT and HCPCS codes are eligible for telemedicine reimbursement. Medicare has a specific list of CPT and HCPCS codes (https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/telehealthsrvcsfctsht.pdf) that are covered under telemedicine services. Since that list is subject to change each year, we recommend yo also periodically check the CMS website for the most up-to-date codes.

When billing, use the GT modifier. When billing for telemedicine visits, you need to include the "GT" modifier with the relevant CPT code to indicate the service was provid virtually.

Find out the Medicare reimbursement rates. Curious what Medicare will reimburse for a telemedicine visit? Use the Medicare Physician Fee Schedule Lookup

(https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PFSlookup/index.html) tool to type in your code and check rates based on yo

11. Telemedicine and Medicaid

location.

Unlike with Medicare, Medicaid programs are state-run and therefore subject to state law on telemedicine practice. That means telemedicine reimbursement through Medicaid is widely dependent on what the policy is in your state.

Based on the <u>Center for Connected Health Policy's recent report</u>

(<a href="http://cchpca.org/sites/default/files/resources/State%20Laws%20and%20Reimburser">http://cchpca.org/sites/default/files/resources/State%20Laws%20and%20Reimburser</a>

nt%20Policies%20Report%20Feb%20%202015.pdf), here's a quick overview of what Medicaid reimbursement for telemedicine looks like across the U.S.:

46 states Medicaid programs cover live video9 state Medicaid programs will cover store-and-forward telemedicine14 state Medicaid programs cover remote patient monitoring



Only 3 state Medicaid programs (AK, MN, MS) offer coverage for all three types of telemedicine

26 state Medicaid programs cover a facility or transmission fee, or both.

So, where do you start the research process? We have 3 reliable sources we use to track <u>Medicaid coverage of telemedicine (http://evisit.com/medicaid-reimbursement-telemedicine/)</u>:

The National Telehealth Policy Resource Center. Check out their fantastic interactive m of telehealth policy (http://cchpca.org/telehealth-medicaid-state-policy), state-by-state. Visit your state Medicaid agency website. Here's a full directory (http://medicaiddirectors.org/about/state-directors) if you don't have the website hanc (http://evisit.com/best-blogs-for-physicians/).

The American Telemedicine Association. The ATA does regular telemedicine policy updates, and releases quarterly reports on the state telemedicine legislation landscape. Check out the latest report here.

(<a href="http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis---coverage-and-reimbursement.pdf?sfvrsn=10">http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis---coverage-and-reimbursement.pdf?sfvrsn=10</a>)

### Factors that Affect Medicaid Reimbursement for Telemedicine

Since telemedicine requirements vary by state and aren't always 100% clear, it's good t know what to look for. Here is a quick list of the factors you should note, that could aff your telemedicine reimbursement through Medicaid.

Health Services covered

Eligible providers (NPs, PAs)

Is cross-state medical licensing allowed?

Is a pre-existing relationship with patient required?

Location restrictions on patient or provider

Applicable CPT codes

Type of fee reimbursed (transmission, facility, or both)



There's a lot to be optimistic about in the future of telemedicine. With rapid advances i technology, it's likely that telemedicine will only become easier and more widely accepted in the coming years. Already, smart glasses (like Google Glass) and smart watches (like the Apple Watch) can monitor patients' health data and transmit them in real time to health professionals. Programs like <u>clmtrackr</u>

(http://www.theatlantic.com/technology/archive/2014/01/this-app-reads-your-emotion on-your-face/282993/) can analyze a person's emotional state based on their facial expressions and could be used to monitor mental wellness. Digital health startups like Augmedix, are experimenting with automatically transcribing documentation during a patient visit. Advances in robotic surgeries allow surgeons to operate on patients from afar.

To keep up with the rate that technology is progressing, the telemedicine will of course need to overcome other administrative barriers, such as restrictions placed on telemedicine practice by state legislation, state-specific licensing requirements by medical boards, and the reimbursement policies that affect whether doctors are reimbursed by payers and patients are not out-of-pocket. But with the projection that telemedicine will be a \$36.3 billion industry (http://rockhealth.com/2015/02/how-laws-policies-shaping-telemedicine-market/) by 2020, over 50 telehealth-related bills in the 113th Congress, and 75% of surveyed patients

(<a href="http://www.softwareadvice.com/medical/industryview/telemedicine-report-2015/">http://www.softwareadvice.com/medical/industryview/telemedicine-report-2015/</a>) reporting interest in telemedicine, telemedicine's future is bright and demand is likely to overcome these barriers.

## 13. Telemedicine Statistics

With all the claims about the benefits of telemedicine, it seems to be a no-brainer. But what is the research telling us about telemedicine? What do the <u>statistics and findings</u> (<a href="http://evisit.com/36-telemedicine-statistics-know/">http://evisit.com/36-telemedicine-statistics-know/</a>) about telemedicine really show?

All the numbers point to the exponential growth of telemedicine – in other words, it's r going anywhere. The global telemedicine market was worth \$17.8 billion in 2014 (http://www.researchandmarkets.com/research/qn3csn/global), and is project well beyond that by 2020. ATA President Dr. Reed Tuckson estimated that

approximately 800,000 virtual consultations (http://medcitynews.com/2015/05/new-at president-tuckson-calls-telehealth-mainstream/) will take place in the U.S. in 2015. And health systems, doctors, legislators, and patients are fueling that upward trend. A rece survey found an incredible90% of healthcare executives (http://www.foley.com/2014-telemedicine-survey-executive-summary/) were in the process of developing or implementing a telemedicine program, and 84% said these program were important. IHS projected the number of patients using telemedicine will rise from roughly 350,00 in 2013 to 7 million by 2018 (http://press.ihs.com/press-release/design-supply-chain-media/global-telehealth-market-set-expand-tenfold-2018). And with this high demand for telemedicine, legislators are scrambling to pass bills that offer both support and needed regulations; in August 2015, Congress had 26 telemedicine-related bills (http://www.americantelemed.org/about-telemedicine/faqs#.Vco0MPlViko) waiting for decision.

The telemedicine foundation is quickly being built. But what do patients think about telemedicine? Are they ready to try it? Recent studies show that a majority of patients interested in using telehealth services, especially once they see how telemedicine wor and the potential benefits for them. NTT Data found 74% of surveyed US patients (http://americas.nttdata.com/Industries/Industries/Healthcare/~/media/Documents/W e-Papers/Trends-in-Telehealth-White-Paper.pdf) were open to using telemedicine services, and were comfortable communicating with their doctors via technology. 67% (http://www.softwareadvice.com/medical/industryview/telemedicine-report-2015/) said telemedicine at least somewhat increases their satisfaction with medical care.

While the loss of an in-person human interaction is often cited by skeptics of telemedicine, 76% of patients

(http://www.merritthawkins.com/uploadedFiles/MerrittHawkings/Surveys/mha2014waurvPDF.pdf) said they care more about access to healthcare than having an in-person interaction with their doctors. Also, only 16% if surveyed patients would rather go to the ER for minor conditions if they could instead use telemedicine

(<a href="http://www.softwareadvice.com/medical/industryview/telemedicine-report-2015/">http://www.softwareadvice.com/medical/industryview/telemedicine-report-2015/</a>) for treatment. With the ongoing shortage of patient slots open with overburdened primar care doctors, these stat says a lot about patients' willingness to try out telemedicine.

While widespread research on the effects of telemedicine is still relatively young, many studies do show positive results. When the Veterans Health Administration implement telemedicine for past heart attack patients, they sawhospital readmissions due to hear failure drop by 51% (http://www.aha.org/research/reports/tw/15jan-tw-telehealth.pdf) Another study on the Geisinger Health Plan showed that telemedicine reduced 30-day hospital readmissions by as much as 44%. And while telemedicine skeptics often claim virtual visits tend to be lower quality than in-person visits, a recent study of 8,000 patients (https://www.poweredbyc2.com/details.aspx?

<u>p=BFC9674642988AE3&ppid=94350&beid=0DEC3E4079E23759</u>) who used telemedicin recorded no difference in care outcomes between in-person and virtual care.

There's a lot to be optimistic about telemedicine. A survey of healthcare executives found improving the quality of patient care (http://www.foley.com/2014-telemedicine-survey-executive-summary/) was their top reason for implementing telemedicine and i another study, respondents said the top benefit was ability to provide round-the-clock care (http://www.fiercehealthit.com/story/himss-analytics-most-providers-adopt-telemedicine-close-patient-care-gaps/2014-08-14). About half of patients (http://www.softwareadvice.com/medical/industryview/telemedicine-report-2015/) also reported that telemedicine increases their involvement in treatment decisions, getting them engaged in managing their care. And with a potential \$6 billion per year (http://www.towerswatson.com/en/Press/2014/08/current-telemedicine-technology-could-mean-big-savings)that US employers could save by offering telemedicine to employees, telemedicine can have a huge impact reaching past the healthcare industry

#### 14. Telehealth Resource Centers

The United States has 14 Telehealth Resource Centers, all funded by the U.S.

Department of Health and Human Services' Health Resources and Services

Administration (HRSA) Office for the Advancement of Telehealth. These resources

⊿nte

serve as a local hub of information and research about telehealth, usually with a focus on increasing <u>healthcare (http://healthyline.com/)</u> access for underserved communities. Plus, the services they provide are generally free!

While all the telehealth resource centers offer helpful information about navigating telehealth, each center has specific strengths. Here's a quick overview of the top cente to check out as you're getting started with telehealth.

For a listing of all centers or to find your regional center, check out the <u>Telehealth</u> Resource Center (http://www.telehealthresourcecenter.org/) site.

National Telehealth Policy Resource Center

(http://cchpca.org/sites/default/files/resources/State%20Laws%20and%20Reimburser/nt%20Policies%20Report%20Feb%20%202015.pdf)

Phone: 877.707.7172

Direct: 916.285.1860

Check out their interactive U.S. map of telehealth policy (http://cchpca.org/state-laws-and-reimbursement-policies), state-by-state

You can follow them on Twitter, Facebook, or by email to get regular provide telemedicine news and policy updates.

Excellent resources section (http://cchpca.org/resources) with fact sheets, policy briefs and even a micro-documentary on telemedicine!

California Telehealth Resource Center (http://www.caltrc.org/)

Phone: 877.590.8144

Great page on best practices (http://caltrc.org/knowledge-center/best-practices/) for developing a telemedicine program

Sample forms (http://caltrc.org/knowledge-center/best-practices/sample-form guidelines to use in your telemedicine program

d

Training page (http://caltrc.org/knowledge-center/training/) with links to webinars, videos, and free on-site training services for California programs

Heartland Telehealth Resource Center (http://heartlandtrc.org/)

Phone: 877.643.HTRC (4872)

Excellent reimbursement guides (http://heartlandtrc.org/billing-reimbursement/) for Kansas, Missouri, and Oklahoma

Comprehensive, up-to-date regulation guides (http://heartlandtrc.org/rules-regs/) for Kansas, Missouri, and Oklahoma

Mid-Atlantic Telehealth Resource Center (http://www.matrc.org/)

Phone: 855.MATRC4U (628.7248)

Direct: 434.906.4960

State-specific resources for Virginia, West Virginia, Kentucky, Maryland, Delaware, North Carolina, Pennsylvania, Washington DC, and New Jersey

Request a speaker (http://www.matrc.org/how-can-we-help/request-a-speaker) on telemedicine

Directory (http://www.matrc.org/where-to-find-telehealth) to find telehealth providers

National Telehealth Technology Assessment Resource Center (http://www.telehealthtechnology.org/)

Phone: 877.885.5672

Direct: 907.729.4703

A great resource for anyone looking for technology and devices to integrate into a telemedicine program.

Toolkits (http://www.telehealthtechnology.org/toolkits) on new technologies, devices, and apps to use with your telemedicine program

User Reviews section (http://www.telehealthtechnology.org/user-reviews) on different telehealth technology and devices

NorthEast Telehealth Resource Center (http://netrc.org/)

Phone: 800.379.2021

Great Telehealth "A to Z" section (http://netrc.org/telehealth-a-to-z/) with resources organized into categories such as clinical, financial, and technology Telehealth toolkits (http://netrc.org/toolkit/) for psychiatry and dermatology

15. Telemedicine Regulations

Telemedicine regulations are in constant flux as medical associations (like the FSMB ar AMA) continue to develop basic guidelines for telemedicine practice, and states introduce new legislation to enact telemedicine policy.

Telemedicine regulations also determine the telemedicine reimbursement rules follow by Medicaid and private payers in that state. With the explosion of new telemedicine companies and patient demand for virtual care, the number of telemedicine-related legislation currently on the table (http://www.emmadaycare.com/) is at an all-time high Most U.S. states have passed new telemedicine regulations recently, or have a propose bill awaiting decision.

Consequently, telemedicine regulations can vary widely from state-to-state in these ke areas.

Parity Laws

Currently, 29 states and the District of Columbia have passed telemedicine parity laws. telemedicine parity law requires private payers to reimburse for telemedicine, though the specific restrictions on reimbursement often vary by state. In many cases, private payers reimburse for the same amount as the comparable in-person medical service.

Parity laws also may affect coverage by the state Medicaid program.

## Cross-state licensing

One of the key <u>advantages of telemedicine (http://evisit.com/advantages-of-telemedicine/)</u> is the ability to provide healthcare to a patient, no matter the patient or provider's location. However, since providers are licensed to practice in a specific state they are only legally allowed to offer telemedicine services to patients in the same stat Currently, 49 state medical boards require physicians practicing telemedicine to be licensed in the state where the patient is located.

Cross-state licensing would allow providers to provide care to a patient in a nearby sta without holding a full license to practice in that state. Some states are moving to pass measures to allow state medical boards to work together and establish cross-licensing requirements.

#### Patient Informed Consent

Some states require providers to get a patient's informed consent for telemedicine services. Some regulations require written consent, others require verbal, or none at a Either way, it's good practice for providers to inform patients about telemedicine service and what to expect.

