STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES
Margaret M. O'Neill Bldg., Suite 1, Room 311
410 Federal Street
Dover, Delaware 19901
302-739-3621

The Honorable John Carney
Governor

John McNeal
SCPD Director

MEMORANDUM

DATE: June 12, 2017

TO: Devashree Brittingham, Executive Director
Division of Professional Regulations/Delaware Board of Medical Licensure and Discipline

FROM: Jamie Wolfe, Chairperson
State Council for Persons with Disabilities

RE: 20 DE Reg. 953 [DPR Proposed Medical Licensure & Discipline Bd. Telemedicine Regulation (6/1/17)]

The Division of Professional Regulation published the initial version of this proposed regulation in November, 2016. At 954. Based on the results of a public hearing and comments submitted on the November initiative, the Division revised its proposed regulation which is being republished. The sole focus of the proposed regulation is physician participation in telemedicine.

SCPD has the following observations.

First, a representative of the Michael J. Fox Foundation for Parkinson's Research promoted an authorization to allow "audio-only" telemedicine. This view is not foreclosed by statute since H.B. No. 69 (enacted in 2015) refers disjunctively to "telemedicine" as "real time two-way audio, visual, or other telecommunications....". In contrast, Nemours recommended, based on studies, that telemedicine be limited to contemporaneous audio and visual communication. The Division deferred to the views of Nemours. This approach merits endorsement and is supported by both federal Medicare and Delaware State Medicaid standards. See attached 42 C.F.R. 410.78(a)(3) and DMMA telemedicine regulations at 16 DE Reg. 314 (9/1/12) and 19 DE Reg. 20 (7/1/15).

Second, Nemours also "supported a ban on opioid prescribing via telehealth technology, with the exception of buprenorphine and naloxone prescribed for the purposes of treating drug addiction." At 954. The proposed regulation may be ambiguous in the context of the recommended exception for overdose "blockers". Section 19.3 recites that "(n)o opioid prescribing is permitted via telemedicine with the exception of addiction treatment programs..." that have received a DSAMH waiver. If a community physician cannot prescribe an opioid reversing drug such as buprenophine or naloxone via telehealth technology that would be unfortunate. Consistent with the attached articles and materials, naloxone is available to trained law enforcement officers, school nurses, and trained laypersons without a prescription. See also 16 Del.C. §§138 and 3001G. Such access suggests that the drugs are not readily subject to abuse. Since the attached February 26, 2016 article notes that many commercial health insurance policies only cover the drugs if purchased with a prescription, community physicians are still appropriate prescribers of the drugs. The Division may wish to clarify that such prescriptions are exceptions to the "no opioid prescribing" ban in §19.3.

Third, many of the patient participants in telemedicine will be persons with disabilities with a right to "effective communication" in the health care context under the Americans with Disabilities Act (ADA). See attached DOJ guidance and DREDF summary. For example, if a physician opts to use telemedicine with a Deaf patient, the physician may be required to enlist an interpreter. To ensure consideration of the ADA in the telemedicine context, the Delaware Division of Medicaid & Medical Assistance added the following provision to its telemedicine regulation:

> The provision of services through telemedicine must include accommodations, including interpreter and audio-visual modification, where required under the Americans with Disabilities Act (ADA), to ensure effective communication.

See attached regulation, 16 DE Reg. 314, 316-318 (September 1, 2012). The Division of Professional Regulation should consider inserting a similar standard in §19.0 or, at a minimum, a conforming regulatory note.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our observations or recommendations on the proposed regulation.

cc: Mr. Brian Hartman, Esq.
Governor's Advisory Council for Exceptional Citizens
Developmental Disabilities Council

20reg953 dpr – medical licensure and discipline board telemedicine 6-12-17

Cornell Law School

42 CFR 410.78 - Telehealth services.

§ 410.78 Telehealth services.

(a) ***Definitions.*** For the purposes of this section the following definitions apply:

(1) ***Asynchronous store and forward technologies*** means the transmission of a patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs visualized by a telecommunications system must be specific to the patient's medical condition and adequate for furnishing or confirming a diagnosis and or treatment plan. Dermatological photographs, for example, a photograph of a skin lesion, may be considered to meet the requirement of a single media format under this provision.

(2) ***Distant site*** means the site at which the physician or practitioner delivering the service is located at the time the service is provided via a telecommunications system.

(3) ***Interactive telecommunications system*** means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.

(4) ***Originating site*** means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous store and forward telecommunications technologies, the only originating sites are Federal telemedicine demonstration programs conducted in Alaska or Hawaii.

(b) ***General rule.*** Medicare Part B pays for covered telehealth services included on the telehealth list when furnished by an interactive telecommunications system if the following conditions are met:

(1) The physician or practitioner at the distant site must be licensed to furnish the service under State law. The physician or practitioner at the distant site who is licensed under State law to furnish a covered telehealth service described in this section may bill, and receive payment for, the service when it is delivered via a telecommunications system.

(2) The practitioner at the distant site is one of the following:

(i) A physician as described in § 410.20.

(ii) A physician assistant as described § 410.74.

(iii) A nurse practitioner as described in § 410.75.

(iv) A clinical nurse specialist as described in § 410.76.

(v) A nurse-midwife as described in § 410.77.

(vi) A clinical psychologist as described in § 410.71.

(vii) A clinical social worker as described in § 410.73.

(viii) A registered dietitian or nutrition professional as described in § 410.134.

(ix) A certified registered nurse anesthetist as described in § 410.69.

(3) The services are furnished to a beneficiary at an originating site, which is one of the following:

(i) The office of a physician or practitioner.

(ii) A critical access hospital (as described in section 1861(mm)(1) of the Act).

(iii) A rural health clinic (as described in section 1861(aa)(2) of the Act).

(iv) A Federally qualified health center (as defined in section 1861(aa)(4) of the Act).

(v) A hospital (as defined in section 1861(e) of the Act).

(vi) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(vii) A skilled nursing facility (as defined in section 1819(a) of the Act).

(viii) A community mental health center (as defined in section 1861(ff)(3)(B) of the Act).

(4) Originating sites must be:

(i) Located in a health professional shortage area (as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) that is either outside of a Metropolitan Statistical Area (MSA) as of December 31st of the preceding calendar year or within a rural census tract of an MSA as determined by the Office of Rural Health Policy of the Health Resources and Services Administration as of December 31st of the preceding calendar year, or

(ii) Located in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act as of December 31st of the preceding year, or

(iii) An entity participating in a Federal telemedicine demonstration project that has been approved by, or receive funding from, the Secretary as of December 31, 2000, regardless of its geographic location.

(5) The medical examination of the patient is under the control of the physician or practitioner at the distant site.

(c) ***Telepresenter not required.*** A telepresenter is not required as a condition of payment unless a telepresenter is medically necessary as determined by the physician or practitioner at the distant site.

(d) ***Exception to the interactive telecommunications system requirement.*** For Federal telemedicine demonstration programs conducted in Alaska or Hawaii only, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system.

(e) ***Limitations.***

(1) A clinical psychologist and a clinical social worker may bill and receive payment for individual psychotherapy via a telecommunications system, but may not seek payment for medical evaluation and management services.

(2) The physician visits required under § 483.40(c) of this title may not be furnished as telehealth services.

(f) ***Process for adding or deleting services.*** Changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process. A list of the services covered as telehealth services under this section is available on the CMS Web site.

[66 FR 55330, Nov. 1, 2001, as amended at 67 FR 80041, Dec. 31, 2002; 69 FR 66423, Nov. 15, 2004; 70 FR 70330, Nov. 21, 2005; 72 FR 66399, Nov. 27, 2007; 73 FR 69934, Nov. 19, 2008; 74 FR 62005, Nov. 25, 2009; 75 FR 73615, Nov. 29, 2010; 76 FR 73470, Nov. 28, 2011; 77 FR 69363, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014; 80 FR 71373, Nov. 16, 2015]

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Rita M. Landgraf, Secretary, DHSS

***Please note that no changes were made to the regulation as originally proposed and published in the July 2012 issue of the *Register* at page 42 (16 DE Reg. 42). Therefore, the final regulation is not being republished. A copy of the final regulation is available at:**

State Survey Agency State Long-Term Care Ombudsman Program

DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

ORDER

Telemedicine

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance (DMMA) initiated proceedings to amend existing rules in the Delaware Title XIX Medicaid State Plan regarding *Telemedicine Services*. The Department's proceedings to amend its regulations were initiated pursuant to 29 **Delaware Code** Section 10114 and its authority as prescribed by 31 **Delaware Code** Section 512.

