SUBSTITUTE FOR

HOUSE BILL NO. 4447

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending sections 6237, 6238, 20104, 20106, 20145, 20155, 20161, 20501, 20521, and 20551 (MCL 333.6237, 333.6238, 333.20104, 333.20106, 333.20145, 333.20155, 333.20161, 333.20501, 333.20521, and 333.20551), sections 6237 and 6238 as amended by 2012 PA 501, section 20104 as amended by 2010 PA 381, section 20106 as amended by 2014 PA 449, section 20145 as amended by 2004 PA 469, section 20155 as amended by 2012 PA 322, and section 20161 as amended by 2013 PA 137; and to repeal acts and parts of acts.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 6237. ~~The~~ **UNTIL OCTOBER 1, 2019, THE** department shall ~~issue a license~~ **ASSESS A $500.00 FEE FOR LICENSES ON AN ANNUAL**

BASIS upon determining that the applicant has complied with this part and rules promulgated under this part. A licensee shall prominently display the license while it is in effect.

Sec. 6238. **(1)** A standard license issued under this part is effective for **NO LONGER THAN** 1 year after the date of issuance. The department may issue a provisional license to an applicant temporarily unable to comply with this part or the rules promulgated under this part. The department may renew or extend a provisional license issued under this section for not more than 1 year. The department may issue a temporary, nonrenewable permit for not more than 90 days if additional time is needed for the department to properly investigate or for the applicant to undertake remedial action.

(2) THE DEPARTMENT SHALL MAKE AT LEAST 1 VISIT TO EACH LICENSED SUBSTANCE USE DISORDER PROGRAM EVERY 3 YEARS FOR SURVEY AND EVALUATION FOR THE PURPOSE OF LICENSURE.

(3) THE DEPARTMENT MAY WAIVE THE VISIT REQUIRED BY SUBSECTION (2) IF THE LICENSED PROGRAM REQUESTS A WAIVER AND SUBMITS THE FOLLOWING:

(A) EVIDENCE THAT IT IS CURRENTLY FULLY ACCREDITED BY AN ACCREDITING BODY WITH EXPERTISE IN THE HEALTH FACILITY TYPE AND THE ACCREDITING ORGANIZATION IS ACCEPTED BY THE DEPARTMENT.

(B) A COPY OF THE MOST RECENT ACCREDITATION EXECUTIVE SUMMARY SUBMITTED TO THE DEPARTMENT AT LEAST 30 DAYS FROM LICENSURE RENEWAL. SUBMISSION OF AN EXECUTIVE SUMMARY DOES NOT PREVENT OR PROHIBIT THE DEPARTMENT FROM REQUESTING THE ENTIRE ACCREDITATION REPORT IF THE DEPARTMENT CONSIDERS IT NECESSARY.

(4) ACCREDITATION INFORMATION PROVIDED TO THE DEPARTMENT UNDER SUBSECTION (3) IS CONFIDENTIAL, IS NOT A PUBLIC RECORD, AND IS NOT SUBJECT TO COURT SUBPOENA. THE DEPARTMENT SHALL USE THE ACCREDITATION INFORMATION ONLY AS PROVIDED IN THIS SECTION. THE DEPARTMENT SHALL PROPERLY DESTROY THE DOCUMENTATION AFTER A DECISION ON THE WAIVER REQUEST IS MADE.

(5) THE DEPARTMENT SHALL GRANT A WAIVER UNDER SUBSECTION (3) IF THE ACCREDITATION REPORT SUBMITTED IS LESS THAN 3 YEARS OLD AND THERE IS NO INDICATION OF SUBSTANTIAL NONCOMPLIANCE WITH LICENSURE STANDARDS OR OF DEFICIENCIES THAT REPRESENT A THREAT TO PUBLIC SAFETY OR PATIENT CARE IN THE ACCREDITATION REPORT.

(6) DENIAL OF WAIVER REQUEST BY THE DEPARTMENT IS NOT SUBJECT TO APPEAL.

(7) THIS SECTION DOES NOT PROHIBIT THE DEPARTMENT FROM CONDUCTING AN INSPECTION OR CITING A VIOLATION OF THIS PART RELATED TO A COMPLAINT.

Sec. 20104. (1) "Certification" means the issuance of a document by the department to a health facility or agency attesting to the fact that the **HEALTH** facility or agency meets both of the following:

(a) It complies with applicable statutory and regulatory requirements and standards.

