

**HEALTH**

**HEALTH SYSTEMS BRANCH**

**DIVISION OF CERTIFICATE OF NEED AND LICENSING**

**CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE PROGRAM**

**Registration Standards for Telemedicine and Telehealth Organizations**

**Proposed New Rules: N.J.A.C. 8:53**

Authorized By: Judith M. Persichilli, R.N., B.S.N., M.A., Commissioner, Department of Health.

Authority: P.L. 2017, c. 177 (N.J.S.A. 45:1-61 through 45:1-66, particularly N.J.S.A. 45:1-64).

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2020-032.

Submit electronic comments to <http://www.nj.gov/health/legal/ecomments.shtml> or written comments to the address below, by June 5, 2020, to:

Joy L. Lindo, Director

Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

PO Box 360

Trenton, NJ 08625-0360

The agency proposal follows:

**Summary**

The Department of Health (Department) is proposing new N.J.A.C. 8:53 to implement the requirements of P.L. 2017, c. 117, codified at N.J.S.A. 45:1-61 et seq. (the Act). The Act requires each telemedicine or telehealth organization operating in the State of New Jersey (State) to register with the Department prior to commencing services. The proposed new chapter implements the Act by setting forth the registration requirements for telemedicine and telehealth organizations and the penalties that may be imposed for failing to comply with these requirements.

In addition to the registration requirements, the Act also sets forth an annual reporting requirement for registered telemedicine and telehealth organizations. The reporting requirements are not included in this rulemaking, as the Department is in the process of drafting a separate notice of proposal to effectuate this requirement. However, the Department has determined that the proposed new rules establishing the registration requirements for telemedicine and telehealth organizations should be promulgated absent the reporting requirements, so that these organizations may begin providing services as contemplated by the Act.

A summary of the proposed new rules follows.

Proposed new Subchapter 1 addresses general provisions. Proposed new N.J.A.C. 8:53-1.1 and 1.2 would contain the scope and purpose of the rules. Proposed new N.J.A.C. 8:53-1.3 would provide the definitions that are used throughout the chapter.

Proposed new Subchapter 2 would address the registration and renewal standards for telehealth or telemedicine organizations. Proposed new N.J.A.C. 8:53-2.1 would establish the registration requirements for telehealth or telemedicine

organizations. Proposed new subsection (a) would require all telemedicine or telehealth organizations, whether operating as distant sites, originating sites, or both, to register with the Department prior to providing services in the State. Proposed new subsection (b) would set forth the requirements for obtaining a telehealth or telemedicine organization registration, provide the registration application form CN-25, incorporated herein by reference as N.J.A.C. 8:53 Appendix , as well as set the registration fee at \$1,500. Proposed new subsection (c) would set the registration period as one year. Proposed new subsection (d) would establish penalties for the failure to register. Proposed new subsection (e) recognizes that some business entities are registered with the New Jersey Division of Revenue and Enterprise Services under a single name, but operate one or more subentities that do business under a different name or names. Each name requires separate registrations. Proposed new subsection (f) would establish the requirements to be followed by a telemedicine or telehealth organization that is closing or ceasing operations. Proposed new subsection (g) would provide that registrations are not assignable or transferable.

Proposed new N.J.A.C. 8:53-2.2 would address the renewal of registrations. Proposed new subsection (a) would require renewal annually on the anniversary of the initial registration date and set forth the renewal process, which involves the return of the completed renewal packet to the Department. Proposed new subsection (b) would provide the standards for renewal, as well as set the renewal fee at \$1,500.

Proposed new N.J.A.C. 8:53-2.3 would set forth the requirements for a telehealth or telemedicine organization to update its information on file with the Department. Proposed new subsection (a) would require telemedicine and telehealth organizations

to update any changes to information that was previously submitted to the Department within five business days of the change occurring and sets forth the process for providing the updated information to the program. Proposed new subsection (b) would require a new registration and submission of the registration fee in the event the legal entity operating the telehealth or telemedicine organization changes.