## Online Prescribing

Most states have specific regulations on which medications can be eprescribed and which cannot. For the most part, schedule III to V drugs can be prescribed online. But many schedule II drugs (commonly used for chronic pain management) cannot be prescribed via telemedicine services, as regulations require an in-person exam.

## Pre-existing Physician-patient relationship

In many states, current regulations require that any provider and patient doing a telemedicine visit have a pre-existing relationship. Usually this means that the provide and patient need to have had at least one in-person visit. This regulation is slowly changing as more companies like Teladoc and DoctoronDemand seek to conr patients with a random, on-call doctor for immediate care.

#### Resources

Want to learn more about telemedicine legislation? Here are the sites we use to stay u to-date:

The National Telehealth Policy Resource Center (http://cchpca.org/telehealth-medicaid state-policy)

Visit your state Medicaid agency website (http://medicaiddirectors.org/about/state-directors)

American Telemedicine Association state legislation matrix (http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis---coverage-and-reimbursement.pdf?sfvrsn=10)

### 16. Barriers to Telemedicine

While the field of telemedicine has taken off in the past few years, there are still barrie to widespread adoption.

## Legislation

State legislation determines the restrictions and often, the reimbursement rates for telemedicine services administered in that state. For instance, any state that has passe a telemedicine parity law has mandated that private payers in that state to reimburse telemedicine visits at the same rate as a comparable in-person visit. While a majority o states have now passed telemedicine parity laws, changing state legislation is often a time-consuming, unwieldy process and can have a huge impact on the telemedicine practices in that state.

# Reimbursement process

Reimbursement for telemedicine services is often not as straightforward for traditional medical services. State telemedicine policy landscape is continuously shifting, affecting rules around reimbursement through state Medicaid programs and through private payers. Medicare does now reimburses for real-time telemedicine services, but places restrictions on the eligible healthcare providers, the location of the patient, the location of the l

procedures that can be done, etc. The good news is, there is a shift towards more widespread reimbursement for telemedicine through all third-party payers, with less restrictions.

### Implementation/Equipment costs

The growth in telemedicine solutions means that telemedicine options are now more diverse, with many more affordable solutions. However, most telemedicine programs require the purchase, set-up and staff training of new technology and equipment – sor of which may be outside the budget of providers in smaller independent practices. Ma providers are already stretched thin on new technology budgets and staff training for EHR systems, imposed by the Meaningful Use program. Also, for patients who may not have access to a smartphone or a computer with internet, real-time telemedicine may out of reach.

### State Licensing requirements

Healthcare providers currently earn their medical licenses for a specific state. This lets them practice medicine legally in that state, and only that state. This presents a proble for telemedicine, as the entire goal is to break down geographical barriers between a patient and provider. According to medical licensing regulations, a specialist based in Colorado would not be legally allowed to treat a patient in New Mexico.

In response to this barrier, some telemedicine groups and providers have started pushing for cross-state medical licensing.

# 17. Who Pays for Telemedicine

#### Medicare

Medicare pays for telemedicine services under certain circumstances. Primarily, Medicare covers live telemedicine services, or virtual visits delivered via interactive auc and video (think videochat). The goal is to cover medical services delivered virtually where an in-person visit may be difficult for the patient or provider. Store-and-forward telemedicine services are only covered in Hawaii and Alaska at this time.

Additionally, Medicare will only pay for telemedicine services when the patient is locate in a Health Professional Shortage Area and receives care from an eligible provider. The medical service itself also has to fall under one of these (https://www.cms.gov/Outreac and-Education/Medicare-Learning-Network-

MLN/MLNProducts/downloads/telehealthsrvcsfctsht.pdf)covered CPT/HCPCS codes. When all these conditions are met, Medicare pays for 80% of the physician fee (other 20% is paid by the patient) and will additionally pay a facility fee to the originating site.

#### Medicaid

Medicaid will cover telemedicine services depending on the legislation passed in that state. Since Medicaid programs are state-run, they follow state-specific telemedicine regulations. In 46 states, Medicaid offers some kind of physician reimbursement for telemedicine services delivered over live video. 26 state Medicaid programs will also paramaditional facility or transmission fee to cover the cost of hosting a telemedicine vis or transmitting patient medical data in a secure way. The specific restrictions and regulations around telemedicine vary widely by state. To find out more about you're you state Medicaid program will cover, visit the Center for Connected Health Policy's recent report (http://cchpca.org/state-laws-and-reimbursement-policies).

# Private Payers

Private payers are increasingly paying for telemedicine services based on popular demand and evidence of cost-savings from virtual care. For instance, <u>United Healthcar</u> (<a href="http://www.uhc.com/news-room/2015-news-release-archive/unitedhealthcare-covers-virtual-care-physician-visits">http://www.uhc.com/news-room/2015-news-release-archive/unitedhealthcare-covers-virtual-care-physician-visits</a>) recently announced it would expand coverage for 24/7 on demand virtual visits to people enrolled in employer health plans.

How does telemedicine work and which telemedicine services private payers pay for again can vary widely by state. While the trend is toward broader coverage of telemedicine services for plan enrollees, private payers are still deciding on exactly wh they will cover and what they won't. 29 states

(http://www.americantelemed.org/policy/state-policy-resource-

<u>center#.VbKBG7NVikp)</u> and Washington, DC have passed telemedicine parity laws, whi mandate that private payers in those states pay for telemedicine services at the same rate as in-person visits.

#### **Patients**

In many cases, telemedicine visits are actually paid by patients directly. Online services that offer patients 24/7 on-demand access to a virtual doctor will often charge a per-vi fee or a monthly or yearly subscription for access. Those charges are not billed throug insurance and come directly out of the patient's pocket.

Many doctors who choose to offer virtual visits to their patients will do so as part of a direct-pay or concierge practice model. Instead of having their doctor bill through an insurance carrier, these patients might have a high-deductible insurance plan for emergencies and then pay a yearly fee to essentially have their doctor on retainer. The patients might pay an additional convenience fee for each virtual visit, or just have access to virtual visits with their doctor as part of their subscription fee for the practice

### 18. HIPAA and Telemedicine

Like all technology in the healthcare space, telemedicine solutions need to be <u>HIPAA</u> compliant (http://evisit.com/telemedicine-skype-hipaa-compliant/) to protect patient privacy. While an app like Skype might offer a doctor an easy way to consult a patient remotely, using it in that way is not in compliance with HIPAA. Technology used for telemedicine services needs to ensure high-level security and prevent any breaches of patient personal health data.

But as the <u>National Policy Telehealth Resource Center (http://caltrc.org/wp-content/uploads/2014/01/HIPAA-for-TRCs-2014.pdf)</u> notes, "Compliance with the Healt Insurance Portability and Accountability Act (HIPAA) is more complex than simply using products that claim to be 'HIPAA-compliant." Not only does the telemedicine platform need to be compliant, all providers, patients, and staff using the tool need to ensure the



are in compliance with HIPAA. A telemedicine software vendor, for instance, not only needs to build a secure product, but also ensure their telemedicine company is operating in accordance with HIPAA.

HIPAA compliance entails an organized set of secure, monitored, and documented practices within and between covered entities. Though products cannot ensure compliance, some products may contain elements or features that allow them to be operated in a HIPAA-compliant way.

# 19. Telemedicine And Telehealth Terminology

The following are some of the most commonly used definitions and terms that are use in telehealth and telemedicine.

Application Service Provider (ASP): Various applications are hosted by an ASP on a cent server. Customers can pay a fee to access the applications they want to use over eithe private network or secure Internet connection. This allows customers to rent applications that they need to use from an ASP instead of having to buy, install and the maintain software on their own. Usually software upgrades and new releases are included in the rental price.

Asynchronous: Sometimes this term is used for describing the process of store and forward transmission for sending information or medical images since typically the transmission takes place in one direction, as opposed to synchronous which transmits both directions.

Authentication: This is a method that is used to verify an individual's identity who is receiving or sending information. Keys, passwords or another type of automated identifier is used for the verification.

Bandwidth: Measures a communications channel's information carrying capacity; for a telemedicine service, this is a practical limit to its capabilities, cost and size.



Bluetooth Wireless: Bluetooth refers to an industrial specification that applies to wirele area networks. Bluetooth technology offers a way of connecting and exchanging information between devices, including laptops, mobile phones, PCs, video game consoles, digital cameras and printers over a globally unlicensed and secure short-rangeradio frequency. The Bluetooth Special Interest Groups has developed and licensed the Bluetooth specifications.

Broadband: Communications (e.g. satellite, microwave and broadcast television) that he capability to carry a wide range of various frequencies; it refers to signals being transmitted in a frequency-modulated manner, over a portion of the total available bandwidth, which permits several messages to be transmitted simultaneously.

Clinical Information System: Exclusively relates to information concerning patient care, as opposed to administrative data. It is a hospital-based information system that has been designed for the collection and organization of data.

CODEC: This is an acronym for coder-decoder. It is a videoconferencing device (e.g., Panasonic, Sony, Tandberg, Polycom, etc) that converts analog audio and video signals into audio and digital video code and vice versa. Typically CODECs compress digital cool in order to conserve a telecommunication path's bandwidth.

Compressed video: In order to send information over a phone network, video images often need to be processed in order to reduce how much bandwidth is needed for capturing the required information.

Computer-based Patient Record (CPR): Individual patient information in electronic format that has been designed to provide access to accurate and complete patient information.

Data Compression: A method that is use for reducing the volume of data. Encoding is used to reduce storage space requirements, bandwidth requirements, transmission times and image processing. Some information loss make take place with some compression techniques, this might be clinically important or not, depending respectific circumstances.

Diagnostic Equipment: (Cameras, Scope and Other Types Of Peripheral Devices): A hardware device that is separate from a central computer (e.g. camera, stethoscope or digitizers) that can offer <a href="mailto:medical data">medical data</a> (<a href="http://www.well-beingsecrets.com/how-to-lose-love-handles-belly-fat/">http://www.well-beingsecrets.com/how-to-lose-love-handles-belly-fat/</a>) input into a computer or accept output from one.

Digital Camera: Typically used for taking still images of patients. Some of the general uses that this kind of camera is used for include wound care and dermatology. The images that this type of camera produces can be download onto to a PC and then sent over a network to a consultant or provider.

Digital Imaging and Communications in Medicine (DICOM): This is a communications standard for medical imaging devices; it is a set of protocols that are vendor-independent and describe how to identify and format images. It was developed by the National Electronic Manufacturers Association and American College of Radiology.

Disease Management: A coordinated and continuous <u>health process (http://www.well-beingsecrets.com/apple-cider-vinegar-health-benefits/)</u> for the purposes of managing and improving the health status of a specifically defined population of patients over th complete course of the disease (e.g., DM, CHF). The targeted patient populations are high-cost, high-risk patients that have chronic conditions that require appropriate care order to be maintained properly.

Distance Learning: The use of audio and video technologies allows students to attend training sessions classes that are conducted from a remote location. Usually distance learning systems are interactive. They are a useful tool for delivering education and training to students that are widely dispersed, or in some cases where an instructor is unable to travel to the site where the students are located.

Distant Site: Refers to a telehealth site where a specialist or provider either consults wi the patient's provide or see the patient from a distance. Other common names that ar used for this term include referral site, physician site, provider site, specialty site, consulting site and hub site. Document Camera: This type of camera is able to display type or written information (e.g., lab results), graphics (e.g. ECG strips), photographs, and x-rays in some cases.

Electronic Data Interchange (EDI): Directly receiving and sending data between two trading partners without human invention or paper.

Electronic Patient Record: Individual patient information in electronic format which provides access to accurate and complete patient data, links to <a href="mailto:medical information">medical information</a> (<a href="http://www.well-beingsecrets.com/increase-metabolism-naturally/">http://www.well-beingsecrets.com/increase-metabolism-naturally/</a>), clinical decision support systems, reminders, alerts and other types of aids.

Encryption: A system for encoding data on an email or web page where only the computer system or person authorized to access the information can retrieve and decode it.

Firewall: Computer software and hardware that blocks unauthorized communications between external networks and an organization's computer network.

Full-motion Video: Refers to a standard video signal which makes it possible for video to be displayed at a distance in uninterrupted, smooth images.

Guideline: A procedure or policy statement for determining a course o action or providing guidance on setting standards.

H.320: A technical standard pertaining to videoconferencing compression standards which enables <u>various equipment (http://evisit.com/telemedicine-telehealth-equipment/)</u> to interoperate via IDSN or T1 connections.

H.323: A technical standard pertaining to videoconferencing compression standards which make it possible for various equipment to interoperating using Internet Protoco

H.324: A technical standard pertaining to videoconferencing compression standards which make it possible for various equipment to interoperate through using Plain Old Telephone Service (POTS).

HL-7 (Health Level-7 Data Communications Protocol): A communication standard guidi health-related information transmission. HL-7 allows various applications to be integrated into one system, including patient accounting, order entries, hospital censu radiological imaging stations, and bedside terminals.

HIPAA: Health Information Portability Act acronym.

Home Health Care And Remote Monitoring Systems: Care that is provided to patients and their families in their residences to promote, <u>maintain or restore</u>
(<a href="http://www.restorationexpertsct.com/">http://www.restorationexpertsct.com/</a>) health; or to minimize the effects of illness and disability, including terminal illnesses. In Medicare enrollment data and claims as well a Medicare Current Beneficiary Survey, home health care is defined as home visits made by professionals, including physicians, nurses, home health aides, therapist and social workers. The use of interactive devices and remote monitoring enable a patient's vital signs to be sent on a regular basis to health care providers without the patient having travel.

Informatics: Utilizing information technologies and computer science in order to proce and manage knowledge, information and data.

Integrated Services Digital Network (ISDN): A common dial-up transmission path used videoconferencing. ISDN services are on demand services where another IDSN based device is dialed, and per minuted charges are accumulated at a certain <u>contracted rate (http://www.hvacexpertsnyc.com/)</u>. The site that places the call is then billed. The servi is similar to the dialing features that come with making long distance phone calls. The person how initiates the call pays the bill. Connections of up to 128Kbps are permitted by ISDN.