(b) It is eligible to participate as a provider of care and services in a specific federal or state health program.

~~(2) "Clinical laboratory" means a facility patronized by, or at the direction of, a physician, health officer, or other person authorized by law to obtain information for the diagnosis,~~

~~prevention, or treatment of disease or the assessment of a medical condition by the microbiological, serological, histological, hematological, immunohematological, biophysical, cytological, pathological, or biochemical examination of materials derived from the human body, except as provided in section 20507.~~

(2) ~~(3)~~ "Consumer" means a person who is not a provider of health care as defined in section 1531(3) of title 15 of the public health service act, 42 USC 300n.

(3) ~~(4)~~ "County medical care facility" means a nursing care facility, other than a hospital long-term care unit, ~~which~~ **THAT** provides organized nursing care and medical treatment to 7 or more unrelated individuals who are suffering or recovering from illness, injury, or infirmity and ~~which~~ **THAT** is owned by a county or counties.

(4) ~~(5)~~ "Direct access" means access to a patient or resident or to a patient's or resident's property, financial information, medical records, treatment information, or any other identifying information.

(5) ~~(6)~~ "Freestanding surgical outpatient facility" means a facility, other than the office of a physician, dentist, podiatrist, or other private practice office, offering a surgical procedure and related care that in the opinion of the attending physician can be safely performed without requiring overnight inpatient hospital care. ~~It~~ **FREESTANDING SURGICAL OUTPATIENT FACILITY** does not include a surgical outpatient facility owned by and operated as part of a hospital.

(6) ~~(7)~~ "Good moral character" means that term as defined in section 1 of 1974 PA 381, MCL 338.41.

Sec. 20106. (1) "Health facility or agency", except as provided in section 20115, means:

(a) An ambulance operation, aircraft transport operation, nontransport prehospital life support operation, or medical first response service.

~~(b) A clinical laboratory.~~

(B) ~~(c)~~ A county medical care facility.

(C) ~~(d)~~ A freestanding surgical outpatient facility.

(D) ~~(e)~~ A health maintenance organization.

(E) ~~(f)~~ A home for the aged.

(F) ~~(g)~~ A hospital.

(G) ~~(h)~~ A nursing home.

(H) ~~(i)~~ A hospice.

(I) ~~(j)~~ A hospice residence.

(J) ~~(k)~~ A facility or agency listed in subdivisions (a) to ~~(h)~~ **(G)** located in a university, college, or other educational institution.

(2) "Health maintenance organization" means that term as defined in section 3501 of the insurance code of 1956, 1956 PA 218, MCL 500.3501.

(3) "Home for the aged" means a supervised personal care facility, other than a hotel, adult foster care facility, hospital, nursing home, or county medical care facility that provides room, board, and supervised personal care to 21 or more unrelated, nontransient, individuals 60 years of age or older.

Home for the aged includes a supervised personal care facility for 20 or fewer individuals 60 years of age or older if the facility is operated in conjunction with and as a distinct part of a licensed nursing home. Home for the aged does not include an area excluded from this definition by section 17(3) of the continuing care community disclosure act, **2014 PA 448,** MCL 554.917.

(4) "Hospice" means a health care program that provides a coordinated set of services rendered at home or in outpatient or institutional settings for individuals suffering from a disease or condition with a terminal prognosis.

(5) "Hospital" means a facility offering inpatient, overnight care, and services for observation, diagnosis, and active treatment of an individual with a medical, surgical, obstetric, chronic, or rehabilitative condition requiring the daily direction or supervision of a physician. Hospital does not include a mental health hospital licensed or operated by the department of community health or a hospital operated by the department of corrections.

(6) "Hospital long-term care unit" means a nursing care facility, owned and operated by and as part of a hospital, providing organized nursing care and medical treatment to 7 or more unrelated individuals suffering or recovering from illness, injury, or infirmity.

Sec. 20145. (1) Before contracting for and initiating a construction project involving new construction, additions, modernizations, or conversions of a health facility or agency

with a capital expenditure of $1,000,000.00 or more, a person shall obtain a construction permit from the department. The department shall not issue the permit under this subsection unless the applicant holds a valid certificate of need if a certificate of need is required for the project ~~pursuant to~~ **UNDER** part 222.