Proposed new Subchapter 3 would address enforcement actions. Proposed new N.J.A.C. 8:53-3.1 would set forth the standards for the issuance of a summary suspension, suspension, revocation, denial of registration or renewal request, and/or monetary penalty. Proposed new subsection (a) would contain the standards for the issuance of a monetary penalty, suspension, revocation, and/or refusal to issue or renew a registration of a telemedicine or telehealth organization. Proposed new subsection (b) would address the standards for the issuance of a summary suspension of a telehealth or telemedicine registration. Proposed new subsection (c) would address actions that may be taken against a telemedicine or telehealth organization that operates without a valid registration issued by the Department, including civil monetary penalties. Proposed new subsection (d) would set the monetary penalties that may be imposed against a telehealth or telemedicine organization and the violations that may result in the issuance of a penalty. Proposed new subsection (e) would set the time frame for the payment of a monetary penalty. Proposed new subsection (f) would address the enforcement action that may be taken against a telehealth or telemedicine organization that fails to pay a monetary penalty.

Proposed new N.J.A.C. 8:53-3.2 would set the process for the telemedicine or telehealth organization to appeal a summary suspension, denial, suspension, or

revocation of its registration and/or a monetary penalty issued to it. Proposed new subsection (a) would address the manner in which a telehealth or telemedicine organization may seek emergency relief for a summary suspension. Proposed new subsections (b) through (d) would address hearing requests to the Office of Administrative Law to contest a suspension, refusal to issue or renew, or revocation of a registration and/or a monetary penalty.

As the Department has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar, pursuant to N.J.A.C. 1:30-3.3(a)5.

### **Social Impact**

The proposed new rules are expected to have a positive social impact by ensuring that telemedicine or telehealth services are provided by only telemedicine or telehealth organizations that have registered to operate in the State. Overall, the proposed new rules are designed to maintain the quality of services for patients in the State and to increase access to care through telemedicine and telehealth services.

### **Economic Impact**

Telemedicine is expected to have a positive impact on patient access to care and have a corresponding positive effect on health care costs due to improved management of certain chronic health conditions and more efficient use of existing health care resources. Short-term savings may also be found in reduced transportation costs, particularly in the Medicaid program.

The State may also experience an increase in registration revenue through fees for telehealth or telemedicine organizations registering with the Department. It is not possible for the Department to quantify the additional revenue that may be generated.

Telemedicine and telehealth organizations will experience costs associated with the registration requirements to operate in the State, namely the application fees for initial registrations and registration renewals, as outlined in the Summary above.

Telemedicine and telehealth organizations may also be subject to monetary penalties and monetary losses due to suspensions or revocations. No additional compliance costs are set by the proposed new rules.

### **Federal Standards Statement**

These new rules are not proposed under the authority of, or in order to implement, comply with, or participate in any program established under Federal law. In addition, the new rules are not proposed under the authority of a State statute that incorporates or refers to Federal law or Federal standards. Therefore, no Federal standards analysis is required.

### **Jobs Impact**

The Department does not expect that any jobs will be generated or lost in the State as a result of the proposed new rules.

### **Agriculture Industry Impact**

The proposed new rules would have no impact on the agriculture industry of the State of New Jersey.

### **Regulatory Flexibility Analysis**

Some telemedicine or telehealth organizations may be considered small businesses, as the term is defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. Regardless of the size, the law requires registration and the proposed new rules implement this statutory requirement. Although the proposed new rules impose application fees and have potential compliance requirements that may bring about monetary penalties and potential suspensions (as discussed in the Summary and Economic Impact Statement), no lesser requirements or exceptions can be provided based upon business size in the interest of public health, quality of care, and safety.

### **Housing Affordability Impact Analysis**

The proposed new rules would have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that they would evoke a change in the average costs associated with housing because the proposed new rules would only impact telemedicine or telehealth organizations.

### **Smart Growth Development Impact Analysis**

The proposed new rules should not have an impact on the achievement of smart growth and the proposed new rules are unlikely to evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan, as they would only affect telemedicine or telehealth organizations.

### **Racial and Ethnic Community Criminal Justice and Public Safety Impact**

The Department has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies

concerning adults and juveniles in the State. Accordingly, no further analysis is required.

**Full text** of the proposed new rules follows:

CHAPTER 53  
REGISTRATION STANDARDS FOR TELEMEDICINE  
AND TELEHEALTH ORGANIZATIONS

SUBCHAPTER 1. GENERAL PROVISIONS

8:53-1.1 Scope

This chapter applies to all telemedicine or telehealth organizations providing services in the State.

8:53-1.2 Purpose

The purpose of this chapter is to implement the requirements of N.J.S.A. 45:1-61 et seq., by establishing registration provisions for telemedicine or telehealth organizations seeking to provide services in New Jersey.

