

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

Adopted New Rules: N.J.A.C. 8:53

Proposed: April 20, 2020, at 52 N.J.R. 851(a). (The notice of proposal would have expired on April 6, 2021, but was extended by Executive Order No. 127 (2020) and P.L. 2021, c. 104, to January 1, 2022.

Adopted: July 13, 2021, by the Department of Health, Judith M. Persichilli, R.N., B.S.N., M.A., Commissioner.

Filed: July 14, 2021, as R.2021 d.083, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3), **and with proposed N.J.A.C. 8:53**

Appendix A not adopted.

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).

Effective Date: August 16, 2021.

Expiration Date: August 16, 2028.

Summary of Public Comments and Agency Responses:

The Department of Health (Department) received comments from the following commenters during the 60-day public comment period, which ended on June 5, 2020.

1. Mercedes Camacho-Walsh, RN, DNP, APN, FNP-BC, Occupational & Community Health Services, Union City, NJ

2. Claudia Duck Tucker, Vice President Government Affairs, Teladoc
3. Jean Publice, Whitehouse Station, NJ
4. Melissa Velez, Clifton, NJ

Quoted, summarized, and/or paraphrased below, are the comments and the Department's responses to them. The numbers in parentheses following each comment below correspond to the commenters listed above.

Provider Comment

1. COMMENT: The commenter states, "I want to thank you for recognizing the value of Telemedicine in times of Covid pandemic. I have been delivering health services to an immigrant population in their native language for 20 years. I have adapted to social distancing measures by shifting healthy check-ups to in-office and sick visits by phone so as to not abandon my sick patients. In this process I have managed Covid patients from their homes, with frequent (most often gratuitous) monitoring with good patient response and prevention of illness to their household members (my patients live in overcrowded apartments). I am concerned, however, for the prohibitive cost that you have placed on the registration for Telemedicine services." The commenter also indicates that "My clinic is a corporation, is non-profit 501(c)3 that while not funded, has incurred severe financial loss from not being able to open daily. My question is: 1. Do existing non-profit corporations or other health care offices who are continuing to deliver health care to their patients by performing phone & video examinations (especially observation of breathing of Covid patients) need to register separately if their organization is already registered? Can the registration fee for the Telemedicine aspect be made similar to professional licensing fees rather than the prohibitive \$1500 as currently stated? I call upon your good sense and genuine concern for our poorest patients as they could also infect the general population. If

re-registration is still required to address the same population, then please make it affordable for the providers who have lost income and have chosen to altruistically care for their communities in any way possible. By keeping the registration fee amount as currently stated, it would require an itemized detailed explanation of how this unusual registration fee is necessary. Thank you.”

(1)

RESPONSE: The Department acknowledges the support of the commenter. The Department also appreciates the services that are provided by the commenter’s organization in support of the COVID-19 pandemic. The proposed new chapter implements the registration requirements for telemedicine and telehealth organizations, which are defined as a corporation, sole proprietorship, partnership, or limited liability company that is organized for the primary purpose of administering services in the furtherance of telemedicine or telehealth. Healthcare facilities that simply utilize telemedicine or telehealth services in addition to in-person evaluation and care services are not required to register or pay registration fees.

Registration Process Comments

2. COMMENT: The commenter states that “Several key motivating factors resulted in the enactment of P.L. 2017, c. 117. Two of these factors included providing guardrails for patients, and clarity for businesses involved in the telemedicine and telehealth field. However, telemedicine and telehealth existed prior to the statute's enactment three years ago, and since then, telemedicine and telehealth organizations continue to provide high quality services that are part of the continuum of care. Therefore, we question why the proposed rule under 8:53-2.1 (b)(4)(d) would require telemedicine or telehealth organizations to obtain a registration prior to providing services, especially at the risk of suspension or penalties? Instead, we recommend that

8:53-2.1(b)(4)(d) be amended to allow six months from the close of the public comment period for the submission of a registration by a telemedicine or telehealth organization. Accordingly, we recommend the following language: After December 21, 2020, a telemedicine or telehealth organization that provides services in New Jersey without first submitting a registration from the Program shall be subject to an enforcement action as set forth at N.J.A.C. 8:53-3.1.” (2)

RESPONSE: The Department agrees with the commenter. The Department’s intent was not to require currently operating telehealth and telemedicine organizations to cease operations until they register with the Department in accordance with this rulemaking or to subject the already existing telehealth and telemedicine organizations to an enforcement action for operating prior to the adoption of this rulemaking. Accordingly, the Department will make a non-substantial change at N.J.A.C. 8:53-2.1(d) upon adoption to provide that telemedicine or telehealth organizations currently providing services in New Jersey, upon August 16, 2021 (the effective date of this rulemaking) will have 60 days from August 16, 2021 (the effective date of N.J.A.C. 8:53) to submit a registration application to the Department. The Department will also make a non-substantial change at N.J.A.C. 8:53-2.1 to make clear that the suspension and penalty provisions are not applicable to currently operating organizations that register within the 60-day window following August 16, 2021 (the effective date of this rulemaking).