(2) To protect the public health, safety, and welfare, the department may promulgate rules to require construction permits for projects other than those described in subsection (1) and the submission of plans for other construction projects to expand or change service areas and services provided.

(3) If a construction project requires a construction permit under subsection (1) or (2), but does not require a certificate of need under part 222, the department shall require the applicant to submit information considered necessary by the department to assure that the capital expenditure for the project is not a covered capital expenditure as defined in section 22203(9).

(4) If a construction project requires a construction permit under subsection (1), but does not require a certificate of need under part 222, the department shall require the applicant to submit information on a 1-page sheet, along with the application for a construction permit, consisting of all of the following:

(a) A short description of the reason for the project and the funding source.

(b) A contact person for further information, including address and phone number.

(c) The estimated resulting increase or decrease in annual operating costs.

(d) The current governing board membership of the applicant.

(e) The entity, if any, that owns the applicant.

(5) The information filed under subsection (4) shall be made publicly available by the department by the same methods used to make information about certificate of need applications publicly available.

(6) The review and approval of architectural plans and narrative shall require that the proposed construction project is designed and constructed in accord with applicable statutory and other regulatory requirements. In performing a construction permit review for a health facility or agency under this section, the department shall, at a minimum, apply the standards contained in the document entitled "Minimum Design Standards for Health Care Facilities in Michigan" published by the department and dated ~~March 1998.~~ **JULY 2007.** The standards are incorporated by reference for purposes of this subsection. The department may promulgate rules that are more stringent than the standards if necessary to protect the public health, safety, and welfare.

(7) The department shall promulgate rules to further prescribe the scope of construction projects and other alterations subject to review under this section.

(8) The department may waive the applicability of this section to a construction project or alteration if the waiver will not affect the public health, safety, and welfare.

(9) Upon request by the person initiating a construction

project, the department may review and issue a construction permit to a construction project that is not subject to subsection (1) or (2) if the department determines that the review will promote the public health, safety, and welfare.

(10) The department shall assess a fee for each review conducted under this section. The fee is .5% of the first $1,000,000.00 of capital expenditure and .85% of any amount over $1,000,000.00 of capital expenditure, up to a maximum of $60,000.00.

(11) As used in this section, "capital expenditure" means that term as defined in section 22203(2), except that ~~it~~ **CAPITAL EXPENDITURE** does not include the cost of equipment that is not fixed equipment.

Sec. 20155. (1) Except as otherwise provided in this section and section 20155a, the department shall make ~~annual and other visits to each health facility or agency licensed under this article for the purposes of survey, evaluation, and consultation.~~ **AT LEAST 1 VISIT TO EACH LICENSED HEALTH FACILITY OR AGENCY EVERY 3 YEARS FOR SURVEY AND EVALUATION FOR THE PURPOSE OF LICENSURE.** A visit made according to a complaint shall be unannounced. Except for a county medical care facility, a home for the aged, a nursing home, or a hospice residence, the department shall determine whether the visits that are not made according to a complaint are announced or unannounced. ~~Beginning June 20, 2001, the~~ **THE** department shall ensure that each newly hired nursing home surveyor, as part of his or her basic training, is assigned full-time to a licensed nursing home for at least 10 days within

a 14-day period to observe actual operations outside of the survey process before the trainee begins oversight responsibilities.

(2) The state shall establish a process that ensures both of the following:

(a) A newly hired nursing home surveyor shall not make independent compliance decisions during his or her training period.

(b) A nursing home surveyor shall not be assigned as a member of a survey team for a nursing home in which he or she received training for 1 standard survey following the training received in that nursing home.

(3) ~~Beginning November 1, 2012, the~~ **THE** department shall perform a criminal history check on all nursing home surveyors in the manner provided for in section 20173a.

(4) A member of a survey team shall not be employed by a licensed nursing home or a nursing home management company doing business in this state at the time of conducting a survey under this section. The department shall not assign an individual to be a member of a survey team for purposes of a survey, evaluation, or consultation visit at a nursing home in which he or she was an employee within the preceding 3 years.

(5) Representatives from all nursing home provider organizations and the state long-term care ombudsman or his or her designee shall be invited to participate in the planning process for the joint provider and surveyor training sessions. The department shall include at least 1 representative from

nursing home provider organizations that do not own or operate a nursing home representing 30 or more nursing homes statewide in internal surveyor group quality assurance training provided for the purpose of general clarification and interpretation of existing or new regulatory requirements and expectations.