8:53-1.3 Definitions

(a) The following words and terms are defined at N.J.S.A. 45:1-61 and are used in this chapter as defined therein:

“Distant site”;

“Originating site”;

“Telehealth”;

“Telemedicine”; and

"Telemedicine or telehealth organization".

(b) The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Department" means the New Jersey Department of Health.

"Doing business as" or "DBA" means the name under which a telemedicine or telehealth organization operates its business, if it differs from its legal name filed with the Division of Revenue and Enterprise Services in the New Jersey Department of Treasury.

"Entity representative" means any individual or individuals duly authorized by the telehealth or telemedicine business organization to act on its behalf.

"Program" means the Department of Health's Certificate of Need and Healthcare Facility Licensure Program, PO Box 358, Trenton, NJ 08625-0358, telephone: (609) 292-8773, telefacsimile: (609) 292-3780.

"Registrant" means a telemedicine or telehealth organization that has submitted a completed telemedicine and telehealth organization application, which is approved by the Program in accordance with this chapter.

## SUBCHAPTER 2. ORGANIZATION REGISTRATION

### 8:53-2.1 Telemedicine or telehealth organization registration

(a) A telemedicine or telehealth organization, whether operating as a distant site, originating site, or both, shall register with the Department prior to providing services in the State.

(b) The Department shall issue a registration for a telemedicine or telehealth organization provided that the:

1. Telemedicine or telehealth organization fully and accurately completes and submits to the Program the registration application form CN-25, which is incorporated herein by reference as N.J.A.C. 8:53 Appendix, and available on the Department's website at <https://healthapps.state.nj.us/forms/subforms.aspx?pro=healthfacilities>;

2. Registration of the telemedicine or telehealth organization was not previously suspended or revoked by the Program;

3. Telemedicine or telehealth organization includes a nonrefundable fee of \$1,500 with the submission of the registration application; and

4. Telemedicine or telehealth organization is in compliance with this chapter, N.J.S.A. 45:1-61 et seq., and any other applicable State or Federal rules or statutes.

(c) A registration is valid for one year and is subject to the annual renewal registration and fees, as set forth at N.J.A.C. 8:53-2.2.

(d) A telemedicine or telehealth organization that provides services in New Jersey without first obtaining a registration from the Program shall be subject to an enforcement action as set forth at N.J.A.C. 8:53-3.1.

(e) A telemedicine or telehealth organization with more than one DBA shall file a separate registration for each name.

(f) If a telemedicine or telehealth organization intends to close or cease operations of any registration, then the telemedicine or telehealth organization must first report the closure or cessation of operations to the Program no later than 30 days prior to said closure or cessation.

1. To report the closure or cessation of operations, the telemedicine or telehealth organization must complete and submit to the Program the registration application form CN-25 with the box marked "Discontinue Registration" checked.

2. A telemedicine or telehealth organization that has voluntarily discontinued a registration must submit a new registration application to resume telemedicine or telehealth services.

(g) A registration is not assignable or transferable and is immediately void if the facility ceases to operate.

#### 8:53-2.2 Registration renewal

(a) A registration, unless previously suspended or revoked, shall be renewed annually on the original licensure date.

1. The Program shall send a renewal packet to each registrant at least 30 days prior to the expiration of the registration.

2. A telemedicine or telehealth organization shall return a completed renewal packet to the Program prior to the expiration of its registration.

(b) The Department shall renew the registration of the telemedicine or telehealth organization, provided:

1. The telemedicine or telehealth organization timely submits to the Program a completed renewal packet;

2. The registration of the telemedicine or telehealth organization is not currently suspended or revoked by the Program;

3. The telehealth or telemedicine organization submits a nonrefundable fee of \$1,500 with the submission of the renewal packet; and

4. The telemedicine or telehealth organization is in compliance with this chapter, N.J.S.A. 45:1-61 et seq., and any other applicable State or Federal rules or statutes.

#### 8:53-2.3 Requirement to update information

(a) If any of the information provided by the registrant on the initial or renewal application changes, then the registrant must file an amended application documenting the changes within five business days of the change in information.

1. To report the updated information, the registrant must complete and submit to the Program the registration application form CN-25 with the updated information and with the box marked "Process Change(s)" checked.

(b) A change of the legal entity operating the telemedicine or telehealth organization requires an application for a new registration and registration fee.