Interactive Television/Video: Similar to video conferencing technologies that make is possible for synchronous, two-way interactive audio and video signals to be transmitte for delivering distance education, telemedicine or telehealth services. The acronyms ar often used to refer to it- VTC (video teleconference), IATV or ITV.

Internet Protocol (IP): The protocol for sending data from one computer over the Internet to another. Every computer that is on the Internet has one address at least the identifies it uniquely from all of the other computers that are on the Internet. Internet Protocol is a connectionless form of protocol, meaning there isn't a connection that is established between the two points that are communicating with one another. A videoconferencing system's IP address is its telephone number.

Interoperability: This refers to two systems ((software, networks, communication devic computers and other types of information technology components))or more being abl to interact with each other and exchange information so that predictable results can b achieved. There are three different kinds of interoperability: technical; clinical and human/operational.

ISDN Basic Rate Interface (BRI): A type of ISDN interface that provides 128K of bandwit tht is used for videoconferencing as well as simultaneous data and voice services. A multiplexer can be used to link together multiple BRI lines in order for higher bandwid levels to be achieved. For example, one popular option among telehealth networks is combining 3 BRI lines in order for video-conferencing to be provided with 384K of bandwidth. BRI services are unavailable in some rural areas. Before videoconferencing equipment is order for using this kind of service, one needs to check with their telecommunications provider to see if BRI services are available.

ISDN Primary Rate Interface (PRI): An ISDN interface standard which operates using on 64K data channel and 23, 64K channels. When the right multiplexing equipment is use the user can selected the IDN PRI channels for a video call. As an example, if a user would like to have his videoconference at 384K bandwidth, the multiplexer can be instructed to utilize channels 1-6 (6 x 64k= 384k). It is actually quite importance since usually the user pays charges that are based on how many 64k channels get used on a videoconference. So the fewer channels that have to be used to get a quality video signal, the lower the cost of the call will be.

JCAHO – This is an acronym for Joint Commission on Accreditation of Healthcare Organizations.

Lossless – This is a kind of data compression which allows users to reconstruct images without losing the information from the original copies. It can achieve a compression ratio 2:1 for images with color.

Lossy – This is a process of compressing data with high ratio. The unnecessary information are discarded when reconstructing the images.

Nursing Call Center – This is a centralized office where nurses are the ones who are working. The nurses are responsible for answering telephone calls from patients. They should also make responses to faxes, electronic mails and letters from patients. Nursing (<a href="http://evisit.com/what-is-telehealth-nursing/">http://evisit.com/what-is-telehealth-nursing/</a>) call centers may also provide the callers with the basic information regarding their health, but they should not disclose the diagnosis made by the doctors on their conditions. They should not prescribe medications as well. They may just provide basic instructions when patients are having health complaints.

Mobile Telehealth Clinic – This involves using vehicles like van, trailer or any mobile un to provide health care services for patients. The services are given by health care professionals. This is helpful to those who are living on areas far from the hospital. Sor mobile units (http://www.ghostekproducts.com/) are equipped with medical technologies that are found in the hospital like mobile CT, MRI and TeleDentistry.

Multiplexer or MUX – This is a device that chooses several digital inputs and combines them into a to be transmitted on a single line.

Multi-point Control Unit or MCU – This is a device used to connect a few videoconferencing sites into a single system. Multi-point Control Unit is also referred to as the "bridge".

Multi-point Teleconferencing – This is the process of connecting multiple users from different sites. It allows electronic communication between the users as well as transmission of video, voice and data between computers and systems. Multi-point teleconferencing requires the use of a multi-point control unit or the bridge to the connect the different sites for the videoconference.

Network Integrators – These are the organizations that give services and develop software to allow sharing of data, videos and voices and communication between different devices and systems.

Originating Site – This is where the patient and physician are located during the time o consultation. This site is also called as patient site, remote site, spoke site or rural site. This allows the patients to access their personal <a href="https://www.well-beingsecrets.com/how-much-water-should-you-drink-per-day/">health (http://www.well-beingsecrets.com/how-much-water-should-you-drink-per-day/</a>) information from anywhere with the help of the Internet.

Patient Exam Cameras – These cameras are used to examine the patient's overall condition. The different types of patient exam cameras are handheld cameras, camcorders, gooseneck cameras and those which may be placed above the set-top un Analog and digital cameras are available and the ones that should be used depend on the connection to the set-top unit.

Peripheral Device – This is a device that can be connected to the computer. Examples of peripheral devices include mouse pointers, keyboards, video camera, scanner and monitors used for clinic and hospitals including <a href="weight">weight</a> (<a href="http://www.well-beingsecrets.com/lose-20-pounds-one-month/">http://www.well-beingsecrets.com/lose-20-pounds-one-month/</a>) scales and pulse oximeters.

<u>Telepharmacy Solutions (http://evisit.com/what-is-telepharmacy/)</u> – This refers to the provision of pharmacy services to the patients with the use of communication technology and electronic information. This is used when the patients cannot go personally to avail such services.

POTS – This is the acronym for Plain Old Telephone Service.

Presenters or Patient Presenters – They are the ones who provide telehealth services and perform the overall exam for patients. Such presenters should be on the medical field and they must have experiences in providing health services to patients like registered nurses and licensed practical nurses. They were trained in the use of the

equipment like cameras and computers, and they are the ones who communicate with the patients on the originating site. They can also perform the different activities which are part of the diagnostic examination.

Regional Health Information Organization/Health Information Exchange (RHIO/HIE) – These are the organizations that ensure the quality, efficiency and safety of the health services delivered by the Telehealth.

Router – This is a device which provides connection to at least two networks on an organization. It provides network connection on multiple locations and it is responsible in finding the best route between two sites. It tells the videoconferencing devices wher the destination devices can be found and it will find the best way to gather the information from that specific destination.

Standard – This term refers to the benchmark used to measure the quality of the resul The standard is established by the authority to make sure that organizations are achieving the desired results.

Store and Forward – This is a form of telehealth consultation which uses images from 1 patients to come up with the medical diagnosis. The different types of Store and Forward services include dermatology (https://www.aad.org/public/diseases/why-see-adermatologist), radiology (https://en.wikipedia.org/wiki/Radiology) and wound care (http://www.well-beingsecrets.com/how-to-gain-weight-fast-ultimate-guide/). It may als include transferring of patients' clinical data like ECG and blood test results from the patients' site to the hospital's site.

Switch – In the videoconferencing world, switch refers to the device responsible for selecting the path that will be used in transmitting the video. It is similar to an intellige hub and it can direct traffic on hub ports to different destinations. The hub ports will then feed the devices with the same information.

Synchronous – This term refers to the interactive connections between two videos whe the information are transmitted at the same time for both directions.

System Integration – This involves bringing together two systems and devices and sharing data and information between the two systems.

T1/DS1 – This is a type of service for telephone lines that provides a bandwidth data service of 1.544 Mbps.

T3/DS3 – This is a carrier that allows the users to have a bandwidth data service of up 1 45 Mbps.

Transmission Control Protocol/Internet Protocol – This involves the standard rules for establishing and maintaining network conversation between two computers with the help of the Internet.

Telecommunications Providers – These are the entities authorized by the U.S. government to provide telecommunications services to all residents and institutions in the U.S.

Telemedicine/Telehealth: Basically, these two terms are used to describe the use of technology and telecommunications to exchange medical information from one place another with an aim of improving the patient's <a href="https://www.well-beingsecrets.com/lose-20-pounds-one-month/">https://www.well-beingsecrets.com/lose-20-pounds-one-month/</a>) status. Telemedicine is sometimes involved in direct patient clinical services which include diagnosis and treatment of patients.

Teleconferencing: This is the interaction between multiple users across various sites with the use of interactive electronic communication. This involves transfer of video ar audio through computer and video systems. This interaction is usually live and is most used in the diagnosis or monitoring a patient in home care.

However, there are other terms that fall under telecommunication in health care. They are:

1. Telementoring- which is basically the use of video, audio and other electronic and telecommunication processing technologies to offer individual guidance. A good example of this would be a physician mentoring a local healthcare provider w' nev in the healthcare industry.

2. Telemonitoring- this is process of using video, audio and other electronic and telecommunication systems to transfer live information between computers with an a of monitoring the <a href="http://www.well-beingsecrets.com/health-benefits-of-honey-ultimate-guide/">http://www.well-beingsecrets.com/health-benefits-of-honey-ultimate-guide/</a>) status of a patient from a distance. A good example would be home care.

Telematics: This is the integration or use of information processing that is based on a computer, and using telecommunications to allow programs and data transfer betwee computers.

Telepresence: Technically, this is the use of robotics and other technologies to allow a medical practitioner to perform a procedure at a certain location by using devices and receiving sensory information or feedback which contributes to a sense of presence ar allowing certain achievement in a procedure.

A good example would be the utilization of lasers or even hand pieces as well as receiving pressure that is equal or similar to that created by physical hands. This gives the perception of presence, thus achieving a satisfactory degree of achievement.

Teleradiology: This is the transfer of radiological images. X-Rays, MRIs and CTs are all types of radiological images. These images are used for consultation, diagnosis or interpretation. They can be transferred through satellite connections, local area networks or even standard telephone lines. The Picture Archiving and Communication Systems allow centralized storage and the access of these images over information systems such as computers.

Universal Service Administrative Company: Abbreviated as USAC, the Universal Service Administrative Company is responsible for administering USFs or Universal Service Funds to allow easy access to telecommunication services across the country. The Rura Health Care Division which is under USAC as well manages discount programs for telecommunications health care.

Ultrasound Device: This is any device that employs high frequency sound technology t examine internal body organs. These devices are used to detect tumors and other innebody organs abnormalities.

WiFi: Wifi was originally licensed bu the Wi-Fi alliance and it is used to describ

technology of wireless local area networks, abbreviated as WLAN. This technology was primarily developed for mobile computing devices like laptops in Local Area Networks, but with technological advancements, it is now used for an array of services which include VoIP phone access, gaming as well as basic connection of electronics such as smartphones, DVD players, Home theaters and Televisions.

Videoconferencing Systems: This is equipment and software that allows real time two way communication, which is usually in the form of digitized audio and video. These systems are mainly used for meetings without necessary having to be in the same rook Each individual needs equipment that can send and receive audio and visual information.

Only certain CPT and HCPCS codes are eligible for telemedicine reimbursement

Check this list (https://ocm.ama-assn.org/OCM/CPTRelativeValueSearch.do? submitbutton=accept) for the eligible CPT/HCPCS codes. CMS updates this list on a yea basis. The code will need to accurately describe the medical service provided via telemedicine.

When billing, you'll need to use the GT modifier

In addition to the right CPT or HCPCS code, you'll need to use the "GT" modifier when billing to show that the service was delivered via telemedicine. If you're a proviocated in Hawaii or Alaska using a store-and-forward telemedicine solution, L 2 G

modifier instead.

# Only certain providers can get reimbursed for telemedicine

Here's the list of eligible providers:

**Physicians** 

**Nurse Practitioners** 

Physician Assistants

**Nurse Midwives** 

Clinical nurse specialists

**Clinical Psychologists** 

**Clinical Social Workers** 

Registered dietitians or nutrition professionals

The originating Site can also charge a facility fee

Since the originating site is essentially hosting the telemedicine visit, Medicare allows t originating site to bill a separate facility fee. For more details on the facility fee, look up HCPCS code Q3014.



Medicare reimburses telemedicine at the same rate as a comparable in-person vi

Whether you're billing a 99213 that was done in-person or via telemedicine, your billat rate should match the standard Medicare physician fee schedule (\$72.81). Want to che the Medicare physician rates? Lookup reimbursement rates for any code here.

Medicare Advantage plans have much more flexibility than traditional Medicare

All the guidelines and restrictions we've listed above are for billing telemedicine througe traditional Medicare. Medicare Advantage plans under a commercial payer have complete flexibility to cover telemedicine however they want! This means, Advantage plans may cover telemedicine for your patient and not have any of those restrictions of what qualifies as an eligible originating site. Call the payer and ask what they'll cover as what their telemedicine guidelines are.

# The future of Medicare & Telemedicine

What's likely to change in the coming years? It's hard to say, but Medicare's coverage o telemedicine seems to expand every year.

On July 7th, 2015, House representatives introduced the Medicare Telehealth Parity Ac of 2015. If passed, the bill will expand what telemedicine services Medicare w'r a get rid of many limitations (like the requirements for what qualifies as an "origon get rid of many limitations").

site"). Legislation like this one could have a huge impact on coverage for remote patier monitoring and other telemedicine services delivered to the patient in their own home

Other helpful resources on Medicare and telemedicine

Want more information? Check out our Top 10 FAQs about Medicare & Telemedicine to 10 FAQs and our complete guide to Telemedicine Reimbursement.