(6) The department shall make available online the general civil service position description related to the required qualifications for individual surveyors. The department shall use the required qualifications to hire, educate, develop, and evaluate surveyors.

(7) The department shall ensure that each annual survey team is composed of an interdisciplinary group of professionals, 1 of whom must be a registered nurse. Other members may include social workers, therapists, dietitians, pharmacists, administrators, physicians, sanitarians, and others who may have the expertise necessary to evaluate specific aspects of nursing home operation.

(8) ~~Except as otherwise provided in this section and section 20155a, the department shall make at least a biennial visit to each licensed clinical laboratory, each nursing home, and each hospice residence for the purposes of survey, evaluation, and consultation.~~ The department shall semiannually provide for joint training with nursing home surveyors and providers on at least 1 of the 10 most frequently issued federal citations in this state during the past calendar year. The department shall develop a protocol for the review of citation patterns compared to regional outcomes and standards and complaints regarding the nursing home survey process. The review will be included in the report

required under subsection (20). Except as otherwise provided in this subsection, beginning with his or her first full relicensure period after June 20, 2000, each member of a department nursing home survey team who is a health professional licensee under article 15 shall earn not less than 50% of his or her required continuing education credits, if any, in geriatric care. If a member of a nursing home survey team is a pharmacist licensed under article 15, he or she shall earn not less than 30% of his or her required continuing education credits in geriatric care.

(9) ~~The department shall make a biennial visit to each hospital for survey and evaluation for the purpose of licensure.~~ Subject to subsection (12), the department may waive the ~~biennial~~ visit required by ~~this~~ subsection **(1)** if a ~~hospital, as part of a timely application for license renewal,~~ **HEALTH FACILITY OR AGENCY,** requests a waiver and submits ~~both of~~ the following **AS APPLICABLE** and if all of the requirements of subsection (11) are met:

(a) Evidence that it is currently fully accredited by a body with expertise in ~~hospital accreditation whose hospital accreditations are~~ **THE HEALTH FACILITY OR AGENCY TYPE AND THE ACCREDITING ORGANIZATION IS** accepted by the United States ~~department of health and human services~~ **DEPARTMENT OF HEALTH AND HUMAN SERVICES** for purposes of section 1865 of part [~~C~~ **E**] of title XVIII of the social security act, 42 USC 1395bb.

(b) A copy of the most recent accreditation report, ~~for the hospital~~ **OR EXECUTIVE SUMMARY,** issued by a body described in subdivision (a), and the ~~hospital's~~ **HEALTH FACILITY'S OR AGENCY'S**

responses to the accreditation report **IS SUBMITTED TO THE DEPARTMENT AT LEAST 30 DAYS FROM LICENSE RENEWAL. SUBMISSION OF AN EXECUTIVE SUMMARY DOES NOT PREVENT OR PROHIBIT THE DEPARTMENT FROM REQUESTING THE ENTIRE ACCREDITATION REPORT IF THE DEPARTMENT CONSIDERS IT NECESSARY.**

(C) FOR A NURSING HOME, A STANDARD FEDERAL CERTIFICATION SURVEY CONDUCTED WITHIN THE IMMEDIATELY PRECEDING 9 TO 15 MONTHS THAT SHOWS SUBSTANTIAL COMPLIANCE OR HAS AN ACCEPTED PLAN OF CORRECTION, IF APPLICABLE.

(10) Except as provided in subsection (14), accreditation information provided to the department under subsection (9) is confidential, is not a public record, and is not subject to court subpoena. The department shall use the accreditation information only as provided in this section and ~~shall return the accreditation information to the hospital within a reasonable time~~ **PROPERLY DESTROY THE DOCUMENTATION** after a decision on the waiver request is made.

