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PUBLIC NOTICE

HEALTH

THE COMMISSIONER

Notice of Receipt of Petition for Rulemaking

Certificate of Need: Application and Review Process

Expedited Review Process

Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers

Hospital Licensing Standards

Cardiac

Percutaneous Transluminal Coronary Angioplasty Policies and Procedures

N.J.A.C. 8:33-5.1 and 8:33 Chapter Appendix A, 8:33E, and 8:43G-7.28

Petitioner: Erin M. Duffy, Esq., on behalf of Hunterdon Healthcare System, CentraState Healthcare System, and St. Peter's Healthcare System.

Take notice that on September 14, 2020, the Department of Health (Department) received a petition for rulemaking from Erin M. Duffy, Esq. on behalf of Hunterdon Healthcare System, CentraState Healthcare System, and St. Peter's Healthcare System.

Substance or nature of the requested rulemaking action:

The petitioner requests that the Department make certain amendments to the following rules: N.J.A.C. 8:33 Certificate of Need: Application and Review Process, N.J.A.C. 8:33E Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers, and the Hospital Licensing Standards in the Cardiac subchapter at N.J.A.C. 8:43G-7.28, PTCA space and environment.

Problem or purpose of the request:

The petitioner states, “In 2005, the Department authorized an elective angioplasty demonstration project to facilitate the State’s involvement in the [Johns] Hopkins Atlantic C-PORT Trial: *Elective Angioplasty Study, Randomized Study of Non-Emergency Percutaneous Coronary Intervention in Hospitals With and Without On-site Cardiac Surgery* (C-PORT-E Study). The CPORT-E Study was designed to provide for scientifically rigorous collection and analysis of data needed to determine that elective angioplasty procedures could be safely performed without cardiac surgery capabilities on-site. The second purpose of the elective angioplasty demonstration project was to assist the Department in determining whether New Jersey should authorize elective angioplasty as a regular licensed service in the ordinary course. As part of the Atlantic C-PORT-E Study, Certificates of Need (CNs) were awarded to twelve community hospitals to participate in the project.”

The petitioner further states, “The Department’s authorization of the C-PORT-E Study has contributed to the scientific data needed to determine that elective angioplasty procedures could be safely performed at hospitals without cardiac surgery capabilities on-site as documented by the C-PORT-E Study. Despite the clear scientific data and even further scientific advancements, the Department has not undertaken a thorough review of the Cardiac Regulations as it committed to do. To the contrary, most recently, it readopted the current Cardiac Regulations without change for a period of seven years, which prompted a court challenge to the regulatory re-adoption and this Petition for Rulemaking.”

The petitioner requests that the Department amend N.J.A.C. 8:33 Certificate of

Need, N.J.A.C. 8:33E Certificate of Need: Cardiac Diagnostic Facilities and Cardiac Surgery Centers (Cardiac Rules), and N.J.A.C. 8:43G-7.28, Percutaneous transluminal coronary angioplasty policies and procedures within Subchapter 7, Cardiac, of the Hospital Licensing Standards, to incorporate the recommendations made in 2011 by the Cardiovascular Health Advisory Panel (the CHAP) by eliminating the low-risk restrictions from all cardiac catheterization laboratories, and permitting elective angioplasty at hospitals without surgical back-up onsite and other cardiac procedures. The petitioner provides an appendix showing requested rule text additions and deletions, reprinted below.

Note: The Department readopted existing N.J.A.C. 8:33E in May 2020 (see 52 N.J.R. 1020(a)). The notice of readoption states, in part:

"The Department is developing rulemaking to revise, update, and reorganize existing N.J.A.C. 8:33E, and anticipates filing this rulemaking with the Office of Administrative Law for processing in the ordinary course. However, the Public Health Emergency that Governor Philip D. Murphy declared in Executive Order No. 103, on March 9, 2020, necessitated the reallocation of many Department personnel and resources to pandemic response activities, which resulted in the Department being unable to finalize the anticipated rulemaking prior to chapter expiration. Moreover, the declaration has made impracticable the convening of a meeting of the Health Care Administration Board to obtain that Board's authorization to process the anticipated rulemaking proposal, as required by the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq. Therefore, the Department will not be able to finalize the anticipated rulemaking prior to the expiration of existing N.J.A.C. 8:33E.