The Department published its notice of proposed regulation changes pursuant to 29 **Delaware Code** Section 10115 in the July 2012 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by July 31, 2012 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

The proposed provides notice to the public that the Division of Medicaid and Medical Assistance (DMMA) intends to amend the Title XIX State Plan *to allow for the use of a telemedicine delivery system for providers enrolled under Delaware Medicaid.*

Statutory Authority

- 42 CFR Part 440, *Services*
- 42 CFR §410.78, *Telehealth services*

Background

For the purposes of Medicaid, telemedicine seeks to improve a patient's health by permitting two-way, real time interactive communication between the patient, and the physician or practitioner at the distant site. This electronic communication means the use of interactive telecommunications equipment that includes, at a minimum, audio and visual equipment. This definition is modeled on Medicare's definition of telehealth services (42 CFR §410.78).

According to the Centers for Medicare and Medicaid Services (CMS), the Medicaid program and the federal Medicaid statute (Title XIX of the Social Security Act) does not recognize telemedicine as a distinct service. CMS does note, however, that "telemedicine is viewed as a cost-effective alternative to the more traditional face-to-face way of providing medical care" (e.g., face-to-face consultations or examinations between provider and patient) that states can choose to cover under Medicaid and that there is "flexibility inherent in federal law to create innovative payment methodologies for services that incorporate telemedicine technology."

States may seek a State Plan amendment to allow the use of telemedicine as a delivery system.

Summary of Proposal

The Division of Medicaid and Medical Assistance (DMMA) proposes to amend the Medicaid State plan to allow for Medicaid reimbursement for medically necessary telemedicine services, a mode of delivery of health care services for covered services rendered to Medicaid eligible recipients by enrolled Delaware Medicaid providers.

DMMA's objectives in recognizing telemedicine-provided services include:

- Improved access to health care services and behavioral health services with no loss in quality, safety or access to existing medical services; and
- Improved access to medical subspecialties not widely available in a service area; and
- Improved recipient compliance with treatment plans; and
- Medical and behavioral health services rendered at an earlier stage of disease; and
- Improved health outcomes for patients; and
- Reduced Delaware Medical Assistance Program (DMAP) costs for covered services such as hospitalizations and transportation.

The proposed plan amendment, when approved, would allow the following telemedicine services, including delivery of consultation services, office visit evaluation and management services, individual psychotherapy services, pharmacologic management, psychiatric diagnostic interview examinations, end stage renal disease related services, and individual medical nutrition therapy via an interactive telecommunications system. For these services, an interactive telecommunications system is considered to meet the requirements of a face-to-face encounter.

The appropriate State plan pages will be amended and the appropriate DMAP provider manuals will be updated with applicable coverage parameters and billing guidelines.

The provisions of this state plan amendment are subject to approval by the Centers for Medicare and Medicaid Services (CMS).

Fiscal Impact Statement

- The fiscal impact of adding telemedicine cannot be estimated.
- The projected number of telemedicine-provided services cannot be determined at this time as the actual number will depend on the number of Medicaid practitioners and beneficiaries who choose to use the technology, as appropriate.
- The coverage and limitations for telemedicine-provided services will mirror the respective service delivered face-to-face to eliminate the possibility of any financial impact on Medicaid.
- Providers who wish to deliver telemedicine-provided services will have to invest in the necessary interactive telecommunications equipment.

SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE AND EXPLANATION OF CHANGES

Insight Telepsychiatry, LLC, the Governor's Advisory Council for Exceptional Citizens (GACEC) and the State Council for Persons with Disabilities (SCPD) offered the following observations and recommendations summarized below. The Division of Medicaid and Medical Assistance (DMMA) has considered each comment and responds as follows.

Insight Telepsychiatry, LLC

As an active provider of telemedicine services in Delaware and throughout the mid-Atlantic region, we applaud the DMMA for its forward thinking in creating these proposed changes, particularly for recognizing the large needs for telemedicine services within the behavioral health arena.

Provider Licensure/Enrollment Requirements:

Of note is the requirement that all eligible telemedicine providers be located within the continental United States. As a local telemedicine entity that presently engages local telemedicine providers, we submit that this geographic requirement should be removed from the final rule.

Placing a geographic requirement around a concept like telemedicine that is specifically designed to break down boundaries and minimize the impact of location is counter-productive to the long-term intent of the revised rule. Given a national shortage of qualified providers, particularly within the field of mental health, we must keep every option open to the delivery of appropriate clinical services through carefully planned and managed telemedicine programs. Regulations and practice guidelines, coupled with careful monitoring from state medical

boards and federal regulators will ensure that qualified professionals deliver services appropriately, and while the licensure and qualifications of the provider should be considered, location should not.

This point is particularly salient within the field of mental health, where our nation faces an increasing prevalence of behavioral health issues pared with a decreasing supply of qualified mental health professionals to serve these consumers. This trend is extremely well documented within the literature, and no recognizable end is in sight. With this trend, the limited supply of providers will grow increasingly in demand. This demand will see an increase in the salaries of these providers as well as considerable demands from providers for preferential work assignments and schedules. Simply put, providers will become more expensive and increasingly resistant to conducting afterhours call. The 24/7 requirements of medical emergencies and psychiatric crises are in direct conflict with a resistance by providers to deliver services beyond normal working hours.

Telemedicine, and its ability to reach across borders and time zones, represents a unique opportunity to leverage time differences. Through telemedicine the limited pool of providers can be granted the ability to work during what are normal business hours at their distant site while providing after hours services to an originating sire within a distant time zone.

Agency Response: DMMA appreciates the interest expressed for permitting providers residing outside the continental United States to participate in the telemedicine program. However, two issues specifically preclude accommodating providers located out of the country.

First, under current Delaware licensure requirements, only providers who are licensed in the State of Delaware but who are located in another State may provide services through the means of telemedicine. On that basis alone, it is unlikely that a provider residing in another country will have a Delaware license.

Second, effective January 1, 2011, Section 6505 of the Affordable Care Act entitled, *Prohibition on Payments to Institutions or Entities Located Outside of the United States*, requires that a State shall not provide any payments for items or services provided under the State plan or under a waiver to any financial institution or entity located outside of the United States (U.S.).

For purposes of implementing this provision, section 1101(a)(2) of the Social Security Act defines the term "United States" when used in a geographical sense, to mean the "States." The Act defines the term "State" to include the District of Columbia, Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, when used under Title XIX (Medicaid).

Further, this provision specifically prohibits payments to telemedicine providers located outside of the U.S., Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

No change to the regulation was made as a result of this comment.

GACEC and SCPD

GACEC and SCPD have the following observations and recommendations.

First, authorizing telemedicine offers many advantages to individuals with disabilities, including less transportation time and expense in reaching providers and improved access to subspecialties not widely available in a local area. The concept therefore merits endorsement.

Agency Response: DMMA thanks the Councils for their endorsement.

Second, the standards omit any requirement that the use of telemedicine be considered only when it is consistent with effective communication. The Americans with Disabilities Act generally contemplates accommodations to ensure effective communication between medical providers and patients. See attachments. Therefore, it would be preferable to "highlight" this consideration in the regulation since it could otherwise be inadvertently overlooked. The following sentence could be added:

> The provision of services through telemedicine must include accommodations, including interpreter and audio-visual modifications, if necessary to ensure effective communication.

Agency Response: DMMA agrees with the suggestion to highlight consideration of accommodations to ensure effective communication between medical providers and patients. Because not all providers will be in a position to provide these accommodations due to size, staffing, and costs, DMMA will slightly modify the suggested language and incorporate it into the telemedicine policy as follows: *"The provision of services through telemedicine must include accommodations, including interpreter and audio-visual modification, where required under the*

Americans with Disabilities Act (ADA), to ensure effective communication."

Third, in Section 27, "Provider Qualifications", second paragraph, first bullet, the verb/predicate has been omitted and the word "within" is misspelled. Consider the following amendment: "Act within their scope of practice".

Agency Response: This was a publication error. The proposed text should have read, *"Act within their scope of practice"*.

Fourth, in the "Covered Services" section, the reference to "illness or injury" is "underinclusive" since it would exclude diagnoses and treatment of "conditions" such as cerebral palsy or epilepsy. Medicaid covers more than illnesses and injuries. Compare attached DHSS definition of "medical necessity".

Agency Response: DMMA also agrees with the comment that telemedicine is available to clients for care beyond those who have sustained an illness or injury. The language under Covered Services will be modified to read as follows: *"DMAP covers medically necessary telemedicine services and procedures covered under the Title XIX State Plan. Telemedicine is not limited based on the diagnosed medical condition of the eligible recipient.* All telemedicine services must be furnished within the limits of provider program policies and within the scope and practice of the provider's professional standards as described and outlined in the Delaware Medical Assistance Program (DMAP) Provider Manuals which can be found at:

http://www.dmap.state.de.us/downloads/manuals.html"

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the July 2012 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend the Delaware Title XIX Medicaid State Plan regarding *Telemedicine Services* is adopted and shall be final effective September 10, 2012.

