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THE POLICY SURVEILLANCE PROGRAM
A LawAtlas Project

Research Protocol for Health Insurance Coverage Laws for Diabetes Self-Management, Education and Training

Prepared by the Policy Surveillance Program Staff

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RESEARCH PROTOCOL
May 2017

Health Insurance Coverage Laws for Diabetes Self-Management, Education and Training

I. Dates of Protocol: December 2016, May 2017

II. Scope: Compile state laws and regulations regarding diabetes self-management education and training (hereafter "DSME/T"). This dataset began as a cross-sectional study in 2016 and was updated in May 1, 2017. The current longitudinal dataset includes relevant laws and regulations effective from August 1, 2016 to May 1, 2017. The Policy Surveillance Program conducted research and created this dataset in collaboration with ChangeLab Solutions.

III. Primary Data Collection

a. Project Timeline: November 1, 2015 – December 1, 2016. Updated in May 2017.

b. Dates Covered in the Dataset: August 1, 2016 – May 1, 2017. This began as a cross-sectional dataset. An update was performed that collected laws through May 1, 2017 to create a longitudinal dataset. The state law fact sheets developed by ChangeLab Solutions to accompany this dataset are not longitudinal and reflect states' DSME/T laws in effect on May 1, 2017. For archived versions of these fact sheets, please contact ChangeLab Solutions.

c. Data Collection Methods: The research team ("Team") building this dataset consisted of two legal researchers ("Researchers") and one supervisor ("Supervisor") from the Policy Surveillance Program. Two colleagues from ChangeLab Solutions collaborated to define the scope of the laws and regulations included in this dataset, checked the coded responses, in addition to creating the fact sheets that accompany each state.

Once relevant statutes and regulations were identified, the Researchers created a Master Sheet for each jurisdiction. A Master Sheet is an internal document that includes citations, effective dates, and statutory history for all relevant statutes and regulations.

The first 10 states assigned were 100% redundantly researched to confirm that all relevant law was being collected by the Researchers; 20% of the remaining states were redundantly researched.

d. Databases used: Searches were conducted using WestlawNext and state-specific legislative websites.

- Full text versions of the laws collected were pulled from each respective state legislature's website.

e. Search terms: "diabet!;" "diabetes and Medicaid;" "diabetes /p education or training;" "diabetes and insulin"

- Keyword searches were supplemented by examination of the table of contents of each relevant section of the state law identified. Researchers also collected effective dates for the most recent version of relevant statutes and regulations.

f. Information about initial returns and additional inclusion or exclusion criteria: Included laws providing definitions of "diabetes self-management training or education," "diabetes equipment," and "diabetes supplies." Excluded laws regarding the provision of diabetes care at schools, and diabetes and professional qualifications (e.g., to qualify as a school bus driver or police officer).

IV. Coding

a. Development of Coding Scheme: The Team developed coding questions based on initial research. The questions were sent to subject matter experts and collaborators for their review. Once the coding questions were finalized, the Researchers entered them into the MonQcle for coding. The MonQcle is a web-based software coding platform.

1. Dataset Terminology: dataset terminology is a set of relevant terms recorded and defined by the Team specifically for purposes of coding within this dataset. As the Team developed the coding scheme, they recorded the dataset terminology below.

i. "DSME/T": States vary on whether they refer to diabetes self-management education (DSME) by that name, or by diabetes self-management training (DSMT). This dataset uses the term "DSME/T" to encompass all state laws that have DSME or DSMT programs, which were coded and collected identically.

ii. "Private insurance plans": For this dataset, private insurance plans are considered to include all individual and group insurance plans, or related insurance instruments, provided by the private insurance industry that are not associated with Medicare or

Medicaid. States use a variety of terms to refer to private insurance plans that they regulate. Examples of terms used: "disability insurance contracts;" "managed health care plan;" "health maintenance organization;" "policy of accident and health insurance;" and "medical service plan."