The Commissioner has reviewed N.J.A.C. 8:33E and has determined that, pending the finalization of the anticipated rulemaking described above, the existing chapter remains necessary, proper, reasonable, efficient, understandable, and responsive to the purposes for which the Department originally promulgated it, as amended and supplemented over time, and should be readopted." *Id.*

Full text of the petitioner's requested changes follows, with technical changes to conform the text submitted by the petitioner to New Jersey Register codification and formatting conventions, especially with respect to text of which the petition requests deletion; however, these changes from the original are not annotated (petitioner's requested additions to existing text indicated in boldface **thus**; petitioner's requested deletions from existing text indicated in brackets [thus]):

CHAPTER 33

CERTIFICATE OF NEED: APPLICATION AND REVIEW PROCESS

SUBCHAPTER 5. EXPEDITED REVIEW PROCESS

8:33-5.1 Statement of purpose

(a) The expedited review process shall be used for the following types of applications:

1.-8. (No change.)

9. Establishment of a cardiac catheterization program or emergency or primary coronary angioplasty (PTCA) services with off-site cardiac surgery backup **or elective PCTA services with off-site cardiac surgery backup** in accordance with N.J.A.C. 8:33E;

10.-12. (No change.)

(b) (No change.)

At N.J.A.C. 8:33, Chapter Appendix A, Exhibit 3, Certificate of Need Review, bed-related health care facility/services new/expansion, the petitioner requests that the Department add, “elective PCI or angioplasty” and list its “type of review” as “Expedited.”

CHAPTER 33E

CERTIFICATE OF NEED: CARDIAC DIAGNOSTIC FACILITIES AND CARDIAC SURGERY CENTERS

SUBCHAPTER 1. CARDIAC DIAGNOSTIC FACILITIES

8:33E-1.1 Scope and purpose

(a) The purpose of this subchapter is to establish standards and general criteria for the planning of cardiac diagnostic facilities and for the preparation of an application for a certificate of need for such a facility. The invasive cardiac diagnostic facility specializes in the detection and diagnosis of cardiac disorders. [Unlike the cardiac surgery center in which both diagnostic and therapeutic services are co-located, the invasive cardiac diagnostic facility does not provide cardiac surgery or percutaneous coronary intervention (PCI) but rather on the basis of diagnostic studies refers patients, where appropriate, to facilities offering cardiac surgery and other advanced cardiac diagnostic and treatment modalities.] To increase access to these services, low risk cardiac catheterization programs have been established that are subject to facility performance standards contained at N.J.A.C. 8:33E-1.4(c) and 1.14 intended to ensure the continual

delivery of safe patient care, efficiently and effectively provided.

1. (No change.)

2. In 2011, the Cardiovascular Health Advisory Panel (the "CHAP) recommended the elimination of the low risk restrictions from all cardiac catheterization laboratories, finding "no evidence" in the New Jersey Cardiac Catheterization Data Registry (the "NJCCDR") that patients undergoing cardiac catheterization in low risk laboratories have a higher rate of complications than patients undergoing the procedure in full service laboratories. Based on these finding, the CHAP recommended allowing all existing low risk laboratories to advance to full service status and giving low risk laboratories transitioning to full service capacity a period of two years to meet the minimum 250 case volume requirement and other standards.

(b)-(d) (No change.)

8:33E-1.2 Definitions

For the purposes of this subchapter, the following definitions shall apply:

…

"Collaboration agreement" means an agreement between a licensed cardiac surgery center and a general hospital that includes:

1. Written protocols for enrolled patients who require transfer to, and receipt at, a cardiac surgery center's operation room within one hour of the determination of the need for such transfer, including the emergency transfer of patients who require an intra-aortic balloon pump;

2. Regular consultation between the two hospitals on individual cases, including the use of technology to share case information in a rapid manner; and

3. Evidence of adequate cardiac surgery on-call backup.

"Commissioner" means the Commissioner of Health.

…

"**C-PORT-E study" means the Atlantic Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study clinical trial.**

…

"Department" means the Department of Health.