Rita M. Landgraf, Secretary, DHSS

DMMA FINAL ORDER REGULATIONS #12-41
REVISION:

ATTACHMENT 3.1-A
Page 12

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: DELAWARE
LIMITATIONS ON AMOUNT, DURATION, AND SCOPE OF MEDICAL AND
REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

27. TELEMEDICINE SERVICES

The Delaware Medical Assistance Program (DMAP) covers medically necessary health services furnished to eligible DMAP members as specified in the Medicaid State Plan. To facilitate the ability of recipients to receive medically necessary services, DMAP allows for the use of a telemedicine delivery system for providers enrolled under Delaware Medicaid.

Telemedicine services under DMAP are subject to the specifications, conditions, and limitations set by the State. Telemedicine is the practice of health care delivery by a practitioner who is located at a site, known as the distant site, other than the site where the patient is located, known as the originating site, for the purposes of consultation, evaluation, diagnosis, or recommendation of treatment.

Providers rendering telemedicine must be able to use interactive telecommunications equipment that includes, at a minimum, audio and video equipment permitting two-way, real time, interactive communication between the recipient and the practitioner to provide and support care when distance separates participants who are in different geographical locations.

[The provision of services through telemedicine must include accommodations, including interpreter and audio-visual modification, where required under the Americans with Disabilities Act (ADA), to ensure

effective communication.]

Telephone conversations, chart reviews, electronic mail messages, facsimile transmissions or internet services for online medical evaluations are not considered telemedicine.

All equipment required to provide telemedicine services is the responsibility of the providers.

PROVIDER QUALIFICATIONS

In order to provide telemedicine under DMAP, providers at both the originating and distant site must be enrolled with DMAP or have contractual agreements with the managed care organizations (MCOs) and must meet all requirements for their discipline as specified in the Medicaid State Plan.

In order for services delivered through telemedicine technology from DMAP or MCOs to be covered, healthcare practitioners must:

- Act within their scope of practice;
- Be licensed (in Delaware, or the State in which the provider is located if exempted under Delaware State law to provide telemedicine services without a Delaware license) for the service for which they bill DMAP;
- Be enrolled with DMAP/MCOs;
- Be located within the continental United States.

COVERED SERVICES

DMAP covers medically necessary telemedicine services and procedures covered under the Title XIX State Plan. **[~~for the diagnosis and treatment of an illness or injury as indicated by the eligible recipient's condition~~ Telemedicine is not limited based on the diagnosed medical condition of the eligible recipient.]** All telemedicine services must be furnished within the limits of provider program policies and within the scope and practice of the provider's professional standards as described and outlined in DMAP Provider Manuals which can be found at: http://www.dmap.state.de.us/downloads/manuals.html

NON-COVERED SERVICES

If a service is not covered in a face-to-face setting, it is not covered if provided through telemedicine. A service provided through telemedicine is subject to the same program restrictions, limitations and coverage which exist for the service when not provided through telemedicine.

(Break in Continuity of Sections)

ATTACHMENT 4.19-B
Page 24

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: DELAWARE
METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES (Continued)

27. TELEMEDICINE SERVICES

Payment for services delivered at the distant site via telemedicine is made according to the standard Delaware Medical Assistance Program (DMAP) payment methodology for the comparable in-person service and provider type.

In addition to the payment for the actual service rendered, qualifying originating patient sites are reimbursed 98% of the Medicare rate for the facility fee for dates of services on or after July 1, 2012.

Fee schedules for telemedicine-provided services are available on the DMAP website at: http://www.dmap.state.de.us/downloads.

Except as otherwise noted in the Medicaid State Plan, State-developed fee schedule rates are the same for both government and private providers.

Separate reimbursement is not made for the use of technological equipment and systems associated with a telemedicine application to render the service.

*Please note that no additional changes were made to the regulation as originally proposed and published in the July 2015 issue of the *Register* at page 10 (19 DE Reg. 10). Therefore, the final regulation is not being republished here in its entirety. A copy of the final regulation is available at:

501 Harness Racing Rules and Regulations

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

ORDER

Telemedicine Services

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance (DMMA) initiated proceedings to submit a state plan amendment regarding telemedicine services specifically, *to recognize the Medicaid beneficiary's place of residence as an originating site*. The Department's proceedings to amend its regulations were initiated pursuant to 29 **Delaware Code** Section 10114 and its authority as prescribed by 31 **Delaware Code** Section 512.

The Department published its notice of proposed regulation changes pursuant to 29 **Delaware Code** Section 10115 in the July 2015 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by July 31, 2015 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

The proposed provides notice to the public that Delaware Health and Social Services/Division of Medicaid and Medical Assistance (DHSS/DMMA) intends to submit a state plan amendment to the Centers for Medicare and Medicaid Services (CMS) regarding telemedicine services, specifically, *to recognize the Medicaid beneficiary's place of residence as an originating site.*

Statutory Authority

- 42 CFR 410.78, *Telehealth services*
- 42 CFR Part 440, *Services*

Background

For the purposes of Medicaid, telemedicine seeks to improve a patient's health by permitting two-way, real time interactive communication between the patient, and the physician or practitioner at the distant site.This electronic communication means the use of interactive telecommunications equipment that includes, at a minimum, audio and visual equipment. This definition is modeled on Medicare's definition of telehealth services (42 CFR §410.78).

According to the Centers for Medicare and Medicaid Services (CMS), the Medicaid program and the federal Medicaid statute (Title XIX of the Social Security Act) does not recognize telemedicine as a distinct service. CMS does note, however, that "telemedicine is viewed as a cost-effective alternative to the more traditional face-to-face way of providing medical care" (e.g., face-to-face consultations or examinations between provider and patient) that states can choose to cover under Medicaid and that that there is "flexibility inherent in federal law to create innovative payment methodologies for services that incorporate telemedicine technology."

Coverage of Telemedicine in the Delaware Medical Assistance Program

Telemedicine is the real-time or near real-time two-way transfer of medical data and information using an interactive audio/video connection for the purposes of medical diagnosis and treatment. The Medicaid member is located with a provider at the originating site, while the "remote" provider renders services via the audio/video

connection at the distant site. The Delaware Medical Assistance Program (DMAP) has covered telemedicine on a statewide basis since July 2012. Consistent with guidance from the Centers for Medicare and Medicaid Services (CMS), DMAP considers telemedicine as a cost-effective alternative for delivering covered services to the Medicaid-eligible populations.

The following are DMAP objectives for reimbursing providers for services delivered via telemedicine:

- Improved access to health care services;
- Improved member compliance with treatment plans;
- Medical services rendered at an earlier stage of disease, thereby improving long-term patient outcomes; and,
- Reduced DMAP costs for covered services such as hospitalization and transportation.

Originating Site and Distant Site

CMS defines the originating site as the location of the Medicaid patient at the time the service being furnished via a telecommunications system occurs; and, the distant site as the site at which the physician or other licensed practitioner delivering the service is located at the time the service is provided via telecommunications system.

Summary of Proposal

Traditional approaches to telemedicine coverage require that the patient be served from a specific type of healthcare facility, such as a hospital or physician's office. Not included are sites where people spend much of their time, such as homes. With advances in decentralized computing power, such as cloud processing, and mobile telecommunications, such as 4G wireless, the current approach is to cover health services to patients wherever they are.

For conditions of coverage and payment, the Division of Medicaid and Medical Assistance (DMMA) proposes to amend Attachment 3.1-A of the Medicaid State Plan to recognize the Medicaid beneficiary's place of residence as an originating site. Upon CMS approval, the proposed state plan amendment (SPA) is effective for dates of service on or after July 1, 2015.

Public Notice

In accordance with the public notice requirements of Title 29, Chapter 101 of the Delaware Code, Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) gives public notice and provides an open comment period for thirty (30) days to allow all stakeholders an opportunity to provide input to the proposed state plan amendment. Comments must be received by 4:30 p.m. on July 31, 2015.

CMS Review and Approval

The provisions of this state plan amendment relating to eligible originating sites for telemedicine services are subject to approval by CMS. The draft SPA page(s) may undergo further revisions before and after submittal to CMS based upon public comment and/or CMS feedback. The final version may be subject to significant change.

Federal Financial Participation

Federal financial participation (FFP) means the federal government's share of expenditures made by a state agency in implementing a medical assistance program. CMS will not provide FFP for any State plan amendment until it is approved.

Provider Manuals Update

Also, upon CMS approval, the applicable Delaware Medical Assistance Program (DMAP) Provider Policy Specific Manuals will be updated. Manual updates, revised pages or additions to the provider manual are issued, as required, for new policy, policy clarification, and/or revisions to the DMAP program. Provider billing guidelines or instructions to incorporate any new requirement may also be issued. A newsletter system is utilized to distribute new or revised manual material and to provide any other pertinent information regarding manual updates.

Fiscal Impact Statement

Current policy allows for the use of telemedicine. The Delaware Medical Assistance Program could potentially achieve savings by reducing transportation expenses, increasing treatment compliance and monitoring for patients with chronic conditions, and other delivery improvements.

SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE

Teladoc, Inc; the Governor's Advisory Council for Exceptional Citizens (GACEC) and, the State Council for Persons with Disabilities (SCPD) offered the following observations and recommendations summarized below. The Division of Medicaid and Medical Assistance (DMMA) has considered each comment and responds as follows.

Teladoc

After providing background information on Teladoc including the Teladoc Delivery Model and noting the company's work with Delaware legislators on House Bill (HB) 69, *An Act to Amend Title 18 and 24 of the Delaware Code Relating to Telemedicine Services*, Teladoc, Inc. offered the following comments:

Teladoc applauds the initiative that the Department has taken in removing the healthcare facility requirement as the originating site and allowing the patient to access healthcare from their home. We suggest that the State also consider that not all patients have access to broadband technology or are skilled in the use of computers or smart phones. You appropriately noted that technology moves at a much faster pace than regulation and legislation. Further, it is understood that electronic communication "means the use of interactive telecommunications equipment that includes, at minimum audio and visual equipment" and that "telemedicine is the real-time or near real-time two way transfer of medical data and information..."

Therefore, we suggest that the State clarify that the intent is to remain "technology neutral", and that video and interactive audio using store and forward technologies are appropriate in telemedicine. By remaining technology, the state is able to incorporate new advances [which] can be applied as they are proven and available. As HB 69 points out, the standard of care should be the same, whether in a traditional office visit or a telemedicine visit.

Agency Response: Your comments raised policy or operational issues that are outside the scope of the proposed rule. Store and forward technologies will be addressed in a future rulemaking. Thank you for your comments.

No change to the regulation was made as a result of these comments.

SCPD and GACEC

As background, DMMA has covered telemedicine in its Medicaid program on a statewide basis since July, 2012. The State has generally been expanding use of telemedicine in recent years. For example, the Legislature passed House Bill (H.B.) 69 in the Spring of 2015 to promote health insurer support of telemedicine. The synopsis to the bill suggests that it is also intended to "encourage all state agencies to evaluate and amend their policies and rules to foster and promote telemedicine services". SCPD endorses and GACEC supports this initiative (subject to amendments referenced below) since it clarifies that an approved originating site can include a patient's place of residence. We recommend the following amendments.

First, the reference to place of residence could be construed to mean that other non-traditional sites are excluded. By solely citing "place of residence", application of interpretive guidance could result in limiting the scope of other settings. At a minimum, it would therefore be preferable to amend the reference as follows: "Without limitation, (A)an approved originating site may include the Delaware Medical Assistance Program (DMAP) member's place of residence."

Second, H.B. 69 broadly defines "originating site" to include "a site in Delaware at which a patient is located at the time health care services are provided....". This would include anywhere the patient is physically present, including non-residential settings such as day programs (e.g. Easter Seal; Elwyn). DMMA could consider the following more expansive standard: "An approved originating site may include the DMAP member's place of residence, day program, or alternate location in which the member is physically present and telemedicine can be effectively utilized."

Agency Response: DMMA agrees. The revision appears in **[bracketed bold type]**.

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the July 1, 2015 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation regarding telemedicine services, specifically, *to recognize the Medicaid beneficiary's place of residence as an originating site*, is adopted and shall be final effective September 10, 2015.

Rita M. Landgraf, Secretary, DHSS

DMMA FINAL ORDER REGULATION #15-16
REVISION:

ATTACHMENT 3.1-A
Introductory Page 1

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: DELAWARE

TELEMEDICINE

The Delaware Medical Assistance Program (DMAP) covers medically necessary health services furnished to eligible DMAP members as specified in the Medicaid State Plan. To facilitate the ability of recipients to receive medically necessary services, DMAP allows for the use of a telemedicine delivery system for providers enrolled under Delaware Medicaid.

Telemedicine services under DMAP are subject to the specifications, conditions, and limitations set by the State. Telemedicine is the practice of health care delivery by a practitioner who is located at a site, known as the distant site, other than the site where the patient is located, known as the originating site, for the purposes of consultation, evaluation, diagnosis, or recommendation of treatment. An approved originating site may include the DMAP member's place of residence**[, day program, or alternate location in which the member is physically present and telemedicine can be effectively utilized]**.

Providers rendering telemedicine must be able to use interactive telecommunications equipment that includes, at a minimum, audio and video equipment permitting two-way, real time, interactive communication between the recipient and the practitioner to provide and support care when distance separates participants who are in different geographical locations.

The provision of services through telemedicine must include accommodations, including interpreter and audio-visual modification, where required under the Americans with Disabilities Act (ADA), to ensure effective communication.

Telephone conversations, chart reviews, electronic mail messages, facsimile transmissions or internet services for online medical evaluations are not considered telemedicine.

All equipment required to provide telemedicine services is the responsibility of the providers.

DEPARTMENT OF LABOR

DIVISION OF INDUSTRIAL AFFAIRS

Statutory Authority: 19 Delaware Code, Section 202(a) (19 **Del.C.** §202(a))
19 **DE Admin. Code** 1101

ORDER

1101 Apprenticeship and Training Regulations

I. NATURE OF PROCEEDINGS

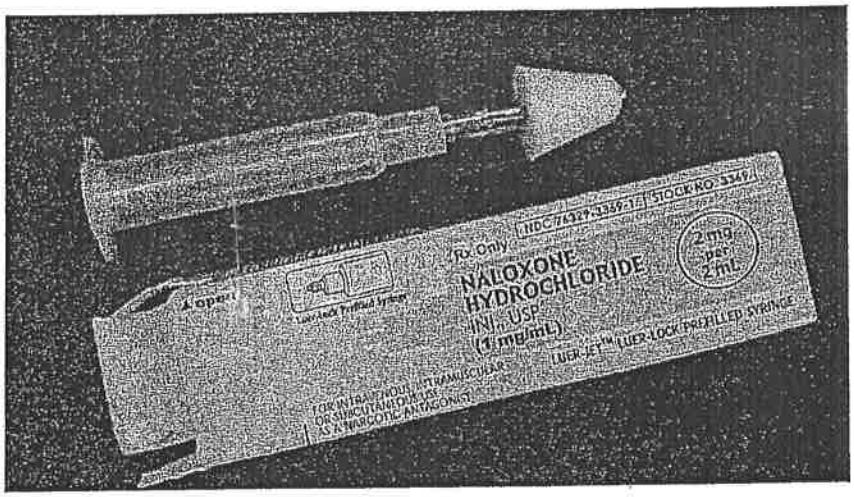
Pursuant to its authority under 29 **Del.C.** §10111(1), the Delaware Division of Industrial Affairs of the State of Delaware, Department of Labor ("the Department") proposed to amend its apprenticeship regulations. The Department's purpose in proposing these amendments was to bring its regulations into legal conformity with the Third Circuit decision in *Tri-M Group, LLC v. Sharp*, 638 F.3d 406 (3rd Cir. 2011). The Department's proceedings to adopt its regulations were initiated pursuant to 29 **Del.C.** §10113(6), with authority prescribed by 19 **Del.C.** §202(a)(2). These regulations are exempt from the standard Administrative Procedures Act process and may therefore be adopted informally.

Delaware House OKs overdose drug naloxone in schools

FIRST STATE POLITICS (//WWW.DELAWAREONLINE.COM/BLOG/FIRSTSTATEPOLITICS/)

Jon Offredo (http://www.delawareonline.com/staff/9805/jon-offredo/) , The News Journal Published 3:22 p.m. ET April 23, 2015 | Updated 9:26 a.m. ET April 24, 2015

Naloxone, the overdose-reversing drug, could now be available to school nurses across Delaware's schools.



(Photo: Getty Images)

A piece of legislation (http://legis.delaware.gov/LIS/lis148.nsf/vwLegislation/SCR+11/%24file/legis.html?open) largely passed by House lawmakers Thursday afternoon endorses the plan to expand access to the drug to school nurses and urges the state's school districts to work closely with the state to ensure access to naloxone is available.

Rep. Mike Barbieri, D-Newark, said the measure, in the form of a concurrent resolution, does not mandate, require, force or obligate schools to keep naloxone on hand.

"If you want to do it, you can do it," he said. "If you want to get the training, you can get the training."

Last year lawmakers passed legislation (/story/news/local/2014/06/19/house-votes-ease-access-heroin-overdose-drug/11029133/) that provides wider distribution of the drug, making it available without a prescription to help reverse life-threatening heroin overdoses.

The legislation, signed by Gov. Jack Markell last June, passed the House unanimously, makes the drug available at a low cost upon completion of a training course administered by the state Department of Health and Social Services.

Thursday afternoon's action extends that wider distribution to schools. The resolution was passed earlier this month by the state Senate and does not need to be signed by the governor.

0

Do you think schools should have the overdose-reversing drug naloxone?