In many states DSME/T coverage mandates for private insurance plans were identical, or substantively the same, though they appeared in different statutes based on insurance type (E.g., individual and group insurance and health maintenance organization (HMO) plan requirements might be addressed in separate statutes). In those cases, the Researchers only included one example of the identical statutes for coding purposes and caution notes were added to explain this scenario on a state-by-state basis.

iii. "Medicaid": As a federal-state partnership, states determine many elements of Medicaid coverage. Medicaid coverage requirements are often located in sub-regulatory policy documents (e.g. contractual agreements with managed care organizations, provider manuals, and other state Medicaid agency guidance) rather than in codified statutes and regulations. Moreover, some Medicaid managed care organizations cover specific services, including DSME/T, even if the state does not require such coverage. This dataset captures when states require Medicaid coverage for DSME/T services within statutes, regulations, or sub-regulatory materials. However, this dataset does not include the text, citations or detailed information on state sub-regulatory materials. Specific information on the sub-regulatory materials used to identify state Medicaid coverage requirements can be found within the state law fact sheets developed by ChangeLab solutions to accompany this dataset. To view these fact sheets, please click here.

b. Coding methods: The legal text coded was limited to requirements relating specifically to private insurance coverage or Medicaid coverage for DSME/T**.**

Below are the coding rules that apply specifically to individual coding questions and responses in the dataset. Not all questions in the dataset are covered in this section.

1. **Question:** "*Does the law require private insurance plans to cover diabetes self-management education (DSME/T)?*"and *"Does the law require the state Medicaid program to cover DSME/T?"*
    - "Yes" was coded when there is generally applicable language that all health plans must include DSME/T. Several states had multiple identical statutes that each applied to a specific type

of private health insurance that must cover DSME/T. These instances were identified with a caution note.
- Mississippi and Missouri require health insurers to offer at least one type of policy including coverage of DSME/T, though this coverage may be waived by consumers, and is therefore not a mandated benefit. This situation was captured in this question by the answer choice "No, but offered coverage must adhere to certain standards," because though coverage may be waived, coverage that is provided must meet certain legal requirements, which the Researchers coded.
- Requirements and policies surrounding state employee coverage of DSME/T were not captured in this dataset.

2. **Question:** *"Is there a coverage cap for DSME/T?"* and *"Is there a Medicaid coverage cap for DSME/T?"*
    - "Yes" was coded when there was a limit placed on the provision of the initial DSME/T or if a limit was placed on subsequent DSME/T trigger by a change in health status, change in treatment, or the need for reeducation. Limits may be monetary or times limits.
    - In situations where another trigger allows coverage for additional treatment beyond an initial cap or where a cap may be applied but is not required, this question is still answered "Yes." Examples:
        - Maine: "Every health insurance policy shall include coverage for a one-per-lifetime training program per insured for DSME/T." Ark. Code § 23-79-602(a). "Every healthcare insurer shall offer, in addition to the one-lifetime-training program provided in subsection (a) of this section, additional diabetes self-management training in the even that a physician prescribes additional diabetes self-management training." Ark. Code § 23-79-602(b).
        - Indiana: "Coverage for DSME/T may be limited to the following: (1) one or more visits after receiving a diagnosis of diabetes." Ind. Code § 27-8-14.5-6(b)(1).

3. **Question:** "*What triggers coverage of DSME/T*?" and "*What triggers Medicaid coverage of DSME/T?"*
    - "No explicit trigger for DSME/T coverage in the law" was coded if the state DSME/T law does not specifically provide any of the triggers listed as answer choices.
    - "Diabetes diagnosis" was only coded when the law explicitly mentions a diabetes diagnosis. States that simply reference DSME/T "for treatment of diabetes" were not coded as having a diagnosis trigger for coverage of DSME/T. This answer was

also not coded when DSME/T was merely "approved" by a physician.

- "Change in health status" was coded for any change in medical status or condition. For example, a trigger indicating that a patient's diabetes is unstable or the patient's medical status increases their risk of complications (e.g. comorbid conditions, or documented severe hypoglycemia) were included in this category.
- "Change in treatment" was coded when the law explicitly identifies DSME/T being triggered by a change in a patient "treatment," "treatment plan" and/or "treatment regimen." This response was not coded where the law only indicates a change to a patient's health status and/or condition without explicitly identifying an actual change in the patient's treatment.
- "Need for reeducation" was coded when the word "reeducation" or a similar variant was explicitly stated in the law, or in instances where the law notes that DSME/T coverage was triggered as a result of new technology or techniques that necessitate a new DSME/T session for the patient. For example, "training and education which is medically necessary because of the development of new techniques and treatment for diabetes;" "periodic or episodic continuing education training prescribed by an appropriate health care practitioner as warranted by the development of new techniques or treatments for diabetes;" DSME/T shall be covered "when new medications or treatment are prescribed;" and "where new medications or therapeutic process relating to the person's treatment and/or management of diabetes has been identified."

