

CERTIFICATE OF NEED FOR PET SCANNER SERVICES

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Senate Bill 440 (S-1) as reported from House committee
Sponsor: Sen. Winnie Brinks
House Committee: Health Policy
Senate Committee: Health Policy and Human Services
Complete to 6-9-21

Analysis available at
<http://www.legislature.mi.gov>

(Enacted as Public Act 35 of 2021)

SUMMARY:

Senate Bill 440 would amend the Public Health Code to allow positron emission topography (PET) scanning services to be provided without obtaining a *certificate of need* (CON), as is generally required under the code.

Certificate of need is defined in the code as a certificate issued under Part 222 (Certificates of Need) authorizing a new health facility, a change in bed capacity, the initiation, replacement, or expansion of a *covered clinical service*, or a covered capital expenditure that is issued in accordance with Part 222.

Covered clinical service under the code currently includes services such as certain neonatal services, open heart surgery, and certain radiation and surgery services, including PET scans.

Under the bill, the Department of Health and Human Services (DHHS) could approve a pilot project to provide PET scans without obtaining a CON if DHHS determined that the pilot project met all of the following requirements:

- The PET scanner is located in the same facility as a radiopharmacy that meets all of the following requirements:
 - Is equipped with a fixed cyclotron.
 - Provides cyclotron-produced radionuclide tracers with pharmaceutical components for on-site patient administration.
 - Develops radiopharmaceuticals for use in diagnostic and theranostic applications.
 - Is licensed under Part 177 of the code, which governs pharmacy practice and drug control.
- The PET scanner services will be provided using no more than two fixed PET scanners.
- The pilot project demonstrates that it will become accredited by the American College of Radiology or the Intersocietal Accreditation Commission or will receive equivalent accreditation from another DHHS-approved body.

If the Certificate of Need Commission adopted standards equivalent to those described above to apply for a CON to initiate, replace, or expand PET scanner services, the pilot project described in the bill would have to apply for a CON within six months after adoption of those standards to continue to provide PET scanner services.

Proposed MCL 333.22224b

BACKGROUND:

According to testimony in the Senate Health Policy committee on May 13, 2021, the bill is necessary to allow for more immediate use of certain PET scanners at a forthcoming Grand Rapids health facility without undergoing the CON process. The workgroup created by the Certificate of Need Commission to consider the technology initially planned to begin the assessment in June 2020, but it was delayed due to the COVID-19 pandemic until February 2021. The technology the bill seeks to exempt is expected to be before the Certificate of Need Commission at its June 24, 2021, meeting, with an anticipated decision in November 2021. Accordingly, the equipment reportedly will not be available for the February 2022 opening date of the facility. The bill is intended to expedite the ordering process by several months by making it no longer necessary to wait for CON approval.

BRIEF DISCUSSION:

According to committee testimony, the bill would expedite the use of a new treatment known as “molecular targeted radiation therapy” at the Doug Meijer Medical Innovation Building in Grand Rapids. Proponents argued that such groundbreaking technology to treat cancer should not be delayed merely because COVID-19 disrupted the approval process. Surely this was an unforeseeable delay that should not be absorbed by the health facility or, especially, by the patients whose lives could be saved or enhanced by the treatment.

However, others held that the CON process exists for a reason: to ensure that issues of cost, quality, and access are balanced and that only needed services are developed in Michigan. If the process can be waived for a popular and exciting treatment, doesn't it risk becoming subjective and failing to serve its purpose?

FISCAL IMPACT:

Senate Bill 440 may have fiscal implications for health care costs in Michigan that are indeterminate, including state-funded and locally funded employee and Medicaid costs, by allowing the CON program in DHHS to exempt certain medical PET scanners from the requirement for a certificate of need. CON program services are supported by fees established in statute under section 20161(3) of the Public Health Code. Current-year funding for the CON program is \$2.8 million.

POSITIONS:

Representatives of BAMF Health testified in support of the bill. (5-27-21)

Trinity Health indicated a neutral position on the bill. (5-27-21)

The Michigan Health and Hospital Association indicated opposition to the bill. (5-27-21)

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.