3. COMMENT: The commenter states, “[t]elemedicine and telehealth organizations provide their services when a licensed physician is in one location, while the patient under their care is in another location. Accordingly, if high quality patient care can be conducted using technology, we believe that the submission, renewal and notifications regarding telemedicine and telehealth organizations can entirely be conducted electronically. A good example of such an online portal

is the existing Department of the Treasury's Division of Revenue and Enterprise Services' Annual reports and Change Services website, available at:

<https://www.njportal.com/DOR/AnnualReports/Business>. Therefore, we recommend the following amendments to 8:53-2.2 (1) and (2) in terms of the registration and renewal in 8:53-2.2 (1), 1. The Program shall electronically send a renewal notification not a renewal packet, and a notice via mail, to each registrant at least 30 days prior to the expiration of the registration. 8:53-2.2 (2): 2. A telemedicine or telehealth organization shall electronically submit completed renewal (not the packet) to the Program prior to the expiration of its registration. Utilizing an on-line portal would also assist with the timeliness of updating information, as per 8:53-2.3, which requires the amended application to be submitted within five business days of the change.” (2)

RESPONSE: Since this rulemaking were proposed, the Department has developed an electronic system for receiving and processing registration applications and renewals and can extend this system to include the registration of telemedicine or telehealth organizations. The Department will instead notify organizations through email at least 30 days prior to the expiration of the registration instead of sending a renewal packet. The Department will require telemedicine and telehealth organizations to register through an online portal as set forth in more detail below in the Agency-Initiated Changes section.

Registration Fees Comments

4. COMMENT: The commenter states, “[I]astly, we recommend increasing the first-time registration fee to \$3,000, and also lowering the annual renewal to \$500. Doing so will serve to protect New Jersey residents by raising a barrier to disreputable businesses, but also by lowering the annual financial burden on businesses that seek to continually provide health care services in

the State. Accordingly, we recommend the following changes regarding registration and renewal to 8:53-2.1(b)(3) and 8:53-2.2 (b)(3). The Department has set the registration fees which are in line with other registration fee standards - 8:53-2.1 (b)(3): 3. Telemedicine or telehealth organization includes a nonrefundable fee of \$3000 not \$1500 with the submission of the initial registration application; and 8:53-2.2 (b)(3): 3. The telehealth or telemedicine organization submits a nonrefundable fee of \$500 with the submission of the annual renewal.” (2)

RESPONSE: The Department disagrees with the commenter’s position. The fees are set at a level to recover administrative costs the Department will incur for the registration process and the provisions of oversight for these registered organizations. Specifically, the establishment of a telehealth and telemedicine registration program will require Department personnel to assume numerous new responsibilities. In addition to the tasks associated with the drafting, promulgation, and future amendment and readoption of these new rules, Department personnel would receive and acknowledge registration applications; respond to inquiries from applicants; issue registrations; and maintain records, among other duties. The fees will offset these costs. Therefore, the Department will make no change on adoption in response to the comment.

5. COMMENT: The commenter states, “[w]e hope that the incorporation of these suggested amendments will build upon the strong foundation established by New Jersey's telemedicine statute. Additionally, we hope that they can assist in providing the proper guardrails for patient protection, while at the same time attract and retain telemedicine and telehealth organizations to the Garden State. Thank you for your time. We are happy to answer any questions.” (2)

RESPONSE: The Department acknowledges the commenter’s comments.

General Comment

6. COMMENT: The commenter states, “[c]ertainly, a sick person will not be helped with telehealth. [I] think if a person is willing to accept such inadequate care and pay money for it that’s ok, but you should never be forced to take telehealth because it is totally inadequate. [M]any pay Medicare funds every month for health care and they are entitled to see a doctor for that health care, not be talked to over the telephone. [S]ending a picture via telephone can be totally deceptive. [N]obody in NJ or America should be forced to use telehealth for medical care. [I]t is outrageously ineffective imo [sic]. [T]his comment is for the public record. [P]lease receipt, [I] wonder why there is no way to comment on email in the [N]ew [J]ersey register. [T]he public needs help in talking to the govt [sic] and not be shut out of using the most used communication system in the modern world. [C]ertainly, snail mail is not the answer and the way the NJDOH puts comment sections in, they are hard to use. [T]here appears to be an attempt of the part of the NJ doh to keep public comment out. [W]hat happened to govt [sic] by the people for the people. [I]t’s certainly missing when you don’t use email. [T]his comment is for the public record.” (3)

RESPONSE: The Department acknowledges the commenter’s comments. The proposed new chapter implements the registration requirements for telemedicine and telehealth organizations, which are defined as a corporation, sole proprietorship, partnership, or limited liability company that is organized for the primary purpose of administering services in the furtherance of telemedicine or telehealth. The new rules do not require patients to use telemedicine to receive medical care in New Jersey.