4. **Questions:** "*What type(s) of health care practitioners can order initial DSME/T?*" and "*What type(s) of health care practitioners can order initial DSME/T covered by Medicaid?*"
    - "Ordering" was coded in the context of an initial diagnosis by a health professional that would necessitate provision of DSME/T. This includes when the law states that a health care practitioner certifies that DSME/T is medically necessary, or when a health care practitioner "prescribes" or "orders" DSME/T.
    - "Health care professional legally authorized to prescribe" is only coded where the provider is explicitly described as being legally authorized to prescribe. Language only indicating that a provider "prescribed" the DSME/T is not sufficient to code the practitioner as being "legally authorized to prescribe."
    - "Any licensed health care practitioner" did not require a health care practitioner to have a specialized license to order

DSME/T. However, this answer choice was also coded when the law included any language indicating a provider specialized in the treatment of diabetes.

5. **Questions:** "*What type(s) of health care practitioners can deliver DSME/T?*" and "*What type(s) of health care practitioners can deliver DSME/T covered by Medicaid?*"
    - "Any licensed health care practitioner" was coded when that phrase is explicitly stated in the law or if no specific limitation is placed on the type of health care provider in the law (E.g., in Alaska: "a health care provider with training in the treatment of diabetes" was coded as "any licensed health care practitioner").

      In instances where "any licensed health care practitioner" was coded and other explicitly mentioned practitioners are included in the law, both "any licensed health care practitioner" and the explicitly mentioned practitioners were coded (E.g., in Kentucky, the law on private insurance provides no explicit limitation on the type of health care provider, but also mentions a certified diabetes educator. Thus, both "any licensed health care practitioner" and "certified diabetes educator" were coded as answer choices).

      When the law(s) referenced only stated "any licensed health care practitioner" or if no specific limitation was placed on the type of health care provider, no other answer choices were coded, even if the answer choice could fall under "any licensed health care practitioner." For example, "physician" would not be coded unless explicitly mentioned, even though a physician could qualify as licensed health care practitioner under another non-DSME/T specific state law.
    - "Any licensed health care practitioner" was coded when a license, certification, or registration is required for the health care practitioner to deliver DSME/T.
    - "Nurse Practitioners" was coded wherever explicitly indicated in the law and/or the law identified registered nurses as a DSME/T healthcare provider, since all nurse practitioners are registered nurses based on their classification as a type of advanced registered practice nurse (APRN).

6. **Questions:** "*What qualifications are required for DSME/T providers?" and "What qualifications are required for DSME/T providers when DSME/T is covered by Medicaid?"*
    - "State licensing or certification" was coded when the state's law mentions that the provider must be "certified" to provide DSME/T, but does not specify whether this was a national or state certification.

- "Designation by a physician" was coded when the state's law requires a physician to designate, consult with, or refer a DSME/T provider.
- "Must have knowledge of DSME/T or diabetes" was coded when the law requires that the DSME/T provider have "expertise" in DSME/T or diabetes. It was also coded when the provider must complete some formal training or additional coursework to expand his or her knowledge of diabetes or DSME/T.
- The qualifications questions are context dependent. If a qualification only applies to a particular provider, the Researchers added a caution note to clarify to whom the qualification applied.

7. **Questions:** "*What program features are required as a part of DSME/T?" and* "*What program features are required as a part of DSME/T covered by Medicaid?"*
    - "Compliance with national DSME/T certification body standards" was coded when the law requires compliance with a national DSME/T certification body's standards or requires accreditation by a national certification body (e.g., American Diabetes Association, American Association of Diabetes Educators, or the American Council on Pharmaceutical Education).
    - "Compliance with state DSME/T standards" was coded when the law requires compliance with state standards or requires state-based certification of the DSME/T program for approval. This state certification often comes from state health departments.
        - When a state requires the program to have either national or state certification, both were coded without a caution note. For example, in South Dakota the program must be "recognized either by the American Diabetes Association or the South Dakota Department of Health."
    - "Nutritional component" was only coded when nutritional therapy or diet education was covered as part of or in conjunction with DSME/T. Medical nutritional therapy (MNT) coverage separate from DSME/T was not sufficient to code this answer.
    - "Patient training on equipment/supply use" was coded when the law explicitly requires training in the use of equipment to self-monitor and/or treat diabetes, including the performance of blood glucose monitoring and/or how to use the results of self-conducted blood glucose monitoring. This response was not coded where the law only requires coverage of equipment and supplies and did not preface this coverage on the actual

training of patients on how to properly use the equipment and/or supplies.
- "Pharmaceutical component" was coded when a state's DSME/T law includes instruction for patients on medication use. This response does not include instruction on equipment or supply use.
- The program features captured by the Researchers represent the most common features found in the state laws regarding DSME/T. Unique features of state laws that were not reflected by common features captured as answer choices were scoped out.