- Yes
- No

Barbieri said schools and the Department of Health and Social Services are looking at potential funding options, including grants.

Susan Hoffmann, president of the Delaware School Nurses Association, said the professional organization has not taken a position on the matter.

Not sure

Vote ()

View Results

"We definitely support it," Hoffmann said, adding that the national organization is expected to come out with an official position on the use of the drug in a school setting.

Rebecca King, a nurse at Brandywine Springs Elementary School and the Delaware director for the association, said schools should be prepared in the event of anything happening. King pointed to the incident (/story/news/crime/2014/10/06/mother-arrested-child-shares-heroin-daycare/16836337/) last year where a 4-year-old unknowingly took 249 bags of heroin to a day care center west of Selbyville and started handing it out, thinking it was candy.

"I want my hands on everything I can possibly have if I'm going to be a first responder in any situation, no matter what it is," she said.

Last year, 3,182 people who were admitted to state-funded clinics said their primary addiction was to heroin. The drug has seen an explosive (/topic/885f595b-ce73-4ce1-9002-092931aba2d0/heroin-delawares-deadly-crisis/) use in Delaware over the last several years.

Contact Jon Offredo at (302) 678-4271 or at joffredo@delawareonline.com or on Twitter @jonoffredo (http://twitter.com/jonoffredo).

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Delaware General Assembly (/)

Senate Concurrent Resolution 11

148th General Assembly (2015 - 2016)

Bill Progress

Current Status:

Passed 4/23/15

What happens next?

The General Assembly has ended, the current status is the final status.

Bill Details

Introduced on:

3/31/15

Primary Sponsor:

Hall-Long (/LegislatorDetail?personId=73)

Additional Sponsor(s):

Rep. Barbieri (/LegislatorDetail?personId=238)

Co-Sponsor(s):

Sen. Cloutier (/LegislatorDetail?personId=14), Lopez (/LegislatorDetail?personId=117), Sokola (/LegislatorDetail?personId=90), Townsend (/LegislatorDetail?personId=13)
Reps. Baumbach (/LegislatorDetail?personId=252), King (/LegislatorDetail?personId=298), Jaques (/LegislatorDetail?personId=111), Keeley (/LegislatorDetail?personId=138), Kenton (/LegislatorDetail?personId=132), Mitchell (/LegislatorDetail?personId=178), Potter (/LegislatorDetail?personId=37), B. Short (/LegislatorDetail?personId=12), Yearick (/LegislatorDetail?personId=223)

Long Title:

ENDORSING INCREASED ACCESS TO NALOXONE IN SCHOOLS IN DELAWARE.

Original Synopsis:

This resolution endorses an expansion of naloxone access in Delaware's schools.

Volume Chapter:

N/A

Fiscal Note/Fee Impact:

Not Required

Effective Date:

Takes effect upon being signed into law

Bill Text

Original Text:

View HTML (/json/BillDetail/GetHtmlDocument?fileAttachmentId=49684)

View MS Word (/json/BillDetail/GetWordDocument?fileAttachmentId=50862)

You may need to disable your browser's pop-up blocker to view linked documents.

Amendments

Amendment	Status	Introduction Date	Primary Sponsor	View Details
		No Records Available		

Committee Reports

Date	Committee	# Members	Favorable	On Its Merits	Unfavorable
		No Records Available			

Roll Calls

Chamber	Result	Date	Vote Type	Yes	No	Not Voting	Absent	
House	Passed	4/23/15 2:24 PM	SM	37	2	0	2	view ()
Senate	Passed	4/1/15 4:40 PM	SM	21	0	0	0	view ()

Actions History

Date	Action
3/31/15	Laid On Table in Senate
4/1/15	Passed by Senate. Votes: Passed 21 YES 0 NO 0 NOT VOTING 0 ABSENT 0 VACANT
4/23/15	Passed by House of Representatives. Votes: Passed 37 YES 2 NO 0 NOT VOTING 2 ABSENT 0 VACANT

Legislation Detail Feeds

SPONSOR: Sen. Hall-Long & Rep. Barbieri
Sens. Cloutier, Lopez, Sokola, Townsend; Reps. Baumbach, Briggs King, Jaques, Keeley, Kenton, Mitchell, Potter, B. Short, Yearick

DELAWARE STATE SENATE
148th GENERAL ASSEMBLY

SENATE CONCURRENT RESOLUTION NO. 11

ENDORSING INCREASED ACCESS TO NALOXONE IN SCHOOLS IN DELAWARE.

WHEREAS, globally, an estimated 69,000 people die each year from opioid overdose; and

WHEREAS, Delaware had the 10th highest drug overdose mortality rate in the United States in 2010; and

WHEREAS, the majority of drug overdose deaths in Delaware occur from opioid usage; and

WHEREAS, persons under the age of twenty five (25) accounted for approximately ten percent (10%) of drug overdose deaths in Delaware in 2010; and

WHEREAS, Delaware had 185 suspected overdose deaths in 2014 from all substances;

WHEREAS, nationwide, states are requiring naloxone to be on the list of must-have medications carried by first responders; and

WHEREAS, naloxone reverses the effects of opioid drugs, such as morphine, heroin and methadone; and

WHEREAS, public schools have a full time registered nurse in every facility; and

WHEREAS, the 147th General Assembly expanded naloxone access to allow family members, friends or individuals with an addiction to be trained on how to use the drug to reduce the effects of an opioid overdose; and

WHEREAS, the 147th General Assembly also greatly expanded access to allow peace officers to administer the drug to individuals suspected to be experiencing an opioid overdose; and

WHEREAS, the Department of Education and Division of Public Health have begun planning to expand naloxone access in the schools to be administered by school nurses in the 2015-2016 school year;

NOW, THEREFORE:

BE IT RESOLVED by the Senate of the 148th General Assembly of the State of Delaware, the House of Representatives concurring therein, that access to naloxone in the schools is an important step in the on-going work to reduce the risk of opioid overdose in Delaware.

SD : JGM : CBK
4761480037

Mar 31, 2015

21 BE IT FURTHER RESOLVED that the General Assembly endorses the state agencies plans to expand

22 naloxone access to school nurses, and urges Delaware school districts to work closely with the state to ensure

23 broad access to students.

SYNOPSIS

This resolution endorses an expansion of naloxone access in Delaware's schools.

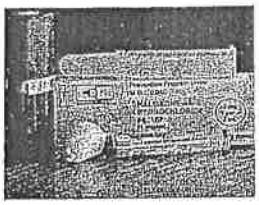
Author: Senator Hall-Long

SD : JGM : CBK
4761480037

Mar 31, 2015

Narcan to be available over the counter in Delaware

Jen Rini, The News Journal Published 10:41 a.m. ET Feb. 25, 2016 | Updated 9:50 p.m. ET Feb. 26, 2016



(Photo: AP)

Some drugstores in Delaware will soon offer the overdose drug Narcan without a prescription.

Most Delaware pharmacies already offer the drug with a prescription. A Walgreens official says his company is working with state officials to sell Narcan, the brand name for the drug naloxone, to people without a doctor's script.

Delaware must first amend its pharmacy regulations legislatively, which Delaware Division of Public Health officials hope will happen by summer.

"The opportunities to truly get naloxone in the hands of friends and family members would enable us to save more lives," said Dr. Karyl Rattay, director of Delaware's Division of Public Health.

Naloxone, which can be administered as an auto-injector similar to an EpiPen or as a nasal spray stops someone from overdosing by blocking the drug's suffocating effect on the body's respiratory system and allowing the person to breathe normally.

Delaware officials see increasing access to Narcan as one way to curb the state's growing number of drug overdose fatalities. There are still questions around how much it will cost without a prescription.

Narcan is available in Delaware without a prescription if community members attend medication training sessions facilitated by the state, but it is available through pharmacists only with a prescription.

The medication, approved by the U.S. Food and Drug Administration, is covered by most commercial insurance plans if purchased with a prescription, a spokesman from the Delaware Department of Insurance said. But without a prescription, coverage is not guaranteed, which could result in higher prices.

Delaware gets another $1 million Narcan donation (http://www.delawareonline.com/story/news/health/2016/02/23/delaware-gets-another-1-million-narcan-donation/80794380/)

A two-dose package of Narcan retails between $60 and $90 without a prescription through CVS in other states.

Delawareans would most likely have to pay about $40, estimated Rattay. The state Health Department is also investigating how Narcan would be available without a prescription for someone with Medicaid.

MaryBeth Cichocki, a certified community naloxone trainer, said when she teaches a class on how to administer the drug, the cost is about $50 for a kit.

"Addicts are not going to be able to afford that," Cichocki said.

Cichocki, a member of the advocacy group atTAck Addiction, said that when her son Matt was actively using drugs, he never had any money, so paying for naloxone would have been a stretch. Tragically he died from a drug overdose last year.