"Full service adult diagnostic cardiac catheterization facility" means an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services to adult patients without cardiac surgery backup. These facilities have laboratories which must meet the requirement of procedures performed on at least [400] **250** patients annually.

…

"Low risk cardiac catheterization facility" means**, until promulgation of amendments to these regulations eliminating low risk restrictions from all cardiac catheterization laboratories,** an acute care general hospital providing invasive cardiac diagnostic (cardiac catheterization) services within its permanent structure as defined in "hospital-based" above that [is] **was** limited in the provision of its service to low risk adult patients. Patients with the following conditions listed below [are to be] **have been** considered high-risk and [shall be] **were** excluded from catheterization at pilot facilities

and transferred in accordance with N.J.A.C. 8:33E-1.8:

1.-9. (No change.)

…

"Low-risk patients" [shall be] **has historically been** defined by the November 1, 1994 participation guidelines of the American College of Cardiology's Database Committee and "low-risk patients" [are] **were** those patients excluded from the definition of "high-risk" who [are] **were** able to be managed by the low risk facilities for diagnostic cardiac catheterization.

…

"Percutaneous coronary intervention (PCI) **or angioplasty**" means the passage of a balloon-tipped catheter (thin tube) to the site of narrowing in an artery and the inflation of the balloon to reduce the obstruction. For purposes of these rules, PCI also includes other invasive procedures to dilate coronary obstruction such as atherectomy of various kinds (for example, excisional, laser) and arterial stenting procedures.

"Primary **PCI or** angioplasty" means the mechanical reopening of an occluded vessel using a balloon-tipped catheter in patients with acute myocardial infarction (AMI) who have not received antecedent thrombolytic therapy.

…

8:33E-1.3 General criteria for invasive cardiac diagnostic facilities

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

(d) Complex electrophysiology studies (EPS) shall only be performed in hospital-based facilities where licensed cardiac surgery services are immediately available on site.

1. (No change.)

2. Elective PCI procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site, unless a certificate of need has been granted in accordance with N.J.A.C. 8:33-3.11 **or 8:33E-2.17.**

3. (No change.)

8:33E-1.4 Utilization criteria for invasive cardiac diagnostic facilities

(a) (No change.)

(b) Except as specifically set forth with respect to low risk cardiac catheterization facility, at (c) below, all facilities licensed to provide full service invasive cardiac diagnostic services shall, as a condition of continued licensure, be required to maintain the following basic utilization criteria:

1. The minimum acceptable number of adult cardiac catheterization patients per full service cardiac laboratory is [400] **250** per year. New full service providers (**i.e.,** those **that had** previously **been** operating as low risk cardiac catheterization laboratories **but is transitioning to full service capacity**) must provide documentation of full compliance with the minimum utilization level **by the end of** [during] their second **full** year of operation or their most recent four quarters of operation, whichever is later and fully documented by the Department using audited data. Existing full service invasive cardiac diagnostic providers (with or without cardiac surgery on site) must achieve minimum utilization levels each year. Compliance with minimum annual facility volume requirements will be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Those new and existing full service

laboratories unable to achieve the minimum level as set forth in this paragraph will be subject to the provisions of N.J.A.C. 8:33E-1.13.

2.-3. (No change.)

(c) All facilities licensed to provide invasive cardiac diagnostic services pursuant to low risk catheterization facility standards described in this subchapter **may continue to do so and** shall, as a condition of continued licensure, be required to maintain the following basic utilization criteria:

1.-3. (No change.)

8:33E-1.8 Agreements for cardiac surgery services

(a) Every facility applying to provide or providing invasive cardiac diagnostic services pursuant to this subchapter which is not also licensed to provide cardiac surgery services on site shall develop and maintain [written agreements] **at least one written Collaboration Agreement** with **a** cardiac surgery center[s] which shall include, but not necessarily be limited to: provisions for insuring quality control, rapid referral for surgery, emergency backup and transport procedures, and regular communication between the cardiologist performing catheterization and the surgeons to whom patients are referred. In addition, one of the [referral agreements] **Collaboration Agreements** must be within one hour travel time from the diagnostic facility and at least one of the [referral agreements] **Collaboration Agreements** shall be written with a New Jersey cardiac center.