Grow your system, profitably. See whe largest systems in the US choose e'

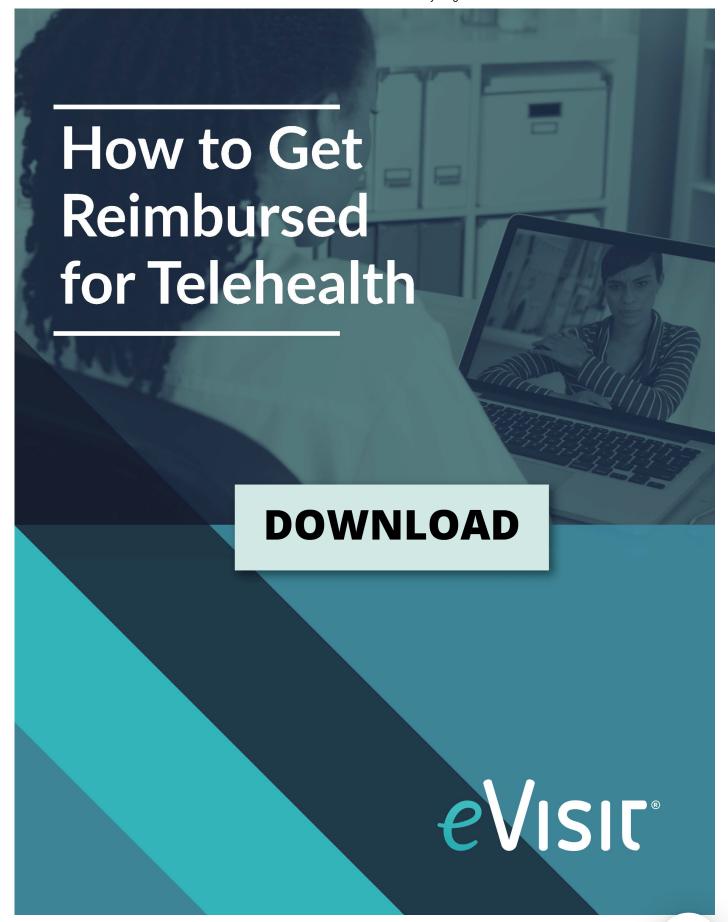
SHOW ME HOW (https://evisit.com/request-a-d





(http://try.evisit.com/how-to-transition-to-concierge-medicine/? utm\_source=blog&utm\_specialdocs=sidebar&utm\_campaign=webinar)





# The Complete Telehealth Software Purchasing Guide

**DOWNLOAD** 

(http://try.evisit.com/doctor-guide-purchasing-telehealth-software/? utm\_source=Blog&utm\_medium=sidebar&utm\_campaign=purchase%20guide%20)

Join thousands of providers and practice managers. Get weekly tips to build a profitable practice.



# **Email Address**

Email must be formatted correctly.

# **SUBSCRIBE**

eVisit	SOLUTIONS	RESOURCES	CUSTOMERS
(https://evisit.com/)	Hospitals & Health	ROI Calculator	Login
Request A Demo	Systems	eVisit Blog	Support
About Us	Urgent Care	Success Stories	Telemedicine Experts
Careers	Primary Care	Resource Library	
Contact	Mental Health	Telemedicine	
Newsroom		Reimbursement	
		State Telemedicine Policy	

Copyright © 2018 eVisit®

Telemedicine Solution

Have any questions? Give us a call! 844-693-8474 (tel:844-693-8474)

Privacy Policy (/privacy-policy/) Terms & Conditions (/terms-and-conditions/)





# 1 340B: WHAT EXECUTIVES NEED TO KNOW

The 340B Drug Pricing Program provides access to prices often up to 50% lower than typical market prices. In order to participate, entities must meet eligibility criteria and agree to comply with program requirements. This program is administered by the Health Resources and Services Administration (HRSA).

# 2 WHY IS 340B COMPLIANCE IMPORTANT?

Covered entities can face sanctions for non-compliance, including being removed from the 340B Program and/or repayment to manufacturers for the time period in which the violation occurred.

# 3 Entities are responsible for ensuring:

- 1. Only eligible patients receive 340B drugs; and
- 2. A Medicaid rebate is not requested on a 340B purchased drug; and
- 3. All entity eligibility requirements are met; and
- 4. Auditable records are maintained to illustrate compliance.

# 4 a patient is eligible for 340b when a covered entity:

- Establishes a health care relationship with the patient; and
- Maintains records of the patient's health care; and
- Provides services by a health care professional who is employed or under contractual or other arrangements with the entity, such that the responsibility for care remains with the entity; and
- Provides health care services consistent with scope of grant (federal grantees only).
- \* The 340B Prime Vendor, managed by Apexus, provides tools that can help covered entities address these components of the program at 340Bpvp.com/tools

# $\begin{array}{c|c} \text{A p e x u s} & \begin{array}{c} 340B \\ \text{Prime Vendor} \\ \hline \text{PROGRAM} \end{array}$

The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

# A BEST PRACTICE:

entities document their use of 340B savings in alignment with this intent.\*

# 340B PROGRAM COMPLIANCE REQUIRES ONGOING ATTENTION:

- Self audits are essential for understanding program integrity.
- Software and systems used to support the program require regular monitoring and maintenance
- Interdisciplinary oversight ensures accountability and broad institutional understanding.
  - Sites often accomplish this through the development of a council consisting of multiple disciplines such as Finance, Billing, Nursing, Medicine, Medical Records, Pharmacy, and Compliance.
- Dedicated resources with defined roles and responsibilities can help improve compliance and create additional accountability.
- Individuals responsible for the program should remain educated about the program so they will be informed of the current HRSA policy.
  - Send them to 340B University or have them complete the online version, 340B University OnDemand. Both are offered for free through the 340B Prime Vendor.

### 340B CONTRACT PHARMACY

Consider this before signing a contract pharmacy agreement:

- 1. It is the covered entity that is responsible for 340B compliance (not vendors).
- 2. A covered entity must have fully auditable records to demonstrate that no diversion or duplicate discounts have occurred at a contract pharmacy.
- 3. Contract pharmacy agreements may present financial risk to the entity. Be aware of the terms in your contract and make sure they are reasonable and consistent with any program or grant requirements you may have.
- 4. Use discretion when considering how many contract pharmacies are appropriate; large numbers of contract pharmacies increase the risk of a HRSA audit and often require additional oversight.
- 5. Fee for Service Medicaid prescriptions should not be included in contract pharmacy arrangements (unless the state has a special arrangement and the entity has notified HRSA).



# HOSPITAL CORNER

### A TIP FOR HOSPITAL LEADERS

Dedicated resources are critical for maintenance of complex software systems. Many hospitals have one or more FTEs dedicated to the program. Tools to address components of the 340B Program can be found on our website.

### AS A HOSPITAL, HOW DO I KNOW WHICH FACILITIES ARE ELIGIBLE FOR 340B?

All clinics/departments/services of the parent hospital must be listed as reimbursable lines with associated outpatient costs and charges on the covered entity's most recently filed Medicare Cost Report. Those clinics/departments/services located outside of the four walls, regardless of whether they are in the same building [including another hospital], must be registered on OPAIS.

### MY HOSPITAL IS SUBJECT TO THE GPO PROHIBITION. CAN WE EVER USE A GPO?

Hospitals registered on OPAIS as disporportionate share hospitals (DSH), freestanding cancer hospitals (CAN), or children's hospitals (PED) are subject to the GPO Prohibition. These hospitals may continue to use GPO for inpatients. Certain off-site outpatient facilities may use a GPO for covered outpatient drugs if they meet all of the following criteria:

- 1 Are located at a different physical address than the parent;
- Are not registered on the OPA 340B OPAIS as participating in the 340B Program
- 3 Purchase drugs through a separate pharmacy wholesaler account than the 340B participating parent; and
- The hospital maintains records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the OPA 340B OPAIS.

The 340B Prime Vendor, managed by Apexus provides tools that can help covered entities address components of the program at 340Bpvp.com/tools





Purpose: Define common terms used in the 340B Program.

Term	Definition
340B ceiling price	The maximum price drug manufacturers can charge a covered entity for a 340B-purchased covered outpatient drug.
	340B Ceiling Price = Average Manufacturer Price (AMP) – Unit Rebate Amount (URA)
	Pursuant to section 340B(a)(1) of the Public Health Service Act and the 340B Ceiling Price and Civil Monetary Penalty final rule (82 Fed. Reg. 1210, January 5, 2017), the 340B ceiling price for a covered outpatient drug is equal to the average manufacturer price (AMP) from the preceding calendar quarter for the smallest unit of measure minus the unit rebate amount (URA). The 340B ceiling price is published in the 340B OPAIS Pricing component.
340B covered entity (CE)	A facility/program that is listed in the 340B statute as eligible to purchase drugs through the 340B Program and appears on 340B OPAIS.
340B Drug Pricing Program (340B Program)	The 340B Drug Pricing Program is a federal program that requires drug manufacturers participating in the Medicaid drug rebate program to provide covered outpatient drugs to enrolled "covered entities" at or below the statutorily defined ceiling price. This requirement is described in Section 340B of the Public Health Service Act and codified at 42 USC §256b. The purpose of the 340B Program is to permit covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992).
	See <a href="http://www.hrsa.gov/opa/eligibilityandregistration/index.html">http://www.hrsa.gov/opa/eligibilityandregistration/index.html</a> for additional information and a complete list of covered entity types.
340B-eligible patient	An individual is a patient of a 340B covered entity (with the exception of state-operated or -funded AIDS drug purchasing assistance programs) only if:
	The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care.  The individual is the latest the covered entity maintains and the latest the covered entity maintains are covered entity maintains.
	<ul> <li>The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.</li> <li>The individual receives a health care service or range of services from the covered entity that is consistent with the service or range of services for which grant funding or federally qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.</li> </ul>
	An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.
	Exception: Individuals registered in a state-operated or funded AIDS Drug Assistance Program (ADAP) that receives federal Ryan White funding ARE considered patients of the participant ADAP if so registered as eligible by the state program.
	For more information: Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility.



Term	Definition
340B ID	A unique identification number provided by HRSA to identify a 340B-eligible entity in 340B OPAIS. This 340B ID is used to purchase 340B drugs.
340B OPAIS	The <u>340B Office of Pharmacy Affairs Information System</u> (OPAIS) provides access to covered entity and manufacturer records, user accounts, change requests, recertification, and registrations. This system increases the integrity and effectiveness of 340B stakeholder information and focuses on three key priorities: security, user accessibility, and accuracy.
340B Orphan Drug List (published by HRSA)	HRSA's list of orphan drug designations is used by 340B regarding the orphan drug exclusion. The list is updated quarterly and is based on the list of orphan drug designations provided by the U.S. FDA, Office of Orphan Products Development. The orphan drug list is found on HRSA's website: <a href="http://www.hrsa.gov/opa/programrequirements/orphandrugexclusion/index.html">http://www.hrsa.gov/opa/programrequirements/orphandrugexclusion/index.html</a> .
	HRSA posts the orphan drug list on the first day of the month prior to the end of the quarter that will govern the following quarter's purchases. The list is updated and archived quarterly. It is downloadable as a data file, searchable line by line, and contains the following fields: row number, generic name, trade name, designation date, orphan designation, contact company/sponsor.
340B Prime Vendor Program (PVP)	The Prime Vendor Program is managed by Apexus through a contract awarded by the Health Resources and Services Administration (HRSA), the federal government branch responsible for administering the 340B Drug Pricing Program. The PVP serves its participants in these primary roles:
	<ul> <li>Negotiating sub-340B pricing on pharmaceuticals</li> <li>Establishing distribution solutions and networks that improve access to affordable medications</li> <li>Stakeholder education through the 340B University programs</li> <li>Providing other value-added products and services</li> </ul>
	The PVP is a voluntary program for 340B covered entities. All covered entities may participate in the PVP, including hospitals that are prohibited from purchasing in a group purchasing arrangement. The PVP negotiates discounts for all participating entities.
5i drugs	Drugs that are inhaled, infused, instilled, implanted, or injectable. 5i drugs are not formally defined in the Covered Outpatient Drugs (COD) Final Rule but 5i is widely adopted by many stakeholders as a convenient way to condense the list of the five specific drug types (see 447.507 of COD Final Rule).
Accountable care organizations (ACOs)	Groups of doctors, hospitals, and other health care providers that come together voluntarily to give coordinated high-quality care to their Medicare patients. The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time while avoiding unnecessary duplication of services and preventing medical errors. When an ACO succeeds in both delivering high-quality care and spending health care dollars more wisely, it will share in the savings it achieves for the Medicare program. HRSA has issued a policy release regarding 340B and ACOs.
Actual acquisition cost (AAC)	CMS/HHS determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers as defined in the Covered Outpatient Drugs Final Rule.



Term	Definition
AMP true-up	Occurs when manufacturers restate their reported AMP for a specific time period and then refund any difference to 340B participating entities that had made purchases above the ceiling price.
Apexus Generics Program (AGP)	The HRSA Prime Vendor subcontracts certain multi-source generic products to channel partners under the 340B Prime Vendor agreement, called the Apexus Generics Program (AGP). The AGP is loaded to both the 340B and WAC accounts as default contract pricing. All contract pricing extended to covered entities under the 340B Prime Vendor provides manufacturers with full price protections and provides contracting infrastructure to support covered entity compliance with the GPO Prohibition.
Apexus Medicaid State Profile Resource	To improve transparency and assist stakeholders with 340B compliance, the Prime Vendor has gathered 340B Medicaid information from multiple federal and state Medicaid sources and compiled them in one location. Access this valuable resource here: <a href="https://www.340bpvp.com/resource-center/medicaid/">https://www.340bpvp.com/resource-center/medicaid/</a> .
	Note: the information and data presented on this website are not endorsed by HRSA and are not dispositive in determining compliance with the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all applicable state and federal laws and regulations. Stakeholders are encouraged to contact the states to verify current policy/requirements.
Apexus PVP sub- 340B pricing	Pricing below the statutory 340B ceiling price that is negotiated by Apexus PVP in the 340B account with branded and/or generic manufacturers.
Apexus value-added contracts	As HRSA's 340B Prime Vendor, Apexus is authorized to contract for other products and services required by the outpatient pharmacy environment. Other value-added contracts are for non-covered drugs including most vaccines, blood glucose monitoring supplies, and prescription vials and labels, and discounts on service contracts such as pharmacy automation hardware and software.
Associated site	"Associated site" is used by HRSA's 340B OPAIS to indicate sites that share grant numbers (CHCs) or a designation number (federally qualified health center look-alikes). Before September 2017, these covered entity types had a parent-child relationship. The 340B ID numbers of these entity types will not be changing, only the terminology—from parent-child to "associated sites." No other type of covered entity will have the associated site terminology.
Average manufacturer price (AMP)	CMS has authority regarding AMP. AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer. This definition applies to covered outpatient drugs of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act). See <a href="Covered Outpatient Drugs Final Rule">Covered Outpatient Drugs Final Rule</a> .
Average sales price (ASP)	Originally created during drug pricing litigation to ensure accurate price reporting, ASP is the weighted average of all non-federal sales to wholesalers. ASP is net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, regardless of whether it is paid to the wholesaler or the retailer. Excluded from ASP are sales that are excluded from the best price calculation. ASP is used as a basis of reimbursement for some Medicare Part B covered drugs and biologicals administered in hospital outpatient departments.