### SUBCHAPTER 3. ENFORCEMENT ACTIONS

#### 8:53-3.1 Suspension, revocation, denial of a registration or renewal, and monetary penalty

(a) The Department may impose a monetary penalty and/or suspend or revoke or refuse to issue or renew a registration of a telemedicine or telehealth organization if the registrant fails to comply with the requirements of this chapter, N.J.S.A. 45:1-61 et seq.,

any other applicable rules or statutes, or if the Department determines that the organization poses a threat to the public health, safety, or welfare.

1. Notice of the suspension, revocation, monetary penalty, denial of registration, or registration renewal and the reason for the action taken shall be afforded to the telemedicine or telehealth organization.

(b) The Department may summarily suspend the registration of a telemedicine or telehealth organization if the continued registration of that organization poses an immediate or serious threat to the public health, safety, or welfare.

1. Notice of the summary suspension and the reason for the action taken shall be afforded to the telemedicine or telehealth organization.

2. A summary suspension is effective on the date of issuance.

3. A telemedicine or telehealth organization whose registration has been summarily suspended shall have the right to apply for emergency relief, as provided for at N.J.A.C. 8:53-3.2.

(c) If a telemedicine or telehealth organization operates without a valid registration issued by the Program, the Department may take the following actions:

1. Issue an order requiring the organization to cease and desist the provision of telehealth or telemedicine services;

2. Take action in the New Jersey Superior Court against the organization to enjoin its provision of telehealth or telemedicine services; and/or

3. Impose a monetary penalty in the amount of \$1,000 per calendar day beginning from the date of the first unauthorized service.

(d) A monetary penalty in the amount of \$1,000 per violation may be imposed against a telemedicine or telehealth organization for:

1. Failing to comply with the requirements of this chapter, the Act, or any other applicable rules or statutes; and/or

2. Posing a threat to the public's health, safety, and welfare.

(e) A monetary penalty issued to a telemedicine or telehealth organization shall become due 45 days after the deadline to file an appeal has ended.

1. If an applicant files an appeal with the Department, then the time frame to pay the penalty under N.J.A.C. 8:53-3.2(b)1 applies.

(f) Failure to pay a monetary penalty within the applicable timeframe set forth at (e) or N.J.A.C. 8:53-3.2(b)1, may result in one or more of the following actions against the telehealth or telemedicine organization:

1. Institution of a summary civil proceeding by the State, pursuant to the Penalty Enforcement Law, N.J.S.A. 2A:58-1 et seq.;

2. Refusal to issue:

i. A registration; or

ii. A registration renewal; and/or

3. Revocation of a current registration.

#### 8:53-3.2 Hearings on enforcement actions

(a) When a telehealth or telemedicine organization's registration is summarily suspended, the organization maintains the right to petition the Commissioner of the Department for emergency relief.

1. To request emergency relief, the telehealth or telemedicine organization must, within 15 business days from the date of the notice of summary suspension, submit to the Department a request in writing accompanied by a response to the notice of summary suspension.

i. Failure to submit written notice, pursuant to this paragraph within 15 business days from the date of the notice of summary, suspension shall result in the telehealth or telemedicine organization forfeiting all rights to emergency relief.

2. All applications for emergency relief will be handled in accordance with N.J.A.C. 1:1-12.6(c).

3. Unless emergency relief is granted, the summary suspension shall remain in effect until lifted by either the Department or a court of competent jurisdiction.

4. Nothing in this subsection shall be construed to prevent the Department from simultaneously or thereafter moving to suspend or revoke a telehealth or telemedicine organization's registration or issuing a monetary penalty.

(b) If the Department proposes to assess a monetary penalty and/or to suspend or revoke a license, or to deny the issuance or renewal of registration for a telehealth or telemedicine organization, the Department shall afford the organization an opportunity for a hearing to contest the proposed action.

1. All monetary penalties, suspensions (excluding summary suspensions), revocations, and denials of renewals shall become effective and final 30 calendar days from the date of the proposed action notice, unless the telehealth or telemedicine organization, within such 30-day period, gives written notice to the Department of its desire for a hearing.

i. Failure to submit a written request for a hearing within the 30-day time period shall result in the organization forfeiting all rights to such a hearing.

ii. If a timely request for a hearing is submitted, then the penalty, suspension (excluding summary suspensions), revocation, and/or denial of the renewal shall be held in abeyance until such time as the hearing is concluded and a final decision rendered.

iii. If a hearing request is timely requested for a monetary penalty, then the penalty is due 45 days after the issuance of a final agency decision by the Commissioner determining the penalty.