(b) To insure that costs are not unnecessarily increased by duplication of procedures, written assurance shall be included within the [referral agreement] **Collaboration**

Agreement stating that, to the greatest extent possible, the receiving facility will accept the results of the diagnostic facility's examinations. Departures from this practice shall be limited to an established peer review mechanism at the receiving center.

8:33E-1.11 Requirements for submission of certificate of need applications to initiate invasive cardiac diagnostic services other than low risk catheterization facilities

(a)-(b) (No change.)

[(c) Except where specifically exempted or superseded, the requirements for submission of certificate of need applications to initiate full service invasive cardiac diagnostic services as set forth in (a) through (b) above, shall be in addition to and not in limitation of any other applicable certificate of need provisions of this subchapter; N.J.S.A. 26:2H-1 et seq.; N.J.A.C. 8:33; and 8:43G.]

[(d)] **(c)** (No change in text.)

8:33E-1.15 Requirements for submission of certificate of need applications to provide full service invasive cardiac diagnostic services

(a) Applications to provide new full service invasive cardiac diagnostic services pursuant to the requirements in this subchapter will be accepted on a monthly basis, with all such applications to be submitted on the first business day of each month. Such applications will be processed on an expedited review basis pursuant to N.J.A.C. 8:33-5.1(b)2. Eligibility for the submission of such applications will be limited to the following:

1. Licensed providers of low-risk cardiac catheterization services that have demonstrated [full unconditional] **substantial** compliance with State licensure

requirements [that includes, but is not limited to, compliance with]**. Failure to include documentation of such substantial compliance will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33-4.5. Providers newly licensed to offer full service cardiac catheterizations must perform** the minimum annual facility volume requirement for full service cardiac catheterization (that is, [400] **250** cases) as set forth at N.J.A.C. 8:33E-1.4(b)1 [throughout their] **by the end of the** second **full** year of **the facility's** operation [or their most recent four quarters of operation, whichever is later and] **of its full service cardiac catherization laboratory which will be** fully documented by the Department using audited data. [Failure to include such documentation will result in the application not being accepted for processing pursuant to N.J.A.C. 8:33-4.5.] **Thereafter, providers will be required to meet the volume requirement set forth at 8:33E-1.4(b) on an annual basis.**

(b)-(c) (No change.)

SUBCHAPTER 2. REGIONAL CARDIAC SURGERY CENTERS

8:33E-2.3 Utilization of cardiac surgical centers

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

(d) The following shall apply to adult cardiac surgery centers providing or seeking to provide PCI services:

1.-2. (No change.)

3. Elective PCI procedures shall be performed only in a hospital-based facility where cardiac surgery services are immediately available on site, unless a certificate of need has been granted in accordance with N.J.A.C. 8:33-3.11 **or 8:33E-2.17**.

4. (No change.)

5. Each PCI facility shall establish a minimum number of PCI procedures for each physician with PCI laboratory privileges. Each physician performing PCI procedures as the primary operator shall perform a minimum of 75 PCI cases a year. (This minimum caseload may be accomplished at more than one laboratory in or out of State.) The physician's minimum annual patient volume is to be achieved at the end of a three year phase-in period, requiring 50 PCI cases as primary operator during the first (CY [2004] **2021**) and second year (CY [2005] **2022**), and 75 PCI cases by the end of the third year (CY [2006] **2023**) and annually thereafter.

i.-iii. (No change.)

(e) (No change.)

8:33E-2.7 Regional responsibilities of cardiac surgery centers

(a) Each cardiac surgery center shall [have] **enter into** written transfer agreements **and Collaboration Agreements** to receive appropriate cardiac patients from hospitals located in the same county as the cardiac surgery center or a contiguous county. Additional transfer **or Collaboration** agreements with hospitals outside the county or a contiguous county are not prohibited. The transfer **and Collaboration** agreements shall include, but not be limited to, provisions establishing the following:

1.-5. (No change.)