Term	Definition
Average wholesale price (AWP)	Publicly available national average of list prices charged by wholesalers to pharmacies. AWP is not defined in legislation, and does not account for discounts. It is sometimes referred to as a "sticker price," as it is not an actual price paid by most purchasers. AWP was once used as a primary basis of pharmacy reimbursement, but there is a trend moving away from this practice.
Best price (BP)	See Medicaid best price.
"Big 4"	The federal government's four largest purchasers of pharmaceuticals: Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS), and Coast Guard.
Billing address	340B OPAIS uses the "billing address" field to denote the address verified as belonging to the covered entity. A billing address is not required to be a physical address; it can be a P.O. box or other mailing address.
Black lung clinics	Clinics that receive funding from the HRSA Black Lung Clinic Program to seek out coal miners, whether they are currently involved in mining or not, and provide services to them and their families, regardless of their ability to pay.
	Services may be provided either directly by grantees or through formal arrangements with appropriate health care providers, such as federally qualified health centers, hospitals, state health departments, mobile vans and clinics
	The Black Lung Clinic Program is authorized by Section 427(a) of the Black Lung Benefits Act (30 USCS§901).
Carve-out/carve-in	See Medicaid carve-out/carve-in.
Centers for Medicare and Medicaid Services (CMS)	The federal agency charged with implementing and overseeing the Medicare and Medicaid programs.
Chargeback	The method wholesalers use to request reimbursement from manufacturers for 340B discounts provided to entities for 340B covered outpatient drugs. Wholesalers purchase drugs from the manufacturer at wholesale acquisition cost (WAC) and sell to 340B entities at the contracted 340B price, which is a lower price. The wholesaler submits a chargeback request to the manufacturer to account for the difference.
Children's hospital (PED)	These nonprofit hospitals serve individuals aged 18 or younger and have CMS-issued 3300 Series Medicare provider numbers to designate them as Medicare-certified children's hospitals. Children's hospitals must meet certain requirements, including a DSH adjustment percentage >11.75% and compliance with the GPO Prohibition, to be eligible to participate in the 340B Program.
Comprehensive hemophilia treatment centers	Hemophilia treatment centers (HTCs) that receive HRSA grant funding are expected to provide optimal care using a multidisciplinary team approach that provides accessible, family-centered, continuous, comprehensive, coordinated, and culturally effective care for individuals with hemophilia and other bleeding disorders. The program is authorized under section 501(a)(2) of the Social Security Act.
Consumer Price Index–Urban (CPI-U)	A measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services. CPI-U is used in determining whether or not to apply a penalty to the manufacturer affecting the 340B ceiling price for single-source and innovator multiple-source drugs.



Term	Definition
Contract pharmacy	340B covered entities may contract with a pharmacy or pharmacies to provide services to the covered entity's patients, including the service of dispensing the entity-owned 340B drugs. To engage in a contract pharmacy arrangement, the entity and pharmacy (or pharmacies) must have a written contract that aligns with the compliance elements, <u>listed in guidance</u> , and list the contract pharmacy on 340B OPAIS during a quarterly registration period. Typically, a bill-to (entity)/ship-to (pharmacy) arrangement is used.
Covered entity (CE)	The term "covered entity" refers to a health care provider or organization that is eligible for the 340B Program per the 340B statute.
Covered outpatient drug (COD)	Defined in section 1927(k) of the Social Security Act (SSA). Manufacturers participating in the Medicaid Drug Rebate Program must also provide 340B pricing on all of their CODs to CEs. Check the labeler code on 340B OPAIS and the Medicaid Drug Rebate Program to help determine whether a drug is a covered outpatient drug in the Medicaid Drug Rebate Program and thus should have a 340B price.  Covered entities should maintain auditable records and policies and procedures related to the definition of covered outpatient drug and the use of a GPO that is consistent with the 340B statute.
Critical access hospital (CAH)	A hospital certified to receive cost-based reimbursement from Medicare. This reimbursement is intended to improve the hospital's financial performance, thereby reducing hospital closures. CAHs are certified under different, more flexible Medicare conditions of participation (CoP) than acute care hospitals, and must meet certain criteria to be designated as CAHs. For the purposes of 340B, CAHs must meet specific 340B eligibility criteria.
Dispensing fee	The charge for the professional services provided in association with prescription dispensing. Most prescription payers reimburse on the basis of a benchmark of the drug cost (e.g., ASP, AMP, AWP, WAC, AAC) plus a dispensing fee.
Disproportionate share adjustment (DSH rate)	See Medicare DSH adjustment percentage.
Disproportionate share hospital (DSH)	Hospitals that serve a significantly disproportionate number of low-income patients; as such, they receive <u>adjustment payments</u> to provide additional help. The primary method of qualification is based on the sum of the percentage of Medicare inpatient days and the percentage of total patient days attributable to patients eligible for Medicaid but not eligible for Medicare Part A. Among other requirements, DSHs must have a <u>DSH adjustment</u> <u>percentage</u> >11.75% and meet <u>certain criteria</u> to be 340B eligible.
Disproportionate share hospital (DSH) inpatient pricing	The voluntary DSH inpatient contracts most GPOs offer their membership; the discount is usually ~2–3%. GPOs offer manufacturers this opportunity to put products on the DSH inpatient portfolio at a lower price than what the manufacturer has given the GPO (i.e., in the GPO acute care file/and/or for products that the manufacturer chooses not to contract under the GPO acute care file).
Duplicate discount	Prohibited by the 340B statute, a duplicate discount occurs when a covered entity obtains a 340B discount on a medication and a Medicaid agency obtains a discount in the form of a rebate from the manufacturer for the same medication.
Edit date	340B OPAIS uses the term "edit date" to denote the date that a 340B entity's information was edited. Edits to 340B OPAIS can occur at any time.



Term	Definition
Electronic Handbook (EHB)	A database that contains grant information for certain HRSA grantees. This is what HRSA uses to determine eligibility for certain entities.
Entity-owned pharmacy	A pharmacy that is owned by, and is a legal part of, the 340B entity. Typically, entity-owned pharmacies are listed as shipping addresses of the entity.
Estimated acquisition cost (EAC)	The estimation of the price typically paid by entities for a particular manufacturer's drug, using the most commonly purchased package size. Some Medicaid agencies use EAC (plus a dispensing fee) as a basis for establishing reimbursement. The exact method of calculating or projecting EAC may vary in different states.
Federal ceiling price (FCP)	The maximum price that a manufacturer may charge for a covered drug sold to the "big 4" federal entities engaged in providing health care services—Veterans Affairs, Department of Defense, Public Health Service (including Indian Health Service), and the Coast Guard. The federal ceiling price is effective for a calendar year, or the portion of a calendar year in which the covered drug is marketed.
Federally qualified health center (FQHC)	Community-based health care providers that receive funds from the HRSA Health Center Program to provide primary care services in underserved areas. They must meet a stringent set of requirements, including providing care on a sliding fee scale based on ability to pay and operating under a governing board that includes patients.  FQHCs may be community health centers, migrant health centers, health care for the homeless, and health centers for residents of public housing.
Federally qualified health center look-alike (FQHC-LA)	Community-based health care providers that meet the <u>requirements</u> of the HRSA Health Center Program but do not receive Health Center Program funding. They provide primary care services in underserved areas, provide care on a sliding fee scale based on ability to pay, and operate under a governing board that includes patients.
Federal Register notice (FRN)	Notices about guidelines and regulations are published in the Federal Register, a federal journal publication; in some situations, comments on the document are requested.
Federal supply schedule (FSS)	Involves large contracts through which federal customers can acquire more than 4 million products and services directly from more than 8,000 commercial suppliers. Products include pharmaceuticals and medical equipment and supplies. These contracts are available for use by all government agencies, including, but not limited to, VA medical centers, Department of Defense, Bureau of Prisons, Indian Health Service, Public Health Service, and some state veterans' homes.
Free-standing cancer hospital (CAN)	A nonprofit entity that is financially and administratively independent (not a part of a larger institution). CANs are exempt from Medicare's prospective payment system. For 340B purposes, a CAN must meet specific eligibility requirements, including a DSH adjustment percentage >11.75% and compliance with the GPO Prohibition. It is also subject to the orphan drug exclusion.
Government Accountability Office (GAO)	An independent nonpartisan agency that works for Congress. Often called the "congressional watchdog," <u>GAO</u> investigates how the federal government spends taxpayer dollars.



Term	Definition
Group purchasing organization (GPO)	An organization created to leverage the purchasing power of entities to obtain discounts from vendors based on the collective buying power of the GPO members. GPOs are common in the drug industry; the GPO may set mandatory purchasing participation levels from its members or be completely voluntary. Certain 340B participating hospitals (disproportionate share hospitals [DSH], children's hospitals [PED], and free-standing cancer hospitals [CAN]) are prohibited from purchasing covered outpatient drugs from a GPO or GPO-like arrangement.
GPO Prohibition	Per 340B statute, 340B participating disproportionate share hospitals (DSH), children's hospitals (PED), and free-standing cancer hospitals (CAN) are prohibited from obtaining covered outpatient drugs through group purchasing organizations (GPOs). Upon enrollment, an entity official signs a form attesting that the hospital will comply with the GPO Prohibition. This applies to the hospital as of the date of listing in 340B OPAIS. Upon recertification of information from 340B OPAIS, the hospital official attests to compliance with the GPO Prohibition. A GPO Prohibition Policy Release was posted by HRSA in 2013.  The following examples are <b>not</b> GPO Prohibition compliant contracting practices:  • An individual DSH accessing contracts executed by an IDN in which it is a member  • A wholesaler's generic source program  • A manufacturer extending a discounted price to a group of covered entities (subject to the GPO Prohibition) through a wholesaler, other third party, or group purchasing arrangement that is not supported by an individual contract between the 340B covered entity and the manufacturer. Such agreements should be reproducible for review during an audit of compliant 340B operations.
Health Industry Number (HIN)	A unique, universal identification number to be used by all trading partners when they communicate with one another via computer. HINs are randomly assigned nine-character alphanumeric identifiers that are issued by the Health Industry Business Communications Council (HIBCC). Drug wholesalers and manufacturers typically use HINs to identify entities.
Health Insurance Portability and Accountability Act (HIPAA)	A US law designed to provide privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals, and other health care providers.
Health Resources and Services Administration (HRSA)	An agency of the US Department of Health and Human Services, HRSA is the primary federal agency for improving access to health care services for people who are uninsured, isolated, or medically vulnerable. Comprising five bureaus and ten offices, HRSA provides leadership and financial support to health care providers in every state and US territory. The Office of Pharmacy Affairs (OPA), the office responsible for administering the 340B Program, falls under the Healthcare Systems Bureau within HRSA.



Term	Definition
Hospital outpatient facility/site	The outpatient facility is listed as a reimbursable facility on a 340B hospital covered entity's most recently filed Medicare cost report and has associated outpatient costs and charges. If the facility is a free-standing clinic of the hospital that submits its own cost reports using a different Medicare number (not under the covered entity's Medicare provider number), then it would NOT be eligible. Specific guidance on this topic was released in 1994.  For hospitals, all clinics located off-site of the parent hospital, regardless of whether those clinics are in the same off-site building must register as child sites of the parent 340B-eligible hospital if the covered entity purchases and/or provides 340B drugs to patients of those facilities. For example, if the off-site outpatient facility is a hospital, all clinics/departments within that off-site location that plan to purchase and/or provide 340B drugs to its patient must register as a child site.  Click here for more information on hospital offsite outpatient facilities.
HRSA 340B OPAIS	See 340B OPAIS.
In-house pharmacy	See entity-owned pharmacy.
Innovator multiple source drug	All covered outpatient drugs approved under a new drug application (NDA), product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA). A covered outpatient drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.
Manufacturer	<ol> <li>The definition of "manufacturer" (for 340B purposes) includes all entities engaged in:</li> <li>The production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or</li> <li>The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law.</li> <li>"Manufacturer" also includes an entity, described in (1) or (2) above, that sells outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program. For more information, visit <a href="https://www.hrsa.gov/opa/manufacturers/index.html">https://www.hrsa.gov/opa/manufacturers/index.html</a>.</li> </ol>
Medicaid best price (BP)	Regarding the Medicaid Rebate Program, Medicaid best price is the lowest manufacturer price paid for a prescription drug, regardless of package size, by any purchaser. BP is reported to CMS and states, but otherwise is confidential. Included in BP are cash discounts, free goods that are contingent upon purchase, volume discounts, and rebates. Excluded from BP are prices paid by the federal government (e.g., prices to the "big 4," 340B covered entities, federal supply schedule, state pharmaceutical assistance programs, depot prices, and nominal pricing to covered entities).
Medicaid carve-in	340B entities may elect to use drugs purchased at 340B prices and bill Medicaid for Medicaid fee-for-service patients. This activity is termed a "Medicaid carve-in." If an entity chooses to use 340B drugs for fee-for-service patients and bill Medicaid, it must indicate this on the Medicaid Exclusion File and list the appropriate Medicaid provider numbers and/or NPIs. Entities must inform HRSA whether they are carving in or out.