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Having naloxone in the community will save lives, she said. It is similar to carrying insulin or cake icing to help someone with low blood sugar, she added.

"What is the difference?" she said. "I just hope that they understand. It needs to be affordable for everyone. My son's not here, and I will be carrying it. ...They all deserved to be saved."

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Preliminary estimates predict that there were over 180 suspected overdose deaths in Delaware in 2015 and nearly three times as many Delawareans died of a fentanyl-related drug overdose through September 2015 as in all of 2014.

The rate of deaths from drug overdoses has increased 137 percent nationally since 2000, according to data from the Centers for Disease Control and Prevention. In 2014, 10,574 of the total 28,647 opioid overdose deaths were due to heroin.

In 2014, paramedics administered naloxone 1,244 times, reviving 668 people, according to information provided by the Division of Public Health.

Newark police revive two with Narcan in first month (http://www.delawareonline.com/story/news/2015/11/30/newark-police-revive-two-narcan-first-month/76575944/)

To combat the nation's drug abuse epidemic, Walgreens announced in early February that the company would make naloxone available in 35 states and Washington, D.C., over the course of 2016.

Delaware was not included on the initial 35-state list, Walgreens spokesman Phil Caruso said, but the company is eager to work with the state separately to make the lifesaving antidote available.

"Walgreens is committed to making naloxone easier to obtain," Caruso said.

At Walgreens, the medication will not be available over the counter in the traditional sense because pharmacists will need to train people on how to administer Narcan before it's purchased. So, it will remain behind the pharmacy counter, but the public will be able to purchase it without a prescription.

Pharmacists will be trained to show community members how to use the medication before purchasing. The training would be about five minutes, Rattay said, and would cover how to identify an overdose, encourage them to call 911 and connect people to substance abuse treatment services.

It's possible other pharmacies could offer the medication without a prescription as well.

"We would happy to put in an agreement with a pharmacy large or small that wants to participate with the program," Rattay said.

New Castle County police get Narcan to fight heroin ODs (http://www.delawareonline.com/story/news/local/2015/05/14/county-police-adopt-narcan-fight-heroin-ods/27323369/)

Data from the National Institute on Drug Abuse and U.S. Department of Heath and Social Services found that there was an 1,170 percent increase in Narcan dispensing at retail pharmacies from 2013 to 2015 in tandem with community-based naloxone programs.

CVS is operating a naloxone program in 15 states, including New Jersey and Pennsylvania, and plans to expand to an additional 20 states in 2016.

The number of police departments administering naloxone to Delawareans is growing as well, said Fred Calhoun, president of the Delaware Fraternal Order of Police President. By Friday 55 police officers with Delaware Technical Community College were expected to be trained on how to administer and carry the drug, adding to the New Castle County, Ocean View, Elsmere, Newark, Smryna and Middletown police departments.

Calhoun supports increasing access to the medication in the community, but said that it may not provide long-term help to families.

"Just administering the drug and walking away doesn't help," he said. "It saves a life, but it doesn't cure the disease."

However, at the end of the day, he added, what if it is only a short-term solution?

"It saves a life," Calhoun said.

Jen Rini can be reached at (302) 324-2386 or jrini@delawareonline.com. Follow @JenRini on Twitter.

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U.S. Department of Justice
Civil Rights Division
Disability Rights Section

Effective Communication

The Department of Justice published revised final regulations implementing the Americans with Disabilities Act (ADA) for title II (State and local government services) and title III (public accommodations and commercial facilities) on September 15, 2010, in the Federal Register. These requirements, or rules, clarify and refine issues that have arisen over the past 20 years and contain new, and updated, requirements, including the 2010 Standards for Accessible Design (2010 Standards).

Overview

People who have vision, hearing, or speech disabilities ("communication disabilities") use different ways to communicate. For example, people who are blind may give and receive information audibly rather than in writing and people who are deaf may give and receive information through writing or sign language rather than through speech.

The ADA requires that title II entities (State and local governments) and title III entities (businesses and nonprofit organizations that serve the public) communicate effectively with people who have communication disabilities. The goal is to ensure that communication with people with these disabilities is equally effective as communication with people without disabilities.

This publication is designed to help title II and title III entities ("covered entities") understand how the rules for effective communication, including rules that went into effect on March 15, 2011, apply to them.

- The purpose of the effective communication rules is to ensure that the person with a vision, hearing, or speech disability can communicate with, receive information from, and convey information to, the covered entity.
- Covered entities must provide auxiliary aids and services when needed to communicate effectively with people who have communication disabilities.
- The key to communicating effectively is to consider the nature, length, complexity, and context of the communication and the person's normal method(s) of communication.
- The rules apply to communicating with the person who is receiving the covered entity's goods or services as well as with that person's parent, spouse, or companion in appropriate circumstances.

Auxiliary Aids and Services

The ADA uses the term "auxiliary aids and services" ("aids and services") to refer to the ways to communicate with people who have communication disabilities.

- For people who are blind, have vision loss, or are deaf-blind, this includes providing a qualified reader; information in large print, Braille, or electronically for use with a computer screen-reading program; or an audio recording of printed information. A "qualified" reader means someone who is able to read effectively, accurately, and impartially, using any necessary specialized vocabulary.
- For people who are deaf, have hearing loss, or are deaf-blind, this includes providing a qualified notetaker; a qualified sign language interpreter, oral interpreter, cued-speech interpreter, or tactile interpreter; real-time captioning; written materials; or a printed script of a stock speech (such as given on a museum or historic house tour). A "qualified" interpreter means someone who is able to interpret effectively, accurately, and impartially, both receptively (i.e.,

understanding what the person with the disability is saying) and expressively (i.e., having the skill needed to convey information back to that person) using any necessary specialized vocabulary.

- For people who have speech disabilities, this may include providing a qualified speech-to-speech transliterator (a person trained to recognize unclear speech and repeat it clearly) , especially if the person will be speaking at length, such as giving testimony in court, or just taking more time to communicate with someone who uses a communication board. In some situations, keeping paper and pencil on hand so the person can write out words that staff cannot understand or simply allowing more time to communicate with someone who uses a communication board or device may provide effective communication. Staff should always listen attentively and not be afraid or embarrassed to ask the person to repeat a word or phrase they do not understand.

In addition, aids and services include a wide variety of technologies including 1) assistive listening systems and devices; 2) open captioning, closed captioning, real-time captioning, and closed caption decoders and devices; 3) telephone handset amplifiers, hearing-aid compatible telephones, text telephones (TTYs) , videophones, captioned telephones, and other voice, text, and video-based telecommunications products; 4) videotext displays; 5) screen reader software, magnification software, and optical readers; 6) video description and secondary auditory programming (SAP) devices that pick up video-described audio feeds for television programs; 7) accessibility features in electronic documents and other electronic and information technology that is accessible (either independently or through assistive technology such as screen readers) .

Real-time captioning (also known as computer-assisted real-time transcription, or CART) is a service similar to court reporting in which a transcriber types what is being said at a meeting or event into a computer that projects the words onto a screen. This service, which can be provided on-site or remotely, is particularly useful for people who are deaf or have hearing loss but do not use sign language.

The free nationwide **telecommunications relay service** (TRS), reached by calling 7-1-1, uses communications assistants (also called CAs or relay operators) who serve as intermediaries between people who have hearing or speech disabilities who use a text telephone (TTY) or text messaging and people who use standard voice telephones. The communications assistant tells the telephone user what the other party is typing and types to tell the other party what the telephone user is saying. TRS also provides speech-to-speech transliteration for callers who have speech disabilities.

Video relay service (VRS) is a free, subscriber-based service for people who use sign language and have videophones, smart phones, or computers with video communication capabilities. For outgoing calls, the subscriber contacts the VRS interpreter, who places the call and serves as an intermediary between the subscriber and a person who uses a standard voice telephone. The interpreter tells the telephone user what the subscriber is signing and signs to the subscriber what the telephone user is saying.

Video remote interpreting (VRI) is a fee-based service that uses video conferencing technology to access an off-site interpreter to provide real-time sign language or oral interpreting services for conversations between hearing people and people who are deaf or have hearing loss. The new regulations give covered entities the choice of using VRI or on-site interpreters in situations where either would be effective. VRI can be especially useful in rural areas where on-site interpreters may be difficult to obtain. Additionally, there may be some cost advantages in using VRI in certain circumstances. However, VRI will not be effective in all circumstances. For example, it will not be effective if the person who needs the interpreter has difficulty seeing the screen (either because of vision loss or because he or she cannot be properly positioned to see the screen, because of an injury or other condition). In these circumstances, an on-site interpreter may be required.

If VRI is chosen, ***all*** of the following specific performance standards must be met:

- real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;
- a sharply delineated image that is large enough to display the interpreter's face, arms, hands, and fingers, and the face, arms, hands, and fingers of the person using sign language, regardless of his or her body position;
- a clear, audible transmission of voices; and
- adequate staff training to ensure quick set-up and proper operation.