8:33E-2.16 Submission of certificate of need applications for the provision of PCI in emergent situations with off-site cardiac surgery back-up

(a) The Department's goal in considering applications for provision of PCI without the availability of on-site cardiac surgery in emergent situations is to promote wider access to appropriate emergency PCI services while assuring quality of care to patients with acute myocardial infarction. Certificate of need applications shall be accepted on the first business day of each month and shall follow the expedited review process.

1. Any general hospital having a full service adult diagnostic cardiac catheterization program [has been licensed for at least six months as a full service adult diagnostic cardiac catheterization program prior to the application submission date] may apply provided it has documented, to the satisfaction of the Department, licensure and full compliance with all cardiac catheterization program and facility utilization requirements as set forth in this chapter and N.J.A.C. 8:43G-7 [for the most recent four quarters of operation fully documented by the Department].

(b)-(e) (No change.)

8:33E-2.17 Submission of certificate of need applications for the provision of elective PCI at hospitals with off-site cardiac surgery back-up

(a) The Department's goal in considering applications for provision of elective PCI without the availability of on-site cardiac surgery is to promote wider access to appropriate elective PCI services while assuring quality of care to patients. Certificate of need applications shall be accepted on the first business day of each month with a non-refundable application fee of $5,000 and shall follow the expedited review process at 8:33-5.2.

1. Any general hospital having a primary PCI program that has been

licensed for at least twelve months as a primary PCI program prior to the application submission date may apply provided it has documented, to the satisfaction of the Department, licensure and full compliance with all cardiac catheterization and primary PCI programs and facility utilization requirements as set forth in this chapter and N.J.A.C. 8:43G-7 for the most recent four quarters of operation.

(b) The criteria at (b)1 through 10 below shall be considered by the Commissioner in determining whether to grant a certificate of need. The Commissioner may also consider additional information provided by an applicant that the Commissioner deems relevant to such determination.

1. The applicant is able to demonstrate the ability to provide elective PCI services consistent with national standards of care and current best practices, including ensuring that all patients considered for elective angioplasty undergo careful selection, screening, and risk stratification pursuant to and ensuring that patients who do not meet such screening criteria are transferred to an appropriate cardiac surgery facility for elective angioplasty;

2. The applicant is able to document a Collaboration Agreement with a New Jersey cardiac surgery center located in the same county as the applicant, or, if there is none in the same municipality, with a New Jersey cardiac surgery center located in the same county or a contiguous county. The documented Collaboration Agreement must include at a minimum:

i. Written protocols assuring that patients will be transferred to and received at the cardiac surgery center's operating room within one hour

from time of the determination by the applicant's operator of the need for transfer. Protocols shall include provisions for emergency transport of patients requiring an intra-aortic balloon pump (IABP);

ii. Regular consultation on individual cases, including use of technology to share case information in a rapid manner; and

iii. Evidence of adequate cardiac surgery on-call back-up.

3. The applicant is able to document how the general public will be advised of the availability of elective PCI with off-site surgical back-up, and of the protocols for transfer, as well as how informed consent will be secured from patients, including, but not limited to:

i. Notice included with the informed consent form that the procedure is not being performed at a licensed cardiac surgery center, and in the event that the patient requires emergency cardiac surgery, the patient will be transferred to a licensed cardiac surgery center;

ii. Details concerning the applicant hospital's plan and protocols for transferring patients who require emergency cardiac surgery;

iii. Including the name and location of the cardiac surgery center with which the applicant hospital has entered into a Collaboration Agreement; and

iv. The applicant hospital shall, upon request, furnish the patient with a written copy of the hospital's transfer protocols, including transportation and associated charges for transportation, and a summary of the Collaboration Agreement.

4. The applicant is able to document based on the elective PCI cases in which the patient was referred to a cardiac surgery center for elective PCI, or other means to the minimum of 200 elective PCI cases per year. The applicant is able to document that it will maintain this minimum volume in subsequent years. Elective PCI must be performed routinely to ensure adequate facility volume. Detailed policies to ensure effective care paths must be developed.

5. The applicant is able to document that each operator performing elective PCI is an experienced intervention list who performed at least 75 PCI cases per year.

6. The applicant is licensed to provide primary PCI and able to document compliance with the criteria for performance of primary PCI at N.J.A.C. 8:33E-2.16.