Term	Definition
Medicaid carve-out	340B entities may elect to use non-340B drugs for Medicaid fee-for-service patients. This activity is termed a "Medicaid carve-out." Entities may choose to do this so they can receive Medicaid reimbursement (many states reimburse entities that use 340B for Medicaid patients on a cost + dispensing fee basis, as the dispensing fee is often not high enough to cover costs). Entities must inform HRSA whether they are carving in or out through the Medicaid Exclusion File.  340B drugs may not be used for Medicaid fee-for-service patients at a contract pharmacy, absent an arrangement between the contract pharmacy, covered entity, and state Medicaid agency to prevent duplicate discounts. HRSA should be notified of this arrangement.
Medicaid Exclusion File (MEF)	HRSA established the Medicaid Exclusion File to help support program integrity regarding the statutory prohibition of duplicate discounts. The Medicaid Exclusion File is maintained on the HRSA 340B website and contains the National Provider Identification (NPI) number or Medicaid provider number of entities that use 340B discounted drugs to bill Medicaid for their fee-for-service patients. The MEF does NOT apply to Medicaid managed care patients. Entities are expected to provide updated information to HRSA for incorporation into the MEF. The covered entity should be billing according to its designation on the MEF. The covered entity should immediately inform HRSA of any changes.  The Medicaid Exclusion File is used for fee-for-service as follows:  All entities must inform HRSA whether they will use 340B drugs for their fee-for-service patients and bill Medicaid.  Entities using 340B purchased drugs for Medicaid fee-for-service patients must inform HRSA of their NPI/Medicaid provider number(s).  Medicaid agencies use the Medicaid Exclusion File to identify the NPI or Medicaid provider number of the entities purchasing at 340B prices.  The state Medicaid agency excludes from its rebate requests to manufacturers all claims associated with entities whose NPIs/Medicaid provider numbers are listed in the Medicaid Exclusion File.  Manufacturers use the Medicaid Exclusion File to verify denial of rebate payment on claims associated with entities purchasing at 340B prices.  340B OPAIS takes a snapshot at 12:01am ET on the 15th day of the month before the start of each quarter (irrespective of weekends or holidays); covered entities may request changes to their decision and/or the specific identifiers listed at any time but changes take effect quarterly and only if approved by OPA before the time of the snapshot.
Medicaid managed care organization (Medicaid MCO)	Managed care is a health care delivery system organized to manage cost, utilization, and quality. Medicaid managed care provides for the delivery of Medicaid health benefits and additional services through contracted arrangements between state Medicaid agencies and managed care organizations (MCOs) that accept a set per-member per-month (capitation) payment for these services.  Some states are implementing a range of initiatives to coordinate and integrate care beyond traditional managed care. These initiatives are focused on improving care for populations with chronic and complex conditions, aligning payment incentives with performance goals, and building in accountability for high-quality care. For more information, visit <a href="https://www.medicaid.gov/medicaid/managed-care/index.html">https://www.medicaid.gov/medicaid/managed-care/index.html</a> .  Covered entities are encouraged to work closely with their state to prevent duplicate discounts for Medicaid managed care claims.



Term	Definition
Medicaid provider number (MPN)	An identifier issued to health care providers by CMS that allows the provider to bill Medicaid for medical services.
Medicaid rebate net price	The price for covered outpatient drugs paid by state Medicaid programs, including the manufacturer rebates received by the states.
Medicare DSH adjustment percentage (DSH %)	An adjustment applied to hospitals that treat a high percentage of low-income patients. This adjustment results in an additional payment to these hospitals. Factors included in this adjustment are the sum of the ratios of Medicare Part A Supplemental Security Income (SSI) patient days to total Medicare patient days and Medicaid patient days to total patient days in the hospital. 340B covered entity hospitals must meet a certain threshold for disproportionate share adjustment percentage: >11.75% for DSH, PED, and CAN, and ≥8% for RRC and SCH.
Mixed-use setting	A hospital area that serves a mixed patient type of both inpatients and outpatients. Often these are facilities such as surgery centers, cardiac catheter labs, infusion centers, and emergency departments or pharmacies serving these locations.
National Drug Code (NDC)	Drug products are identified and reported using a unique three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for human drugs. The FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory, which is currently updated semimonthly. The NDC is an 11-digit number; the first segment (5 digits) of the NDC indicates the manufacturer, the second segment (4 digits) indicates the drug product, and the third segment (2 digits) indicates the package size.
National Provider Identifier (NPI)	A unique 10-digit identification number for covered health care providers. Covered health care providers and all health plans and health care clearinghouses must use the NPIs in the administrative and financial transactions adopted under HIPAA.
Native Hawaiian Health Centers	Native Hawaiian Health Centers receive Native Hawaiian Health Care Systems Program funding (through the HRSA Health Center Program appropriation) to provide medical and enabling services to Native Hawaiians.  Native Hawaiian Health Centers improve the health status of Native Hawaiians by providing access to health education, health promotion, and disease prevention services. Services provided include nutrition programs, screening and control of hypertension and diabetes, immunizations, and basic primary care services.
Non-federal average manufacturer price (non-FAMP)	The average price paid to a manufacturer by wholesalers for drugs distributed to non-federal purchasers. Non-FAMP is not publicly available. 340B and Prime Vendor sub-ceiling prices are excluded from a manufacturer's non-FAMP calculations.
Non-innovator multiple source drug	A drug that is not originally marketed under an original new drug application, and whose therapeutic equivalent is available from multiple sources.



Term	Definition
Office of Inspector General (OIG), Department of Health and Human Services	<ul> <li>An independent and objective oversight unit of the Department of Health and Human Services (HHS) to carry out the mission of promoting economy, efficiency, and effectiveness through the elimination of waste, abuse, and fraud.</li> <li>The OIG: <ul> <li>Conducts and supervises audits, investigations, and inspections.</li> <li>Identifies systemic weaknesses giving rise to opportunities for fraud and abuse in HHS programs and operations and makes recommendations to prevent their recurrence.</li> <li>Leads and coordinates activities to prevent and detect fraud and abuse in HHS programs and operations.</li> <li>Detects wrongdoers and abusers of HHS programs and beneficiaries so appropriate remedies may be brought to bear.</li> <li>Keeps the HHS Secretary and Congress fully and currently informed about problems and deficiencies in the administration of HHS programs.</li> </ul> </li> <li>The OIG has issued several reports relating to 340B. Pursuant to a delegation of authority, the HHS Office of Inspector General (OIG) has the authority to impose civil monetary penalties (CMPs) using the definitions, standards, and procedures under 42 CFR Parts 1003 and 1005, as applicable. For additional information, see the delegation of authority Federal Register notice at <a href="https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31944.pdf">https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31944.pdf</a> (82 Fed Reg. 1356, January 5, 2017).</li> </ul>
Office of Pharmacy Affairs (OPA)	The HRSA office responsible for administering the 340B Program.
Orphan Drug Act (ODA)	Provides for granting special status to a product to treat a rare disease or condition, upon request of a sponsor. The combination of the rare disease or condition <i>and</i> the product to treat it must meet certain criteria. This status is referred to as orphan designation. Orphan designation qualifies the sponsor of the product for the tax credit and marketing incentives of the ODA.
Orphan drug designation	The Orphan Drug Act (ODA) provides for granting special status to a drug or biological product ("drug") to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes "orphan status"). For a drug to qualify for orphan designation, both the drug and the disease or condition must meet certain criteria specified in the ODA and FDA's implementing regulations at 21 CFR Part 316.
Orphan drug exclusion	For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals participating in the 340B Program, the term "covered outpatient drug" does not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition. Therefore, manufacturers are not required to provide orphan drugs to these covered entities under the 340B Program. A manufacturer may, at its sole discretion, offer discounts on orphan drugs to these hospitals.
Orphan drug "sponsor"	The party that owns or has assigned rights to an orphan drug designation granted by the FDA. A sponsor listed on the FDA orphan drug list may not be the current manufacturer for an orphan drug if ownership or rights have been subsequently transferred.
Own use	Purchases that reasonably may be regarded as being used by the hospital in the sense that such use is a part of and promotes the hospital's intended institutional operation in the care of persons who are its patients. Additional information is available from the advisory opinion here: <a href="https://www.ftc.gov/sites/default/files/attachments/price-discrimination-robinson-patman-violations/080213kaiser.pdf">https://www.ftc.gov/sites/default/files/attachments/price-discrimination-robinson-patman-violations/080213kaiser.pdf</a> .



Term	Definition
Patient assistance programs	Programs under which drug manufacturers provide free or greatly subsidized medications to patients in need of assistance.
Patient Protection and Affordable Care Act (PPACA), 2010	<ul> <li>Expanded eligibility to include certain critical access hospitals (CAH), sole community hospitals (SCH), rural referral centers (RRC), and free-standing cancer centers (CAN).</li> <li>Required HRSA to publish ceiling pricing and actual pricing data submitted by drug manufacturers.</li> <li>Increased the Medicaid rebate percentage (from 15.1% to 23.1% for brand-name drugs; to 17.1% for clotting factors and pediatric drugs; and from 11% to 13% for generics).</li> <li>Created integrity provisions for manufacturers, including the ability to impose fines on manufacturers for violations of 340B, increased price transparency, and new processes for dispute resolution and recovery of overcharges.</li> <li>Created integrity provisions for entities, including civil penalties for providers knowingly violating the prohibition against diversion of 340B drugs.</li> <li>Directed the Government Accountability Office (GAO) to prepare a 340B-related report to Congress.</li> </ul>
Penny pricing	When the 340B ceiling price calculation results in an amount less than \$0.01, the ceiling price will be \$0.01. This policy was included in the 2017 <a href="Civil Monetary Penalties">Civil Monetary Penalties</a> <a href="Regulation">Regulation</a> . A 340B ceiling price that equals or rounds to zero will be published in 340B OPAIS as \$0.01 and the manufacturer must charge \$0.01 per unit.
Pharmaceutical pricing agreement (PPA)	The 340B statute requires that the Secretary of Health and Human Services enter into a pharmaceutical pricing agreement (PPA) with each manufacturer of covered outpatient drugs in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under the statute (340B ceiling price).  The PPA, and the subsequent PPA addendum, must be signed by a manufacturer as a condition for participating in the Medicaid program. Signing the PPA does not prohibit a manufacturer from charging a price for a covered outpatient drug that is lower than the 340B ceiling price.  A PPA remains in effect until terminated by either the manufacturer or the secretary of HHS. It is not automatically terminated if a manufacturer terminates its Medicaid rebate agreement.
Pharmacy benefit manager (PBM)	An administrator of prescription drug programs. PBMs are responsible for processing and paying prescription drug claims, and often for developing and maintaining a formulary of drugs. PBMs also may contract with pharmacies and negotiate discounts and rebates with drug manufacturers.
Physician- administered drugs	Drugs administered directly by a physician or a physician designee to a patient during a clinic visit or encounter.
Private label product	Typically, products manufactured or provided by one company for offer to customers/ members under another company's (GPO) brand. These products are typically the same (chemically) as the manufacturer's labeled product, but are just labeled under the offered company's own branding.
Provider-based regulations or status	Medicare sets standards that "provider-based" departments or clinics must meet to enable the entity to bill Medicare a facility fee under the outpatient prospective payment system. Hospitals seek provider-based status for financial reasons.



Term	Definition
Recertification	HRSA is required by statute to conduct annual recertification of participating 340B covered entities' information listed in 340B OPAIS. As part of this process, an authorizing official from each 340B entity certifies basic information about the entity and its 340B compliance.
Replenishment (340B outpatient drug)	340B drug replenishment occurs when a non-340B drug is dispensed to a 340B-eligible patient, and the entity later replaces the non-340B dispensed drug with a 340B purchased drug because of patient eligibility. Although the replacement drug was purchased at a 340B price, is no longer considered 340B inventory because it is replacing a non-340B drug dispensed to a 340B eligible patient.  Replenishment models operate on a neutral inventory premise. The inventory that is purchased "replenishes" a dispensing/administration activity that already occurred in the past. When this reorder arrives in the pharmacy, it becomes neutral and that package can
	be dispensed to any patient. In essence, the arrival of the replenishment order turns the drug that was originally dispensed with neutral inventory to an actual 340B transaction. This leaves that neutral inventory to reside on the shelf for the next dispensation.
Rural referral center (RRC)	A Medicare-participating acute care hospital is classified as an RRC if it is located in a rural area and meets certain criteria.
Ryan White HIV/AIDS Program grantee	Ryan White HIV/AIDS Program grantees receive federal funding to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or underinsured. In addition, the funding is used for technical assistance, clinical training, and the development of innovative models of care.  The Ryan White HIV/AIDS Program is authorized by Title XXVI of the Public Health Service Act.
Sexually transmitted disease clinic	The US Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) oversees and funds the prevention of sexually transmitted diseases (STDs). Section 318 of the Public Health Service Act authorizes <a href="STD funding">STD funding</a> . Projects under Section 318 are awarded to state and local health departments and academic and public health organizations.
Shipping address	340B OPAIS uses the "shipping address" field to denote a location that may have 340B drugs shipped to it. This address must be a physical address (no P.O. boxes). A shipping address may include in-house pharmacies, entity-owned warehouses, central fill facilities, repackagers, and other entity-owned locations purchasing 340B drugs.
Single source drug	A covered outpatient drug that is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application (NDA). It also includes a covered outpatient drug approved under a product license approval (PLA), establishment license approval (ELA), or antibiotic drug approval (ADA).
Sole community hospital (SCH)	A hospital paid under the Medicare Acute Care Hospital Inpatient Prospective Payment System (IPPS) is eligible to be classified as an SCH if it meets specific criteria determined by CMS. Typically, these hospitals furnish short-term, acute care, are paid under the Medicare Acute Care Hospital IPPS, are not critical access hospitals (CAH), and are not paid under any other Medicare prospective payment system.