Many deaf-blind individuals use support service providers (SSPs) to assist them in accessing the world around them. SSPs are not "aids and services" under the ADA. However, they provide mobility, orientation, and informal communication services for deaf-blind individuals and are a critically important link enabling them to independently access the community at large.

Effective Communication Provisions

Covered entities must provide aids and services when needed to communicate effectively with people who have communication disabilities.

The key to deciding what aid or service is needed to communicate ***effectively*** is to consider the nature, length, complexity, and context of the communication as well as the person's normal method(s) of communication.

Some easy solutions work in relatively simple and straightforward situations. For example:

- In a lunchroom or restaurant, reading the menu to a person who is blind allows that person to decide what dish to order.
- In a retail setting, pointing to product information or writing notes back and forth to answer simple questions about a product may allow a person who is deaf to decide whether to purchase the product.

Other solutions may be needed where the information being communicated is more extensive or complex. For example:

- In a law firm, providing an accessible electronic copy of a legal document that is being drafted for a client who is blind allows the client to read the draft at home using a computer screen-reading program.
- In a doctor's office, an interpreter generally will be needed for taking the medical history of a patient who uses sign language or for discussing a serious diagnosis and its treatment options.

A person's method(s) of communication are also key. For example, sign language interpreters are effective only for people who use sign language. Other methods of communication, such as those described above, are needed for people who may have lost their hearing later in life and do not use sign language. Similarly, Braille is effective only for people who read Braille. Other methods are needed for people with vision disabilities who do not read Braille, such as providing accessible electronic text documents, forms, etc., that can be accessed by the person's screen reader program.

Covered entities are also required to accept telephone calls placed through TRS and VRS, and staff who answer the telephone must treat relay calls just like other calls. The communications assistant will explain how the system works if necessary.

Remember, the purpose of the effective communication rules is to ensure that the person with a communication disability can receive information from, and convey information to, the covered entity.

Companions

In many situations, covered entities communicate with someone other than the person who is receiving their goods or services. For example, school staff usually talk to a parent about a child's progress; hospital staff often talk to a patient's spouse, other relative, or friend about the patient's condition or prognosis. The rules refer to such people as "companions" and require covered entities to provide effective communication for companions who have communication disabilities.

The term "companion" includes any family member, friend, or associate of a person seeking or receiving an entity's goods or services who is an appropriate person with whom the entity should communicate.

Use of Accompanying Adults or Children as Interpreters

Historically, many covered entities have expected a person who uses sign language to bring a family member or friend to interpret for him or her. These people often lacked the impartiality and specialized vocabulary needed to interpret effectively and accurately. It was particularly problematic to use people's children as interpreters.

The ADA places responsibility for providing effective communication, including the use of interpreters, directly on covered entities. They cannot require a person to bring someone to interpret for him or her. A covered entity can rely on a companion to interpret in only two situations.

(1) In an emergency involving an imminent threat to the safety or welfare of an individual or the public, an adult or minor child accompanying a person who uses sign language may be relied upon to interpret or facilitate communication only when a qualified interpreter is not available.

(2) In situations ***not*** involving an imminent threat, an adult accompanying someone who uses sign language may be relied upon to interpret or facilitate communication when a) the individual requests this, b) the accompanying adult agrees, and c) reliance on the accompanying adult is appropriate under the circumstances. This exception does ***not*** apply to minor children.

Even under exception (2) , covered entities may ***not*** rely on an accompanying adult to interpret when there is reason to doubt the person's impartiality or effectiveness. For example:

- It would be inappropriate to rely on a companion to interpret who feels conflicted about communicating bad news to the person or has a personal stake in the outcome of a situation.
- When responding to a call alleging spousal abuse, police should never rely on one spouse to interpret for the other spouse.

Who Decides Which Aid or Service Is Needed?

When choosing an aid or service, title II entities are ***required*** to give primary consideration to the choice of aid or service requested by the person who has a communication disability. The state or local government must honor the person's choice, unless it can demonstrate that another equally effective means of communication is available, or that the use of the means chosen would result in a fundamental alteration or in an undue burden (see limitations below). If the choice expressed by the person with a disability would result in an undue burden or a fundamental alteration, the public entity still has an obligation to provide an alternative aid or service that provides effective communication if one is available.

Title III entities are ***encouraged*** to consult with the person with a disability to discuss what aid or service is appropriate. The goal is to provide an aid or service that will be effective, given the nature of what is being communicated and the person's method of communicating.

Covered entities may require reasonable advance notice from people requesting aids or services, based on the length of time needed to acquire the aid or service, but may not impose excessive advance notice requirements. "Walk-in" requests for aids and services must also be honored to the extent possible.

Limitations

Covered entities are required to provide aids and services unless doing so would result in an "undue burden," which is defined as significant difficulty or expense. If a particular aid or service would result in an undue burden, the entity must provide another effective aid or service, if possible, that would not result in an undue burden. Determining what constitutes an undue burden will vary from entity to entity and sometimes from one year to the next. The impact of changing economic conditions on the resources available to an entity may also be taken into consideration in making this determination.

State and local governments: in determining whether a particular aid or service would result in undue financial and administrative burdens, a title II entity should take into consideration the cost of the particular aid or service in light of all resources available to fund the program, service, or activity and the effect on other expenses or operations. The decision that a particular aid or service would result in an undue burden must be made by a high level official, no lower than a Department head, and must include a written statement of the reasons for reaching that conclusion.

Businesses and nonprofits: in determining whether a particular aid or service would result in an undue burden, a title III entity should take into consideration the nature and cost of the aid or service relative to their size, overall financial resources, and

overall expenses. In general, a business or nonprofit with greater resources is expected to do more to ensure effective communication than one with fewer resources. If the entity has a parent company, the administrative and financial relationship, as well as the size, resources, and expenses of the parent company, would also be considered.

In addition, covered entities are not required to provide any particular aid or service in those rare circumstances where it would fundamentally alter the nature of the goods or services they provide to the public. In the performing arts, for example, slowing down the action on stage in order to describe the action for patrons who are blind or have vision loss may fundamentally alter the nature of a play or dance performance.

Staff Training

A critical and often overlooked component of ensuring success is comprehensive and ongoing staff training. Covered entities may have established good policies, but if front line staff are not aware of them or do not know how to implement them, problems can arise. Covered entities should teach staff about the ADA's requirements for communicating effectively with people who have communication disabilities. Many local disability organizations, including Centers for Independent Living, conduct ADA trainings in their communities. The Department's ADA Information Line can provide local contact information for these organizations.

For more information about the ADA, please visit our website or call our toll-free number.

ADA Website

www.ADA.gov

To receive e-mail notifications when new ADA information is available,

visit the ADA Website's home page and click the **link** near the top of the middle column.

ADA Information Line

800-514-0301 (Voice) and 800-514-0383 (TTY)

24 hours a day to order publications by mail.

M-W, F 9:30 a.m. – 5:30 p.m. , Th 12:30 p.m. – 5:30 p.m. (Eastern Time) to speak with an ADA Specialist.

All calls are confidential.

For persons with disabilities, this publication is available in alternate formats.

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RESOURCE GUIDE PART B

ADA Questions and Answers for Health Care Providers

Auxiliary Aids and Services*

Doctors, nurses, dentists, specialists, therapists, and other health care providers must communicate effectively to provide appropriate, effective, quality health care services. Federal disability discrimination laws mandate equal access to and an equal opportunity to participate in and benefit from health care services, and effective communication with individuals who are deaf or hard of hearing. These laws include:

- Section 504 of the Rehabilitation Act of 1973 – applies to federal health care services and facilities; and health care providers who are also recipients of federal financial assistance, usually provided by direct funding (such as federal Medicaid funds) or by grants (such as a federal research grant).
- Title II of the Americans with Disabilities Act – applies to all public (state and local) health care providers.
- Title III of the Americans with Disabilities Act – applies to all private health care providers.

This memorandum focuses on the obligations of private health care providers. However, most of these questions and answers will provide useful guidance for public health care providers (federal, state, and local) as well.

Title III of the Americans with Disabilities Act (ADA) prohibits discrimination against individuals with disabilities by places of public accommodation. 42 U.S.C. §§ 12181 - 12189. Private health care providers are considered places of public accommodation. The U.S. Department of Justice issued regulations under Title III of the ADA at 28 C.F.R. Part 36. The Department's Analysis to this regulation is at 56 Fed. Reg. 35544 (July 26, 1991).

Which private health care providers are covered under the ADA?

Title III of the ADA applies to all private health care providers, regardless of the size of the office or the number of employees. 28 C.F.R. § 36.104. It applies to providers of both physical and mental health care. Hospitals, nursing homes, psychiatric and psychological services, offices of private physicians, dentists, health maintenance organizations (HMOs), and health clinics are included among the health care providers covered by the ADA. If a professional office of a doctor, dentist, or psychologist is located in a private home, the portion of the home used for public purposes (including the entrance) is considered a place of public accommodation. 28 C.F.R. § 36.207.