7. The applicant is able to document that its catheterization laboratory staff, nurses meet the criteria set forth at N.J.A.C. 8:33-3.11(c)4iii, iv, and vi.

8. The applicant is able to document that the catheterization laboratory will be equipped with resuscitative equipment, IABP support, and a broad array of interventional equipment, as well as meeting all equipment standards at N.J.A.C. 8:33E-2.16(b)8 and 8:43G-7.19.

9. The applicant is able to document that it will comply with:

i. The patient selection protocols set forth at N.J.A.C. 8:33-3.11(c)9 and 10;

ii. The exclusionary criteria for patients with high procedure risk at N.J.A.C. 8:33.3.11(c)11; and

iii. The device limitations at N.J.A.C. 8:33.3.11(c)12; and

10. The applicant is able to document its ability to conduct an ongoing program of outcomes analysis and formalized periodic case review, as part of a broader quality assessment and error management system.

(c) In order to facilitate the Department's review of the safety and effectiveness of facilities offering elective PCI services, the Department will:

1. Consistent with N.J.A.C. 8:33E-2.10, develop quarterly reporting requirements for facilities performing elective PCI without on-site surgical back-up; and

2. Communicate guidelines concerning the circumstances under which a licensed cardiac surgery center shall assume porting responsibility for the outcomes of patients transferred from a facility performing elective PCI without on-site surgical back-up.

(d) Facilities granted a certificate of need to provide elective PCI without on-site cardiac surgery are required to operate in accordance with the provisions of N.J.A.C. 8:33E-2.3(d), as applicable, and (b) above, and/or any condition imposed on its certificate of need as a condition of continued licensure. Compliance with minimum annual facility volume requirements shall be calculated on the basis of the last four quarters of operation prior to the facility's licensure anniversary date. Compliance with annual physician volume standards shall be calculated on a calendar year basis. Facilities unable to comply with the requirements of this section will be required to submit to the following:

1. An external review from an independent external organization approved

by the Department to assess the overall performance of the facility and its staff; and

2. A detailed plan of correction to be submitted to the Department within 30 days of notification of its failure to maintain compliance with one or more of the criteria at (b) above, indicating the licensure renewal criteria that have not been achieved, the corrective actions that are to be put in place or the systemic changes that will be employed to ensure future compliance, a timetable for compliance, and the methods used to monitor future actions to ensure eventual compliance. This plan of correction may include a formal request for waivers of licensure requirements as set forth at N.J.A.C. 8:43G-2.8. The plan of correction will not be considered final until it has been approved by the Department.

i. Failure to comply with the provisions of the corrective action plan in accordance with the approved timetables will result in revocation of the facility's license unless an appeal is filed with the Commissioner within 60 days after receiving the Department's notice of revocation. The Department may issue a notice of revocation up to 12 months after the facility's licensure anniversary date following the earliest compliance date within the plan of correction in which the facility was deficient. If the facility requests a hearing, it will be held in accordance with 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. At the Commissioner's discretion, the hearing will be conducted by the Commissioner or transferred to the Office of Administrative Law. In

exercising discretion, the Commissioner may consider the following:

(1) The scope and severity of the threat posed by the failure to comply with the corrective action plan;

(2) The frequency of the non-compliant occurrences;

(3) The presence or absence of attempts at remedial action by the facility;

(4) The presence or absence of any citations, penalties, warnings, or other enforcement actions by any governmental entity pertinent to the condition giving rise to the threat; and

(5) Any other factor which the Commissioner deems to be relevant to assessment of risk presented to patients.

CHAPTER 43G

HOSPITAL LICENSING STANDARDS

SUBCHAPTER 7. CARDIAC

8:43G-7.28 Percutaneous transluminal coronary angioplasty policies and procedures

(a) Elective percutaneous transluminal coronary angioplasty (PTCA) or percutaneous coronary interventions (PCI) shall be performed only in cardiac surgical centers approved by the New Jersey State Department of Health [and Senior Services] unless a certificate of need has been granted in accordance with N.J.A.C. 8:33-3.11(c) **or 8:33E-2.17.**

(b)-(c) (No change.)