Term	Definition
Split-billing software	Split-billing software is voluntary and is often used to help covered entities manage a replenishment inventory model. The entity tracks data feeds (such as inpatient or outpatient status, patient and prescriber eligibility, clinic location, Medicaid status, drug identifier, and quantity dispensed) and loads these data points into split-billing software. This software uses logic based on configurations, chosen by the entity, to virtually separate 340B from non-340B transactions after they occur. The software then determines from which account each transaction should be reordered.  The term "split-billing" is used to describe this software, which "splits" a purchase order into two or three different accounts (e.g., 340B, GPO, non-GPO/WAC). This software can help the entity place orders in appropriate accounts while maintaining auditable records of the accumulations and purchases.
Start date	340B OPAIS uses the term "start date" to denote an entity's start date in the 340B Program. Entity start dates are updated quarterly.
State plan amendment (SPA)	When a state is planning to make a change to its program policies or operational approach, it sends state plan amendments (SPAs) to the Centers for Medicare and Medicaid Services (CMS) for review and approval. States also submit SPAs to request permissible program changes, make corrections, or update their Medicaid or CHIP state plan with new information.
Telepharmacy	Involves the use of electronic information and communication technology to provide and support the delivery of pharmacy services (including drug product and professional pharmacist services) to locations that are remote from a physical pharmacy.
Termination date	340B OPAIS uses the term "termination date" to denote the date that the 340B entity is terminated from the 340B Program. The covered entity is no longer eligible to participate in the 340B Program on the day is terminated from the 340B Program or the day it becomes ineligible. The covered entity must stop purchasing, using, and administering 340B drugs once it is terminated from the 340B Program. Termination dates are updated on a quarterly basis.
Third-party administrator (TPA)	An organization that contracts with pharmacies and covered entities to help manage the operations of a contract pharmacy relationship. TPAs are responsible for determining 340B eligibility of prescriptions, processing and paying prescription drug claims, collecting revenue from payers, and tracking and ordering inventory for the covered entity. 340B entities often use a TPA in multiple contract pharmacy arrangements, but the use of a TPA is not required.
Title X family planning clinics	The <u>Title X Family Planning</u> program is authorized by Title X of the Public Health Service Act and is administered by the US Department of Health and Human Services' Office of Population Affairs. Title X family planning clinics receive funding from the Title X Family Planning Program to provide individuals with comprehensive family planning and preventative health services.
Tribal contract or compact health centers	Also called a 638 contract or compact, these sites are operated by Tribes or Tribal organizations, Urban Indian health centers are outpatient health care programs and facilities that specialize in caring for American Indians and Alaska natives. They are operated under the Indian Self-Determination Act.

# 340B Glossary of Terms



Term	Definition
Tuberculosis clinics	The US Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) oversees and funds the prevention, diagnosis, and treatment of tuberculosis (TB). TB funding is authorized under Section 317E of the Public Health Service Act.
Unit rebate amount (URA)	CMS has authority over URA and computes this amount. State Medicaid programs apply utilization information to it in order to invoice drug manufacturers for rebates. Unit rebate amount is used in the 340B ceiling price calculation. <u>URA Calculations</u> Brand: Greater of (23.1% of AMP or AMP – best price) <u>plus</u> CPI-U adjustment  Generic/OTC: 13% of AMP <u>plus</u> CPI-U adjustment  Blood Factors/Pediatric-only Indications: Greater of (17.1% of AMP or AMP – best price) <u>plus</u> CPI-U adjustment
Urban Indian health center (UIHC)	Designated as federally qualified health centers, UIHCs provide comprehensive primary care and related services to American Indians and Alaska Natives. The facilities are owned or leased by urban Indian organizations and receive grant and contract funding through Title V of the Indian Health Care Improvement Act.
Vendor	340B entities may elect to purchase services, designed to simplify or optimize 340B participation, from a variety of organizations, collectively called 340B vendors.
Wholesale acquisition cost (WAC)	The price paid by a wholesaler (or direct purchaser) in the United States for drugs purchased from the drug's manufacturer or supplier. Publicly available WAC lists do not represent actual transaction prices and do not include prompt pay or other discounts, rebates, or reductions in price.
Wholesaler	A drug wholesaler is an organization that provides drugs to entities, serving as the distributor between the drug manufacturer and the entity. Typically, states define the term "wholesaler," so exact definitions may vary from state to state.

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

© 2019 Apexus. Permission is granted to use, copy, and distribute this work solely for 340B covered entities and Medicaid agencies.





Home > News > Press Releases

# Opioid Epidemic Grows as Alabama Ranks First Nationally Having More Opioid Prescriptions than People

**BIRMINGHAM** – Blue Cross and Blue Shield of Alabama is taking action to help address the opioid epidemic in Alabama.

According to the Centers for Disease Control and Prevention (CDC), Alabama ranks highest in the nation as having more opioid prescriptions than people with Alabama physicians writing an alarming 5.8 million prescriptions for opioids in 2015. Alabama also ranks number one as the highest prescribing state in the nation for opioid pain reliever prescriptions, according to the CDC.

A new national report, "America's Opioid Epidemic and Its Effect on the Nation's Commercially Insured Population," represents a comprehensive study of national medical claims from Blue Cross and Blue Shield (BCBS) members using opioid painkillers, as well as those diagnosed with opioid use disorder over a seven-year period.\*

This new study by the Blue Cross Blue Shield Association (BCBSA) reports that:

In Alabama,

- 26 percent of Blue Cross and Blue Shield of Alabama's commercially insured members filled at least one opioid prescription in 2015, compared to 21 percent nationally.
- 6.5 percent of our members were on a long-duration opioid regimen in 2015, compared to 3.8 percent nationally.
- 16.4 per 1,000 members were diagnosed with opioid use disorder in Alabama in 2016, double that of 8.3 nationally.

• 29 percent of our members with opioid use disorder received medication-assisted therapy in 2016, compared to 37 percent nationally.

# Nationally,

- Opioid use disorder diagnoses among BCBS commercially insured members spiked 493 percent from 2010 through 2016.
- Among those 45 and older, women have a higher rate of opioid use disorder than do men. Among people younger than 45, men have higher rates of opioid use disorder than women. Women fill more opioid prescriptions than males across all age groups.
- Long-duration prescription opioid use and opioid use disorder overlap by region, with the highest rates in the South and the Appalachian Region.
- The 65 percent rate of increase in the use of medication-assisted treatments lags behind the 492 percent rate of increase in opioid use disorder diagnoses from 2010 through 2016.
- States that have experienced the greatest growth in the use of medication-assisted treatments are not necessarily the areas most impacted by opioid use disorders. High rates of treatment relative to opioid use disorder occur in New England, and lower rates occur in the South and parts of the Midwest.

"We recognize that it's crucial for us to be a proactive partner in the fight against the opioid epidemic in Alabama," said Dr. Anne Schmidt, Medical Director for Blue Cross and Blue Shield of Alabama. "We strongly support best practices and are collaborating with primary care doctors to appropriately apply recommendations and guidelines from the CDC."

Blue Cross and Blue Shield of Alabama is taking action to prevent opioid misuse by working in three primary areas:

- 1. Promoting the health and safety of Alabamians through public awareness and education of opioid risk by partnering with local and state agencies including the Governor's Council on Opioid Misuse and Addiction, the Alabama Department of Public Health, and local awareness groups and coalitions.
- 2. Supporting appropriate prescribing of opioids for pain management by providing CDC treatment guidelines to primary care physicians and offering medication-assisted treatment options for members with opioid use disorder.
- 3. Encouraging and supporting public outreach initiatives to prevent prescription opioid misuse, abuse, fraud and diversion. This also includes supporting and promoting "National Drug Take-Back Day" which provides free, anonymous collection of unwanted and expired medications.

The <u>BCBS Health Index SM</u> identifies substance use disorder as the fifth most impactful condition affecting the health of commercially insured members in the U.S. In Alabama, the results are similar with substance use disorder ranked as the fifth most prevailing health condition.

This is the thirteenth study of the Blue Cross Blue Shield: The Health of America Report® series, a collaboration between BCBSA and Blue Health Intelligence, which uses a market-leading claims database to uncover key trends and insights into health care affordability and access to care. For more information, visit <a href="https://www.bcbs.com/healthofamerica">www.bcbs.com/healthofamerica</a>.

\*Members diagnosed with cancer or who were undergoing palliative or hospice care were excluded from this analysis.

## About Blue Cross and Blue Shield of Alabama

Blue Cross and Blue Shield of Alabama has insured Alabamians for 81 years. Blue Cross offers coverage plans to corporations, individuals and the senior market. For more information about Blue Cross, visit <u>AlabamaBlue.com</u>. Connect with us on <u>Facebook</u>, check out our videos on <u>YouTube</u> and follow us on <u>Twitter</u> for more up-to-date information.

Blue Cross and Blue Shield of Alabama is an independent licensee of the Blue Cross and Blue Shield Association.

## **About BHI**

Health Intelligence Company is the nation's premier health intelligence resource, delivering data-driven insights about healthcare trends and best practices, resulting in healthier lives and more affordable access to safe and effective care. HIC accesses healthcare claims data from more than 140 million individuals nationwide, collected over nine years, in a safe, HIPAA compliant and secure database. The resulting conformed, reliable data set has the broadest, deepest pool of integrated medical and pharmacy claims, reflecting medical utilization in every ZIP code. Health Intelligence Company, LLC operates under the trade name Blue Health Intelligence (BHI) and is an Independent Licensee of BCBSA. For more information, visit <a href="http://www.bluehealthintelligence.com/">http://www.bluehealthintelligence.com/</a>.

# ABOUT BLUE CROSS BLUE SHIELD ASSOCIATION

The Blue Cross and Blue Shield Association is a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield companies that collectively provide health care coverage for one in three Americans. BCBSA provides health care insights through The Health of America Report series and the national BCBS Health Index<sup>sm</sup>. For more information on BCBSA and its member companies, please visit BCBS.com. We also encourage you to connect with us on Facebook, check out our videos on YouTube and follow us on Twitter.

Blue Cross and Blue Shield of Alabama June 29, 2017

# **MEDIA CONTACTS**

Koko Mackin 205.220.2713 kmackin@bcbsal.org

# More Press Releases

# BLUE CROSS BLUE SHIELD ASSOCIATION

Blue Cross Blue Shield Association and Blue Health Intelligence Invite Cutting-Edge Companies to Enter the BlueCross BlueShield Data Innovation Challenge April 30, 2019

Blue Cross Blue Shield Association Study Finds Millennials are Less Healthy than Generation X Were at the Same Age

April 24, 2019

Blue Cross Blue Shield Association Statement on Friend-of-Court Brief Filed in Texas et al. v United States et al.

April 1, 2019

Blue Cross Blue Shield Association Study Shows a More Than 30 Percent Increase in ADHD Diagnoses Among Children

Yale's School of Public Health and School of Medicine Researchers Find State Laws Have Some Impact on Breast Ultrasound and Cancer Detection Rates

March 22, 2019

# **BLUE CROSS BLUE SHIELD COMPANIES**

# Blue Cross and Blue Shield of Vermont Promotes Outdoor Recreation Through Annual Mountain Days

May 3, 2019

Blue Cross and Blue Shield of Vermont

# Premera hires Chief Financial Officer to join leadership team

May 2, 2019

Premera Blue Cross

# Arkansas Blue Cross Moves Up On Forbes' List Of America's Best Midsize Employers

May 2, 2019

Arkansas Blue Cross and Blue Shield

# Ann Shelton Promoted To Vice President Of Finance At Blue Cross And Blue Shield Of Kansas

May 1, 2019

Blue Cross and Blue Shield of Kansas

## Free Measles Vaccinations Available To CareFirst Members During Outbreak

April 29, 2019

CareFirst BlueCross BlueShield



Contact Us

Healthcare Fraud

**Privacy Policy** 

Terms & Conditions

Cookie Policy

Sitemap



© 2019 Blue Cross Blue Shield Association. All Rights Reserved.

The Blue Cross Blue Shield Association is an association of independent, locally operated Blue Cross and Blue Shield companies.

Menu

Set Weather



Subscribe

Sign In

Search

**NEWS** 

# National opioid crackdown leads to 8 Alabama arrests, including doctor accused of trading sex for drugs

Updated Apr 17, 2019; Posted Apr 17, 2019



ΑP

Jay Town, U.S. Attorney for the Northern District of Alabama, speaks beside members of Appalachian Regional Prescription Opioid Strike Force, during a news conference, Wednesday, April 17, 2019, in Cincinnati. Federal authorities have charged 60 people, including 31 doctors, for their roles in illegal prescribing and distributing millions of pills with opioids and other dangerous drugs. (AP Photo/John Minchillo)

## 2.8k shares

#### By The Associated Press , Ashley Remkus | aremkus@al.com and Carol Robinson | crobinson@al.com

Federal authorities said Wednesday they have charged 60 people nationwide, including 31 doctors, for their roles in illegally prescribing and distributing millions of pills containing opioids and other dangerous drugs.

Eight of those arrests were made in Alabama.

U.S. Attorney Benjamin Glassman of Cincinnati described the action as the biggest known takedown yet of drug prescribers. Robert Duncan, U.S. attorney for eastern Kentucky, called the doctors involved "white-coated drug dealers."	

#### Huntsville-area doctors among 60 charged in federal pill mill investigation

Authorities said the 60 includes 53 medical professionals tied to some 350,000 prescriptions and 32 million pills. The operation was conducted by the federal Appalachian Regional Prescription Opioid Strike Force, launched last year by the Trump administration.

Authorities said arrests were being made and search warrants carried out as they announced the charges at a news conference.

U.S. health authorities have reported there were more than 70,000 drug overdose deaths in 2017, for a rate of 21.7 per 100,000 people. West Virginia and Ohio have regularly been

among the states with the highest overdose death rates as the opioid crisis has swelled in recent years.



# Hoover doctor and her husband arrested in massive federal opioid takedown

Among those charged was a Tennessee doctor who dubbed himself the "Rock Doc" and is accused of prescribing dangerous combinations of drugs such as fentanyl and oxycodone, sometimes in exchange for sex, authorities said

Others include a Kentucky doctor who is accused of writing prescriptions to Facebook friends who came to his home to pick them up, another who allegedly left signed blank prescriptions for staff to fill out and give to patients he hadn't seen, and a Kentucky dentist accused of removing teeth unnecessarily and scheduling unneeded follow-up appointments.



A Dayton, Ohio, doctor was accused of running a "pill mill" that allegedly dispensed 1.75 million pills in a two-year period. Authorities said an Alabama doctor recruited prostitutes and other women he had sexual relations with to his clinic and allowed them to abuse drugs in his home.

#### Here are those arrested in Alabama:

• Dr. Marshall Plotka, a doctor at Phoenix Emergency Care in Jones Valley, is charged with maintaining drug-involved premises.