(11) The department shall grant a waiver under subsection (9) if the accreditation report submitted under subsection (9)(b) is less than ~~2~~ **3** years old **OR THE STANDARD FEDERAL SURVEY SUBMITTED UNDER SUBSECTION (9)(C) IS LESS THAN 15 MONTHS OLD** and there is no indication of substantial noncompliance with licensure standards or of deficiencies that represent a threat to public safety or patient care**.** ~~in the report, in complaints involving the hospital, or in any other information available to the department.~~ If the accreditation report **OR STANDARD FEDERAL SURVEY** is ~~2 or more years~~ **TOO** old, the department may ~~do 1 of the~~

~~following:~~

~~(a) Grant an extension of the hospital's current license until the next accreditation survey is completed by the body described in subsection (9)(a).~~

~~(b) Grant a waiver under subsection (9) based on the accreditation report that is 2 or more years old, on condition that the hospital promptly submit the next accreditation report to the department.~~

~~(c) Deny~~ **DENY** the waiver request and conduct the visits required under subsection (9). **DENIAL OF A WAIVER REQUEST BY THE DEPARTMENT IS NOT SUBJECT TO APPEAL.**

(12) This section does not prohibit the department from citing a violation of this part during a survey, conducting investigations or inspections according to section 20156, or conducting surveys of health facilities or agencies for the purpose of complaint investigations or federal certification. This section does not prohibit the bureau of fire services created in section 1b of the fire prevention code, 1941 PA 207, MCL 29.1b, from conducting annual surveys of hospitals, nursing homes, and county medical care facilities.

(13) At the request of a health facility or agency, the department may conduct a consultation engineering survey of a health facility and provide professional advice and consultation regarding health facility construction and design. A health facility or agency may request a voluntary consultation survey under this subsection at any time between licensure surveys. The fees for a consultation engineering survey are the same as the

fees established for waivers under section ~~20161(10).~~**20161(8).**

(14) If the department determines that substantial noncompliance with licensure standards exists or that deficiencies that represent a threat to public safety or patient care exist based on a review of an accreditation report submitted under subsection (9)(b), the department shall prepare a written summary of the substantial noncompliance or deficiencies and the ~~hospital's~~ **HEALTH FACILITY'S OR AGENCY'S** response to the department's determination. The department's written summary and the ~~hospital's~~ **HEALTH FACILITY'S OR AGENCY'S** response are public documents.

(15) The department or a local health department shall conduct investigations or inspections, other than inspections of financial records, of a county medical care facility, home for the aged, nursing home, or hospice residence without prior notice to the health facility or agency. An employee of a state agency charged with investigating or inspecting the health facility or agency or an employee of a local health department who directly or indirectly gives prior notice regarding an investigation or an inspection, other than an inspection of the financial records, to the health facility or agency or to an employee of the health facility or agency, is guilty of a misdemeanor. Consultation visits that are not for the purpose of annual or follow-up inspection or survey may be announced.

(16) The department shall maintain a record indicating whether a visit and inspection is announced or unannounced. Survey findings gathered at each health facility or agency during

each visit and inspection, whether announced or unannounced, shall be taken into account in licensure decisions.

(17) The department shall require periodic reports and a health facility or agency shall give the department access to books, records, and other documents maintained by a health facility or agency to the extent necessary to carry out the purpose of this article and the rules promulgated under this article. The department shall not divulge or disclose the contents of the patient's clinical records in a manner that identifies an individual except under court order. The department may copy health facility or agency records as required to document findings. Surveyors shall use electronic resident information, whenever available, as a source of survey-related data and shall request facility assistance to access the system to maximize data export.

(18) The department may delegate survey, evaluation, or consultation functions to another state agency or to a local health department qualified to perform those functions. ~~However, the~~ **THE** department shall not delegate survey, evaluation, or consultation functions to a local health department that owns or operates a hospice or hospice residence licensed under this article. The delegation shall be by cost reimbursement contract between the department and the state agency or local health department. Survey, evaluation, or consultation functions shall not be delegated to nongovernmental agencies, except as provided in this section. ~~The department may accept voluntary inspections performed by an accrediting body with expertise in clinical~~

~~laboratory accreditation under part 205 if the accrediting body utilizes forms acceptable to the department, applies the same licensing standards as applied to other clinical laboratories, and provides the same information and data usually filed by the department's own employees when engaged in similar inspections or surveys.~~ The voluntary inspection described in this subsection shall be agreed upon by both the licensee and the department.

(19) If, upon investigation, the department or a state agency determines that an individual licensed to practice a profession in this state has violated the applicable licensure statute or the rules promulgated under that statute, the department, state agency, or local health department shall forward the evidence it has to the appropriate licensing agency.

(20) The department may consolidate all information provided for any report required under this section and section 20155a into a single report. The department shall report to the appropriations subcommittees, the senate and house of representatives standing committees having jurisdiction over issues involving senior citizens, and the fiscal agencies on March 1 of each year on the initial and follow-up surveys conducted on all nursing homes in this state. The report shall include all of the following information:

(a) The number of surveys conducted.