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What is the obligation of health care providers under the ADA for individuals who are deaf or hard of hearing?

Health care providers have a duty to provide appropriate auxiliary aids and services when necessary to ensure that communication with people who are deaf or hard of hearing is as effective as communication with others. 28 C.F.R. § 36.303(c).

Is this obligation limited to deaf or hard of hearing patients?

No. A health care provider must communicate effectively with customers, clients, and other individuals who are deaf or hard of hearing who are seeking or receiving its services. 56 Fed. Reg. at 35565. Such individuals may not always be "patients" of the health care provider. For example, if prenatal classes are offered as a service to both fathers and mothers, a father who is deaf or hard of hearing must be provided auxiliary aids or services to ensure that he has the same opportunity to benefit from the classes as would other fathers. Similarly, a deaf parent of a hearing child may require an auxiliary aid or service to communicate effectively with health care providers, participate in the child's health care, and to give informed consent for the child's medical treatment. Classes, support groups, and other activities that are open to the public must be also be accessible to deaf and hard of hearing participants.

What kinds of auxiliary aids and services are required by the ADA to ensure effective communication with deaf or hard of hearing individuals?

Auxiliary aids and services include equipment or services a person needs to access and understand aural information and to engage in effective communication. For example, the rule includes qualified interpreters, computer-aided transcription services (also called CART), written materials, assistive listening devices, captioning, or other effective methods of making aural information and communication accessible. 28 C.F.R. § 303(b)(1).

How does a health care provider determine which auxiliary aid or service to provide for a patient who is deaf or hard of hearing?

The auxiliary aid and service requirement is flexible, and the health care provider can choose among various alternatives as long as the result is effective communication with the deaf or hard of hearing individual. An individual who is deaf or hard of hearing likely has experience with auxiliary aids and services to know which will achieve effective communication with his or her health care provider. The U.S. Department of Justice expects that the health care provider will consult with the person and consider carefully his or her self-assessed communication needs before acquiring a particular auxiliary aid or service. 56 Fed. Reg. at 35566-67.

Why are auxiliary aids and services so important in medical settings?

Auxiliary aids and services are often needed to provide safe and effective medical treatment. Without these auxiliary aids and services, medical staff run the grave risk of not understanding the patient's symptoms, misdiagnosing the patient's medical problem, and prescribing inadequate or even harmful treatment. Similarly, patients may not understand medical instructions and warnings or prescription guidelines.

Are there any limitations on the ADA's auxiliary aids and services requirements?

Yes. The ADA does not require the provision of any auxiliary aid or service that would result in an undue burden or in a fundamental alteration in the nature of the goods or services provided by a health care provider. 28 C.F.R. § 36.303(a). Making information or communication accessible to an individual who is deaf or hard of hearing is unlikely ever to be a fundamental alteration of a health care service. An individualized assessment is required to determine whether a particular auxiliary aid or service would be an undue burden.

When would providing an auxiliary aid or service be an undue burden?

An undue burden is something that involves a significant difficulty or expense. For example, it might be a significant difficulty to obtain certain auxiliary aids or services on short notice. Factors to consider in assessing whether an auxiliary aid or service would constitute a significant expense include the nature and cost of the auxiliary aid or service; the overall financial resources of the health care provider; the number of the provider's employees; the effect on expenses and resources; legitimate safety requirements; and the impact upon the operation of the provider. 28 C.F.R. § 36.104. Showing an undue burden may be difficult for most health care providers. When an undue burden can be shown, the health care provider still has the duty to furnish an alternative auxiliary aid or service that would not result in an undue burden and, to the maximum extent possible, would ensure effective communication. 28 C.F.R. § 36.303(f).

Must a health care provider pay for an auxiliary aid or service for a medical appointment if the cost exceeds the provider's charge for the appointment?

In some situations, the cost of providing an auxiliary aid or service (e.g., a qualified interpreter) may exceed the charge to the patient for the health care service. A health care provider is expected to treat the costs of providing auxiliary aids and services as part of the overhead costs of operating a business. Accordingly, so long as the provision of the auxiliary aid or service does not impose an undue burden on the provider's business, the provider is obligated to pay for the auxiliary aid or service.

Can a health care provider charge a deaf or hard of hearing patient for part or all of the costs of providing an auxiliary aid or service?

No. A health care provider cannot charge a patient for the costs of providing auxiliary aids and services. 28 C.F.R. § 36.301(c).

Who is qualified to be an interpreter in a health care setting?

A qualified interpreter is an interpreter who is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary. 28 C.F.R. § 36.104. Interpreters providing services in a medical setting may need to be able to interpret medical terminology.

Do all individuals who are deaf or hard of hearing use the same kind of interpreter?

No. There are various kinds of interpreters. The health care provider should ascertain the particular language needs of the person who is deaf or hard of hearing prior to hiring an interpreter. Some individuals may require interpreters who are fluent in American Sign Language, a language with grammar and syntax that is different from the English language. Others may require interpreters who use Signed English, a form of signing which uses the same word order as does English. Still others who do not know any sign language may require oral interpreters, who take special care to articulate words for deaf or hard of hearing individual, or cued speech interpreters, who give visual cues to assist in lip reading (also called speech reading).

Can a health care provider require family members or friends to interpret for deaf or hard of hearing patients?

Generally, no. Family members and friends often do not possess sufficient skills to interpret effectively in a medical setting. Family members and friends are also very often too emotionally or personally involved, may have interests that conflict with the patient's, may cause role confusion, and are unable to interpret "effectively, accurately, and impartially." Finally, using family members and friends as interpreters can cause problems in maintaining patient confidentiality. 56 Fed. Reg. at 35553.

In what medical situations should a health care provider obtain the services of a qualified interpreter?

An interpreter should be present in all situations in which the information exchanged is sufficiently lengthy or complex to require an interpreter for effective communication. Examples may include, but are not limited to, discussing a patient's medical history, obtaining informed consent and permission for treatment, explaining diagnoses, treatment, and prognoses of an illness, conducting psychotherapy, communicating prior to and after major medical procedures, providing complex instructions regarding

medication, explaining medical costs and insurance, and explaining patient care upon discharge from a medical facility.

Is lip reading an effective form of communicating with individuals who are deaf or hard of hearing?

Not often. The ability of a deaf or hard of hearing individual to speak clearly does not mean that he or she can hear well enough to understand spoken communication or to lip read effectively. Forty to 60 percent of English sounds look alike when spoken. On average, even the most skilled lip readers understand only 25 percent of what is said to them, and many individuals understand far less. Lip reading is most often used as a supplement to the use of residual hearing, amplification, or other assistive listening technology. Because lip reading requires some guesswork, very few deaf or hard of hearing people rely on lip reading alone for exchanges of important information. Lip reading may be particularly difficult in the medical setting where complex medical terminology is often used. Individuals who are deaf or hard of hearing who rely on lip reading for communication may need an oral interpreter to ensure effective communication.

Do written notes offer an effective means of communicating with deaf and hard of hearing individuals?

Exchanging written notes may be effective for brief and simple communication. Communication through the exchange of written notes is inherently truncated; information that would otherwise be spoken may not be written. Moreover, written communication can be slow and cumbersome. If a health care provider is communicating less or providing less information in writing than he or she would provide when speaking to a patient, this is an indication that writing to communicate is not effective in that context.
Understanding written material may also depend on the reading level or literacy skills of the individual. The reading level of deaf and hard of hearing individuals is as variable as the reading levels found in the general population. Additionally, for some deaf and hard of hearing people, American Sign Language (ASL) is their first language. Because the grammar and syntax of ASL differs considerably from English, exchanging written notes may not provide effective communication between a deaf or hard of hearing patient and a health care provider. For some deaf or hard of hearing individuals, the services of a qualified sign language interpreter offer the only effective method of communication.

Must health care providers make conferences, health education, and training sessions that are open to the general public accessible to deaf and hard of hearing individuals?

Yes. Health care providers that offer training sessions, health education, or conferences to the general public must make these events accessible to deaf and hard of hearing individuals. See generally 28 C.F.R. §§ 36.201 and 36.202. Qualified

interpreters, computer-assisted transcription services (also called CART), assistive listening systems/devices, or other auxiliary aids or services may be necessary to ensure equal access to and an equal opportunity to participate for deaf and hard of hearing attendees.

Can health care providers receive any tax credits for the costs of providing auxiliary aids and services?

Eligible small businesses may claim a tax credit of up to 50 percent of eligible access expenditures that are over $250, but less than $10,250. The amount credited may be up to $5,000 per tax year. Eligible access expenditures include the costs of qualified interpreters, CART services, and other auxiliary aids and services. Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, § 44. Please consult with your financial or tax advisor on this issue.