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Senate Bill 440 (as enacted)  
Sponsor: Senator Winnie Brinks  
Senate Committee: Health Policy and Human Services  
House Committee: Health Policy

**PUBLIC ACT 35 of 2021**

Date Completed: 1-5-23

**CONTENT**

**The bill added Section 22224b the Public Health Code to do the following:**

- **Allow the Department of Health and Human Services (DHHS) to approve a pilot program to provide positron emission tomography (PET) scanner services without obtaining a certificate of need (CON) if the pilot program meets certain requirements.**
- **Require a pilot program to provide PET scanner services to obtain a certificate of need to initiate, replace, or expand PET scanner services if the Certificate of Need Commission adopts standards equivalent to those described in the bill.**

The bill took effect on June 24, 2021.

Specifically, under Section 22224b, the DHHS may approve a pilot project that meets the requirements described below and authorize that pilot project to provide PET scanner services without obtaining a CON under Part 222 (Certificates of Need).

The DHHS may approve a pilot project if it determines that the pilot project meets all of the following requirements:

- The positron emission tomography scanner is located in the same facility as a radiopharmacy that 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, and is licensed under Part 177.
- The PET scanner services will be provided using not more than two fixed PET scanners.
- The pilot project demonstrates it will become accredited by the American College of Radiology or the Intersocietal Accreditation Commission, or will receive an equivalent accreditation from another body that is approved by the DHHS.

If the Certificate of Need Commission adopts standards that are equivalent to the requirements described above to apply for a CON to initiate, replace, or expand positron emission tomography scanner services, a pilot project authorized to provide PET scanner services must, within six months after the standards are adopted, apply for a CON to continue to provide PET scanner services.

MCL 333.22224b

## **BACKGROUND**

### Certificates of Need

In Michigan, health facilities must apply for and receive a certificate of need from the DHHS for certain acquisitions or modifications of covered clinical services.

A CON is a state-authorized document that must be acquired before the construction or renovation of certain health facilities and is intended to ensure that only needed services are developed in a state. For the purposes of Michigan's CON program, a health facility means a hospital, a psychiatric hospital or unit, a nursing home or a hospital long-term care unit, a freestanding surgical outpatient facility, or a health maintenance organization (i.e., an HMO). Michigan's CON Program requires an entity to apply and receive approval for a CON from the DHHS to undertake any of the following: the increase in or relocation of licensed beds; the acquisition of an existing health facility, or establishment of a health facility; the modification of a covered clinical service; or the payment of a covered capital expenditure. The list of covered clinical services for which a CON is necessary includes air ambulance services, cardiac catheterization services, computed tomography scanner services, hospital beds, magnetic resonance imaging services, megavoltage radiation therapy services, neonatal intensive care units, nursing home/hospital long-term care unit beds, open heart surgery services, positron emission tomography scanner services, psychiatric beds and services, surgical services, transplantation services, and urinary lithotripter services.

The DHHS uses review standards approved by the CON Commission, an 11-member body appointed by the Governor, to evaluate CON applications. The CON Commission revises the review standards for covered health facilities and each covered clinical service every three years, on a rotating schedule. When the DHHS receives a CON application and considers it complete, a proposed decision is issued by certain deadlines depending on the review type; the shortest deadline is 45 days and the longest is 150 days. If an application is denied, an applicant can request a hearing after which the Director of the DHHS makes a final determination.

### Positron Emission Tomography

Positron emission tomography is a medical imaging technique that allows for the production of three-dimensional scans of organs and tissues. The technique involves the use of a PET scanner and consumable (whether through injection, inhalation, or swallowing) metabolites or drugs that have been tagged with radionuclides (radioactive atoms), which are referred to as tracers or radiotracers. The scanner detects the uptake of tracer in a given organ or tissue, which indicates the level of organ or tissue function. A PET scan can be used to evaluate heart or brain function, to detect cancer and evaluate its treatment, and to diagnose Alzheimer's or Parkinson's disease, among other things.

Legislative Analyst: Stephen P. Jackson

## **FISCAL IMPACT**

The bill will have a minimal fiscal impact on State and local units of government. While changes in certificate of need policy may lead to changes in demand for certain services, the bill is limited to narrowly defined services and devices, so the impact on the State's Medicaid program and health insurance costs for State and local government employees will be limited.

Fiscal Analyst: John P. Maxwell

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This analysis was prepared by nonpartisan Senate staff for use by the Senate in its deliberations and does not constitute an official statement of legislative intent.