(b) The number requiring follow-up surveys.

(c) The average number of citations per nursing home for the most recent calendar year.

(d) The number of night and weekend complaints filed.

(e) The number of night and weekend responses to complaints conducted by the department.

(f) The average length of time for the department to respond to a complaint filed against a nursing home.

(g) The number and percentage of citations disputed through informal dispute resolution and independent informal dispute resolution.

(h) The number and percentage of citations overturned or modified, or both.

(i) The review of citation patterns developed under subsection (8).

(j) Implementation of the clinical process guidelines and the impact of the guidelines on resident care.

(k) Information regarding the progress made on implementing the administrative and electronic support structure to efficiently coordinate all nursing home licensing and certification functions.

(*l*) The number of annual standard surveys of nursing homes that were conducted during a period of open survey or enforcement cycle.

(m) The number of abbreviated complaint surveys that were not conducted on consecutive surveyor workdays.

(n) The percent of all form CMS-2567 reports of findings that were released to the nursing home within the 10-working-day requirement.

(o) The percent of provider notifications of acceptance or rejection of a plan of correction that were released to the

nursing home within the 10-working-day requirement.

(p) The percent of first revisits that were completed within 60 days from the date of survey completion.

(q) The percent of second revisits that were completed within 85 days from the date of survey completion.

(r) The percent of letters of compliance notification to the nursing home that were released within 10 working days of the date of the completion of the revisit.

(s) A summary of the discussions from the meetings required in subsection (24).

(t) The number of nursing homes that participated in a recognized quality improvement program as described under section 20155a(3).

(21) The department shall report March 1 of each year to the standing committees on appropriations and the standing committees having jurisdiction over issues involving senior citizens in the senate and the house of representatives on all of the following:

(a) The percentage of nursing home citations that are appealed through the informal dispute resolution process.

(b) The number and percentage of nursing home citations that are appealed and supported, amended, or deleted through the informal dispute resolution process.

(c) A summary of the quality assurance review of the amended citations and related survey retraining efforts to improve consistency among surveyors and across the survey administrative unit that occurred in the year being reported.

(22) Subject to subsection (23), a clarification work group

comprised of the department in consultation with a nursing home resident or a member of a nursing home resident's family, nursing home provider groups, the American ~~medical directors association,~~ **MEDICAL DIRECTORS ASSOCIATION,** the state long-term care ombudsman, and the federal ~~centers for medicare and medicaid services~~ **CENTERS FOR MEDICARE AND MEDICAID SERVICES** shall clarify the following terms as those terms are used in title XVIII and title XIX and applied by the department to provide more consistent regulation of nursing homes in this state:

(a) Immediate jeopardy.

(b) Harm.

(c) Potential harm.

(d) Avoidable.

(e) Unavoidable.

(23) All of the following clarifications developed under subsection (22) apply for purposes of subsection (22):

(a) Specifically, the term "immediate jeopardy" means a situation in which immediate corrective action is necessary because the nursing home's noncompliance with 1 or more requirements of participation has caused or is likely to cause serious injury, harm, impairment, or death to a resident receiving care in a nursing home.

(b) The likelihood of immediate jeopardy is reasonably higher if there is evidence of a flagrant failure by the nursing home to comply with a clinical process guideline adopted under subsection (25) than if the nursing home has substantially and continuously complied with those guidelines. If federal

regulations and guidelines are not clear, and if the clinical process guidelines have been recognized, a process failure giving rise to an immediate jeopardy may involve an egregious widespread or repeated process failure and the absence of reasonable efforts to detect and prevent the process failure.

(c) In determining whether or not there is immediate jeopardy, the survey agency should consider at least all of the following:

(*i*) Whether the nursing home could reasonably have been expected to know about the deficient practice and to stop it, but did not stop the deficient practice.

(*ii*) Whether the nursing home could reasonably have been expected to identify the deficient practice and to correct it, but did not correct the deficient practice.

(*iii*) Whether the nursing home could reasonably have been expected to anticipate that serious injury, serious harm, impairment, or death might result from continuing the deficient practice, but did not so anticipate.

(*iv*) Whether the nursing home could reasonably have been expected to know that a widely accepted high-risk practice is or could be problematic, but did not know.