8. **Questions:** *"In what settings may DSME/T be conducted?" and "In what settings may Medicaid-covered DSME/T be conducted?"*
    - "Outpatient settings" was coded when a law explicitly mentions DSME/T conducted in an "outpatient" setting or a setting that is typically an outpatient setting, such as a "physician's office."
    - Although some states permit or require DSME/T to be given in group settings rather than individually, that distinction was not captured in the dataset's responses.
    - "Home health" was not coded to include home telehealth.

V. Quality Control

- **Quality Control – Background Research:** The first 10 states assigned were 100% redundantly researched; 20% of the remaining states were redundantly researched. All divergences between research results were resolved through group discussion. The Supervisor reviewed the final results for each jurisdiction to ensure all relevant laws were captured.

- **Quality Control – Coding:** Quality control of the coding consists of the Supervisor exporting the data into a Microsoft Excel document each day the researchers completed coding to examine the data for any missing entries, citations, and caution notes.

  Redundant coding was completed in batches of 10 jurisdictions at a time.. The Supervisor met with the Researchers after each batch of redundant coding was completed to resolve any divergences between coded responses. All divergences were resolved. Of the records, 100% were redundantly coded throughout the duration of the project (51 of 51).

  Prior to publication, the Supervisor downloaded all coding data into Microsoft Excel to do a final review of coding answers, citations, and caution notes. All unnecessary caution notes were deleted, and all necessary caution notes were edited.

VI. Update (May 2017)

a. **Scope:** During the May 2017 update, all newly enacted laws and amendments to existing laws were collected to ensure any updates that occurred between August 1, 2016 and May 1, 2017 were captured. This update changed this dataset from cross-sectional to longitudinal, capturing all relevant laws in effect from August 1, 2016 to May 1, 2017.

b. **Data Collection Methods:** The Supervisor and two Researchers checked all existing legal citations on Westlaw and legislative tracking websites for any amendments after August 1, 2016. In addition, the search terms listed in section III(e) were used to search for any new laws that had been enacted since the last data collection phase. The Researchers created new records with updated legal text for states with new laws or changes to existing laws that affected answer choices. Researchers cloned records and updated the legal text for states with changes that did not affect answer choices.

c. **Updated Findings:** Two jurisdictions (FL, SD) had updates and only one jurisdiction (FL) contained amendments that impacted coding.

d. **Coding Methods:** During the May 2017 update, the following coding questions for DSME/T Medicaid were removed: "*What type of cost-sharing does the law on DSME/T explicitly permit for Medicaid*" and "*Does the law on DSME/T specify cost-sharing amounts*?" These questions were removed after consultation with ChangeLab Solutions due to ambiguity and complexity in the law regarding cost-sharing requirements for Medicaid patients.

e. **Quality Control**

- **Quality Control – Background Research:** At the start of the update, the Researchers used search terms (see Section III.e. above) to research each jurisdiction in the dataset (51 jurisdictions). Researchers collected any relevant statute or regulation that was amended or newly enacted. There were two states with amendments (FL and SD). These states were also redundantly researched. The Supervisor reviewed the Researchers' results to ensure all amendments were accurately captured.

- **Quality Control – Coding:** The one state with a substantive change (FL) was redundantly coded. Redundant coding revealed a divergence rate of 2.5% on May 15, 2017. The Team discussed all divergences and re-coded as necessary.

- **Quality Control – Statistical Quality Control:** In order to assess the overall error rate of the dataset, Statistical Quality Control (SQC) was performed after all of the original and redundant coding was completed. First, 10% of the 936 total coding instances included in the dataset were selected by a random number generator. This yielded 94 coding instances for redundant coding (10% of 936). The Supervisor calculated the rate of divergence, the first round of SQC yielded a divergence rate of 9.57%. All divergences were reviewed and discussed in a team meeting

and resolved. All jurisdictions were revisited to ensure that any resolution reached during the SQC review were uniformly applied across all coding instances that were not selected during SQC.

Due to the high divergence rate, a second round of SQC was conducted. During this round, 7% of the 936 total coding instances included in the dataset were selected by a random number generator. This yielded 65 coding instances for redundant coding (7% of 936). The Supervisor calculated the rate of divergence, the second round of SQC yielded a divergence rate of 3.63%. All divergences were reviewed in a coding review meeting, discussed with the team and resolved. All jurisdictions were revisited to ensure that any resolutions reached during the second round of SQC review were uniformly applied across all coding instances that were not selected for redundant coding during the second round of SQC.

Prior to publication, the Supervisor downloaded the coding data into Microsoft Excel to do a final review of responses, citations, and caution notes.