Plotka is accused of letting people use heroin, methamphetamine, cocaine and marijuana at his southeast Huntsville home, according to federal court records. The drug users were often women that Plotka hired as prostitutes and recruited as patients, according to a federal indictment. During a raid in March, authorities found drug paraphernalia in Plotka's home, court records show.

Police were called 35 times to Plotka's Chamlee Place home since October 2015, including for an overdose.

Authorities got search warrants for his electronic devices and found messages in which Plotka discussed buying drugs for a woman two months after she overdosed at his home, records show.

 Dr. Celia Lloyd-Turney, of Choice Medicine, a clinic in the northwest Madison County community of Toney, is indicted on nine charges of distributing controlled substances, according to federal court records.

In August 2017, the Alabama Board of Medical Examiners restricted Lloyd-Turney's ability to dispense controlled substances, including limiting the drugs she's allowed to prescribe and how much she could legally prescribe per patient per day. As part of an agreement with the medical board, Lloyd-Turney admitted she had excessively prescribed controlled substances to 10 patients. The agreement, which included restrictions, allowed her to keep her certificate to prescribe controlled substances.



The restrictions stemmed from an investigation by the Board into Lloyd-Turney's prescribing behavior at Choice Medicine. Board investigators said she over-prescribed substances to several patients and that she did so with no legitimate medical purpose.

In May 2018, Lloyd-Turney was <u>sued for wrongful death</u> by the family of Felicia Ann Kelly, a former patient who died two years earlier at age 30. The lawsuit says she died from "mixed drug toxicity," with toxicology tests detecting "fatal levels" of oxycodone and other drugs.

Federal court records allege Lloyd-Turney "prescribed dangerous combinations of drugs known to heighten the risk of overdose and death."

- Dr. John Cimino, of the Center for Women's Healthcare in Huntsville, is charged along with Katherine Barnett, a marketer for a pharmacy and the owner of Medical Sports Performance LLC, in a health care fraud case, according to federal court records.
- Dr. Elizabeth Korcz, 46, and Matthew Korcz, 45, who served as her office manager at the former Hoover Alt MD on South Shades Crest Road, were taken into custody shortly before 7:30 a.m. by Drug Enforcement Administration Agents and Hoover police in a traffic stop near their home.

The couple, whose office was first raided in August 2017, is named in a 15-count federal
indictment issued under seal in March and made public Wednesday following their arrests.
They are charged with one count of conspiracy to distribute a controlled substance; one
count of maintaining a drug-involved premises; five counts unlawful distribution of a
controlled substance; one count conspiracy to commit healthcare fraud; and seven counts
health care fraud.

Their pharmacy technician, Austin Haskew, also was indicted on similar charges.

Hoover Alt MD, which is now believed to be closed, touted an innovative type of medical practice, combining traditional family medicine as well as alternative medical therapies and practices. That alternative care, according to their website at the time of the 2017 raid, included natural medicine, acupuncture, biofeedback, hypnosis, bioidentical hormone balancing, sensory stimulation and breast thermography, according to the website.

The practice also offered counseling, prayer, relaxation therapy, natural and medicated weight loss treatments, fitness advice, pain management, suboxone addiction recovery services, Botox, facials, chemical peels and blemish removal, according to the website.

Federal agents on Aug. 25, 2017 seized \$56,045 from two accounts held by Hoover Alt MD PC, according to federal court documents. Since then the clinic has fought in federal court to get the money back.

Christopher Wray was charged with forging prescriptions. He's accused of creating
falsified prescriptions, at least once using a computer at the Guntersville Public
Library, court records show. Between December 2018 and February 2019, Wray used
falsified documentation to have more than 1,400 pills filled at local pharmacies,
according to a federal indictment.

"Sometimes the only difference between a drug dealer and a doctor is the white coat," said U.S. Attorney Jay Town, of the Northern District of Alabama.

Most of those charged came from the five strike force states of Alabama, Kentucky, Ohio, Tennessee and West Virginia. One person each was also arrested in Pennsylvania and Louisiana.

"The opioid crisis is the deadliest drug crisis in American history, and Appalachia has suffered the consequences more than perhaps any other region," U.S. Attorney General William Barr said in a statement in Washington.

Alabamians who are seeking help for opioid addiction can call 1-866-264-4073.

Information about substance abuse and opioids is available at the following websites:

http://www.alabamapublichealth.gov/pharmacy/opioid-and-heroin.html

https://mh.alabama.gov/understanding-the-opioid-crisis/

AL.com reporter Anna Claire Vollers contributed to this story.

Correction: An earlier version of this story incorrectly stated the location of Phoenix Emergency Care.



View Comments (72)

Note to readers: if you purchase something through one of our affiliate links we may earn a commission.

SPONSOR CONTENT

# Getting your chronic pain treated: debunking 3 myths about pain management



**By Tennessee Valley Pain Center** 

Several years ago, the celebrated PBS host Martha Pullen – one of Alabama's own homegrown entrepreneurs who turned her passion for sewing into an acclaimed TV show and magazine Sew Beautiful – was...

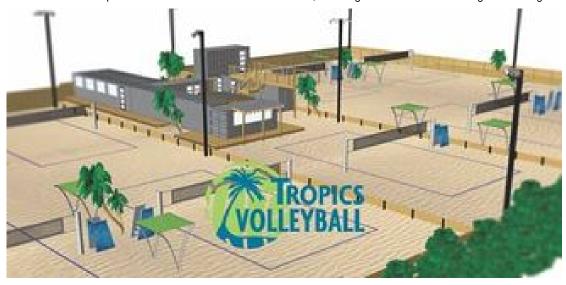
Learn More

**NEWS** 

Filling sand volleyball void: After Daphne debate, Tropics looks to bring 'exploding' sport elsewhere

Today 10:56 AM

1



A rendering of Tropics Volleyball's site plan. (rendering provided by Weston Hawkins with Tropics Volleyball)

Comment

0 shares

#### By John Sharp | jsharp@al.com

Gulf Shores has become the epicenter of the collegiate sand volleyball world by hosting of the NCAA national championships for the past four years. This past weekend's tournament set a record for attendance, and competitions were broadcast all weekend on the ESPN networks.

"The interest from the general population has increased," said Beth Gendler, vice president of sales and sports with the Gulf Shores & Orange Beach Tourism and Sports Commission.

But outside the white sands of the Gulf Shores Public Beach, supporters for sand volleyball in coastal Alabama argue there are few options in Mobile and Baldwin counties for the general public to participate in a sport that's growing in popularity.

In Daphne on Monday, the attempts of Weston Hawkins to build a nine-court sand volleyball and restaurant complex along U.S. 98 officially came to an end.

And though Hawkins claims he has a handful of possible options, he expressed disappointment and frustration over a nearly two-month process that met with disapproval from neighbors and denials from City Hall.

"We were working hard to change public opinion," Hawkins said. "But as you saw (Monday night), they said, 'Basically, we don't care what your public opinion is.'"

#### Land use debate

At a brief <u>Board of Zoning Adjustments</u> meeting, Hawkins requested the four-member body to review what he felt was an error made by the city's director of community development within his original application.

Hawkins asked the board to postpone the hearing for a month, so he could get closer to a more "concrete decision" about his project. After the board decided not to grant the postponment, Hawkins withdrew his request.

Hawkins said that his requested use for the property along U.S. 98 – directly across from Walmart Supercenter – was for a restaurant, rather than for outdoor amusement. Daphne does not specifically cite "volleyball courts" or "sand volleyball" as a use within the city's zoning districts.

The 3.75-acre property is zoned for commercial, but its western edges abut homes along Main Street, often referred to as "Scenic 98." And because of that nearby residential zoning, Hawkins needed permission for his venture from the city's Planning Commission.

The Planning Commission voted 4-1 in late March to deny the project based largely on objections from residents concerned over noise, traffic and lights. Also, they worried about having a sand volleyball complex with a bar and grill sitting next door on U.S. 98 to a funeral home and counseling center.

"Volleyball is wonderful and I played it myself," said Connie Whitaker, a nearby resident. "That's not the discussion. It's about the land use. We have a counseling center and a funeral home where people are mourning. We just ask them to make the proper decision on this land."

"And not put it in a residential area where babies are being pushed and old ladies are walking," added Starr Turk, a nearby resident along Jackson's Oak Drive.

Hawkins said he met with 200 residents after the public worries surfaced. He also assembled an online petition in support of Tropics Volleyball, gathered up nearly 2,000 signatures and pushed for support through social media.

"We had constructive dialogue and attempted to address their issues and I think we were successful in doing so whether it was noise, lights or reshaping what we were trying to do in more of a restaurant than what everyone seemed to be perceiving, which was a bar," said Hawkins. "That is not what we are about. We are a family environment."

### 'Opportunities for kids'

A sand volleyball practice in Gulf Shores, Ala. (file photo)

A sand volleyball practice in Gulf Shores, Ala. (file photo) Hawkins was banking on the past five or so years at Tropics Bar & Grill in Spanish Fort at the U.S. 98 Causeway. The volleyball complex adjacent to the Bar & Grill was a separate venture from the eatery, so when it closed in January, Hawkins said he had to find another place to set up.

"We made a run and thought we'd be able to take over the site we were at," said Hawkins. "It didn't work out."

Tropics enjoyed a good reputation among beach volleyball aficionados.

Joe Alaimo, founder of <u>Birmingham Beach Volleyball</u>, said the complex provided a topnotch set-up with five sand volleyball courts, next to a "good social restaurant atmosphere" that simply felt "beachy."

"What set it apart was the lights," said Alaimo. "Having been able to play at night past sundown is a huge advantage."

Hawkins said the U.S. 98 property that he's eyed is owned by a parent of a junior participant in his leagues. Hawkins said his junior leagues, which involve youths ages 7 to 18, are his most popular activities and he says it's not uncommon for his participants to continue playing sand volleyball into college.

"I think we've done a phenomenal job in providing opportunities for kids to learn the sport, grow in it and hopefully make a career at whatever college they choose to go to," he said. "We have a five-year track record of bringing scholarships to kids."

Hawkins, though, said he had nowhere for his junior members to practice ahead of this year's events in Gulf Shores. About 40 courts are set up next to the NCAA championship complex, drawing junior league teams from around the country.

#### 'Short-sighted'

Hawkins declined to disclose the alternative locations, although he said he aims to make a comeback that's "bigger and better than ever."

Daphne officials, and the concerned residents nearby the U.S. 98 site, suggested he consider locating the sand volleyball complex in or near a public park, such as the Trione Park in Daphne.

Daphne City Council President Pat Rudicell, who represents the area near the U.S. 98 site, said the city is planning to examine its parks soon to see what kind of investments and events are needed. The city is completing an expansion of its parks, including the addition of new tennis courts at W.O. Lott Park in the downtown area along Main Street. The \$16 million Daphne Sports Complex opened in March with 10 new baseball and softball fields.

Rudicell said that the privately-operated Daphne Strike soccer organization is planning to build its own facility soon, and that the city will be constructing a new \$150,000 road to accommodate it.

"That's just one item," said Rudicell. "We need to talk about what we want to spend our money on."

Hawkins, though, lamented what he felt was an anti-business approach from the city.

"One of my biggest gripes is there really isn't a lot of 'content," said Hawkins. "You go out to dinner and choose among six different restaurants in our area. Fairhope does a great job with their content. Daphne needs more. I'm not a bank. There is a bank next door. I Just think we add to the enrichment of the community."

Rudicell said Hawkins' comments were "short-sighted," pointing to the millions of dollars the city has spent on recreational facilities in recent years.

And Councilman Ron Scott said the complex simply didn't conform to the area it was proposed to locate into surrounded by residential, a funeral home and a counseling center.

He also said that the restaurant design -- inside a shipping container, similar to the containers that recently opened at the Spanish Fort Town Center – isn't allowed on U.S. 98.

"You cannot have a metal building on U.S. 98," said Scott. "In our opinion, it was not an appropriate use. We're not anti-volleyball. We'd love to have that facility someplace else."

#### 'Exploding sport'

Daphne Mayor Dane Haygood agreed, saying he supported the general concept that Hawkins had pitched to the city: A privately-owned sporting venue in the city that wouldn't require the support of taxpayer dollars.

"Generally speaking, it's a positive," said Haygood, who was concerned about the property connecting to the residential Main Street/Scenic 98 roadway.

"In general, the people who care about the sport and having the private sector fund these things instead of looking to a body of government to provide those facilities, is a positive," he added.

It's also something that's in demand in Alabama.

Alaimo said the six-court Brahan Park in Huntsville and a four-court lighted complex in Pelham are the state's biggest attractions for sand volleyball. He said a new, 12-court and lighted complex opening soon at <u>John Hunt Park in Huntsville</u> will replace <u>Rally in Cartersville</u>, Georgia, as the largest outdoor and sand volleyball court center in the South.

Aside from that, most of the larger complexes are private and located at a college or university. Numerous one- or two-court facilities exist at apartment complexes, and public beaches. In Birmingham, the popular club Sidebar <u>regularly hosts sand volleyball</u> tournaments.

"There definitely needs to be a Southern hub of sand volleyball, a place to go to," said Alaimo. "We work a lot with Huntsville and Nashville, with our three-hour 'bubble' to travel, see different competitions, and work together."

He added, "Tropics has been our Southern part and we would want nothing more than the new place to be built especially down there so we can start growing our sport further south as well."

Hawkins said he's willing to fill what he says is a "void" in the Mobile area.

"There is a need for it," he said. "There were 440 junior teams in Gulf Shores ... we have this exploding sport but literally no public infrastructure to support it and no private club to support it. When you look at that, there is a giant need the community is not filling."

**View Comments** 

Note to readers: if you purchase something through one of our affiliate links we may earn a commission.



ADVATCE Registration on or use of this site constitutes acceptance of our User Agreement and Privacy Policy

© 2019 Alabama Media Group. All rights reserved (**About Us**).

The material on this site may not be reproduced, distributed, transmitted, cached or otherwise used, except with the prior written permission of Alabama Media

Group.

Community Rules apply to all content you upload or otherwise submit to this site.

Ad Choices