2. Denials of registration issuance for a telehealth or telemedicine organization are effective immediately.

i. To contest the Department's denial of a telehealth or telemedicine's request for registration, the telehealth or telemedicine organization must, within 30 days of the date of the notice of denial, submit a written hearing request with a response to the denial notice to the Department.

ii. Failure to submit such written notice within 30 days of the date of the notice shall result in the telehealth or telemedicine organization forfeiting all rights to a hearing.

(c) The Department shall transmit hearing requests to the Office of Administrative Law.

(d) Hearings shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

## APPENDIX



Product Type (Select item)		SAMPLE COTTAGE FOOD PRODUCT LABEL	
Product Name		Ingredients:	
List of ingredients		Contains: Net Wt.: *This food is prepared pursuant to N.J.A.C. 8:26-11 in a home kitchen that has not been inspected by the Department of Health.* NJDOH CFO Permit #:	
Major Food Allergens	Contains:	Net Wt.	
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SECTION IV – APPLICANT REPRESENTATIONS AND CERTIFICATION

**Facility Requirements**

- (Y/N) The cottage food operation is in a private dwelling where I reside.
- (Y/N) All cottage food products are prepared in the private kitchen within my home.
- (Y/N) Sleeping quarters are excluded from areas used for cottage food preparation and storage.

**Sanitation Requirements**

- (Y/N) Handwashing facilities are conveniently located, accessible, and supplied with warm running water, soap, and clean paper towels
- (Y/N) Kitchen equipment and utensils used for cottage food preparation are clean and in good repair.
- (Y/N) Food contact surfaces are cleaned and sanitized before each use.
- (Y/N) The premises are maintained free of rodents and insects.xx

**Cottage Food Preparation and Packaging Requirements**

- (Y/N) Food workers wash their hands before working with food, and after any activity that contaminates the hands such as after using the restroom, eating, smoking, or touching pets.
- (Y/N) Food workers do not handle ready-to-eat food with their bare hands. Single-use gloves, tongs, or other effective means are used.
- (Y/N) If used, single-use gloves are changed or replaced as often as handwashing is necessary.

**Limitations/Exclusions During Cottage Food Preparation and Packaging**

- (Y/N) Domestic activities such as family meal preparation, dishwashing, clothes washing, and kitchen cleaning are not conducted.
- (Y/N) Infants, children and pets are excluded from the kitchen.
- (Y/N) Potable drinking water is used for handwashing and warewashing, and as a cottage food product ingredient.
- (Y/N) Smoking is prohibited.
- (Y/N) Ill food workers are excluded from the kitchen.

**Prerequisite Information**

- (Y/N) I have checked with my local municipal government and there are no local ordinances or zoning requirements that would prevent me from operating a home-based food business.
- (Y/N) Does the cottage food kitchen use private well water?

-If Yes, submit a copy of an analysis of the private well water conducted no earlier than one year before the date of this application. **Attach**  
-If No, submit a copy of most recent water bill for the location of the cottage food kitchen.

- (Y/N) I am a certified food protection manager in good standing with the accredited program. I attach a true copy of my food protection manager certificate or other proof of my credential.
- (Y/N) I am aware that my gross annual sales from cottage food products cannot exceed \$50,000. If this is an application to renew my existing cottage food operator permit, I represent that in the past year, gross sales receipts from cottage food products did not exceed \$50,000.
- (Y/N) Photocopies of original records that I am submitting with this application are true, complete, and correct copies of the original records.

*I certify that the statements I make in this application are true. I am aware that if any statement I make in in this application is willfully false, I am subject to civil administrative penalties under N.J.A.C. 8:24-8.9, denial of my application and/or revocation of my permit.*

Signature of Applicant: \_\_\_\_\_ Date: \_\_\_\_\_

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Major Food Allergens	Contains:	Net Wt.	
Product Type (Select item)		SAMPLE COTTAGE FOOD PRODUCT LABEL	
Product Name		Ingredients:	
List of ingredients		Contains: Net Wt.: *This food is prepared pursuant to N.J.A.C. 8:26-11 in a home kitchen that has not been inspected by the Department of Health.* NJDOH CFO Permit #:	
Major Food Allergens	Contains:	Net Wt.	

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