7. COMMENT: The commenter states, “I believe in registration and regulation to grant both the flexibility while ensuring safety and ethical practices of telemedicine and telehealth orgs. Thank you!” (4)

RESPONSE: The Department acknowledges the commenter’s support of the rulemaking.

Summary of Agency-Initiated Changes:

As the Department has moved to an electronic licensing system since this rulemaking was initiated, the Department is modifying the rules upon adoption by codifying the requirements of the CN-25 Application, which was proposed at N.J.A.C. 8:53 Appendix A, at N.J.A.C. 8:53-2.1(b)1 upon adoption, and directing telehealth and telemedicine organizations to the Department’s licensing portal in order to register, renew, or amend a registration instead of doing so through the paper process that was originally proposed. The information to be provided through the portal during the registration process will remain the same. Therefore, the Department will also not be adopting N.J.A.C. 8:53 Appendix A because the process will be done electronically. As the manner in which the registration, and not the required information, is the only change the Department is proposing upon adoption, reproposal is not necessary. The change to this portal is made throughout the chapter, as appropriate

Federal Standards Statement

These new rules are not adopted 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 adopted under the authority of a State statute that incorporates or refers to Federal law or Federal standards. Therefore, no Federal standards analysis is required.

Full text of the adopted new rules follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks ***[thus]***):

8:53-1.3 Definitions

(a) (No change from proposal.)

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

...

“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]* **Enterprise**** Services in the New Jersey Department of ***the*** Treasury

8:53-2.1 Telemedicine or telehealth organization registration

(a) (No change from proposal.)

(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;>]*** ***on the telehealth/telemedicine (TH) application portal at the Department’s licensing website at**

<https://dohlicensing.nj.gov/>. The required fields on the registration application are as follows:

i. Name of the telemedicine/telehealth organization;

ii. EIN (Employer/Tax ID) of the telemedicine/telehealth organization;

iii. Address of the telemedicine/telehealth organization;

iv. Doing business as (DBA), if any, for the telemedicine/telehealth organization;

v. Full name, title, address, email address, and telephone number of a contact person for the telemedicine/telehealth organization; and

vi. Name, address, email address, and telephone number of a registered agent, if the telemedicine/telehealth organization is located outside of New Jersey;*

2.-4. (No change from proposal.)

(c) (No change from proposal.)

(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.

***1. Telemedicine or telehealth organizations providing services in New Jersey as of August 16, 2021, shall submit a registration application within 60 days from August 16, 2021, or cease providing telehealth or telemedicine services.**

i. A telehealth or telemedicine organization providing services as of August 16, 2021, that continues to operate without registering within 60 days of August 16, 2021, will be subject to the enforcement actions set forth at N.J.A.C. 8:53-3.1.*

(e) (No change from proposal.)

(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 ***go to the telehealth/telemedicine (TH) application portal at the Department's licensing website at <https://dohlicensing.nj.gov/> and*** complete ***[and submit to the Program]*** the ***[registration]* ***electronic*** application form ***[CN-25 with the box marked "Discontinue Registration" checked]* ***to discontinue registration*****.**

2. (No change from proposal.)

(g) (No change from proposal.)

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]* ***notify*** 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]* ***renew their registration*** prior to the ***registration's*** 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]** ***registration***;

2. (No change from proposal.)

3. The telehealth or telemedicine organization submits a nonrefundable fee of \$1,500 **[with the submission of the]** ***and completes its*** renewal **[packet]** ***on the telehealth/telemedicine (TH) application portal at the Department’s licensing website at <https://dohlicensing.nj.gov/> which shall include the verification of the information required at N.J.A.C. 8:53-2.1(b)1***; and

4. (No change from proposal.)

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]** ***do so electronically at the telehealth/telemedicine (TH) application portal on the Department’s licensing website at <https://dohlicensing.nj.gov/> to provide*** the updated information **[and with the box marked “Process Change(s)” checked]**.

(b) (No change from proposal.)

SUBCHAPTER 3. ENFORCEMENT ACTIONS

8:53-3.2 Hearings on enforcement actions

(a)-(c) (No change from proposal.)

(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 A (CN-25)]