(*v*) Whether the nursing home could reasonably have been expected to detect the process problem in a more timely fashion, but did not so detect.

(d) The existence of 1 or more of the factors described in subdivision (c), and especially the existence of 3 or more of those factors simultaneously, may lead to a conclusion that the

situation is one in which the nursing home's practice makes adverse events likely to occur if immediate intervention is not undertaken, and therefore constitutes immediate jeopardy. If none of the factors described in subdivision (c) is present, the situation may involve harm or potential harm that is not immediate jeopardy.

(e) Specifically, "actual harm" means a negative outcome to a resident that has compromised the resident's ability to maintain or reach, or both, his or her highest practicable physical, mental, and psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. Harm does not include a deficient practice that only may cause or has caused limited consequences to the resident.

(f) For purposes of subdivision (e), in determining whether a negative outcome is of limited consequence, if the "state operations manual" or "the guidance to surveyors" published by the federal ~~centers for medicare and medicaid services~~ **CENTERS FOR MEDICARE AND MEDICAID SERVICES** does not provide specific guidance, the department may consider whether most people in similar circumstances would feel that the damage was of such short duration or impact as to be inconsequential or trivial. In such a case, the consequence of a negative outcome may be considered more limited if it occurs in the context of overall procedural consistency with an accepted clinical process guideline adopted under subsection (25), as compared to a substantial inconsistency with or variance from the guideline.

(g) For purposes of subdivision (e), if the publications described in subdivision (f) do not provide specific guidance, the department may consider the degree of a nursing home's adherence to a clinical process guideline adopted under subsection (25) in considering whether the degree of compromise and future risk to the resident constitutes actual harm. The risk of significant compromise to the resident may be considered greater in the context of substantial deviation from the guidelines than in the case of overall adherence.

(h) To improve consistency and to avoid disputes over avoidable and unavoidable negative outcomes, nursing homes and survey agencies must have a common understanding of accepted process guidelines and of the circumstances under which it can reasonably be said that certain actions or inactions will lead to avoidable negative outcomes. If the "state operations manual" or "the guidance to surveyors" published by the federal ~~centers for medicare and medicaid services~~ **CENTERS FOR MEDICARE AND MEDICAID SERVICES** is not specific, a nursing home's overall documentation of adherence to a clinical process guideline with a process indicator adopted under subsection (25) is relevant information in considering whether a negative outcome was avoidable or unavoidable and may be considered in the application of that term.

(24) The department shall conduct a quarterly meeting and invite appropriate stakeholders. Appropriate stakeholders shall include at least 1 representative from each nursing home provider organization that does not own or operate a nursing home

representing 30 or more nursing homes statewide, the state long-term care ombudsman or his or her designee, and any other clinical experts. Individuals who participate in these quarterly meetings, in conjunction with the department, may designate advisory workgroups to develop recommendations on the discussion topics that should include, at a minimum, all of the following:

(a) Opportunities for enhanced promotion of nursing home performance, including, but not limited to, programs that encourage and reward providers that strive for excellence.

(b) Seeking quality improvement to the survey and enforcement process, including clarifications to process-related policies and protocols that include, but are not limited to, all of the following:

(*i*) Improving the surveyors' quality and preparedness.

(*ii*) Enhanced communication between regulators, surveyors, providers, and consumers.

(*iii*) Ensuring fair enforcement and dispute resolution by identifying methods or strategies that may resolve identified problems or concerns.

(c) Promoting transparency across provider and surveyor communities, including, but not limited to, all of the following:

(*i*) Applying regulations in a consistent manner and evaluating changes that have been implemented to resolve identified problems and concerns.

(*ii*) Providing consumers with information regarding changes in policy and interpretation.

(*iii*) Identifying positive and negative trends and factors

contributing to those trends in the areas of resident care, deficient practices, and enforcement.

(d) Clinical process guidelines.

(25) Subject to subsection (27), the department shall develop and adopt clinical process guidelines. The department shall establish and adopt clinical process guidelines and compliance protocols with outcome measures for all of the following areas and for other topics where the department determines that clarification will benefit providers and consumers of long-term care:

(a) Bed rails.

(b) Adverse drug effects.

(c) Falls.

(d) Pressure sores.

(e) Nutrition and hydration including, but not limited to, heat-related stress.

(f) Pain management.

(g) Depression and depression pharmacotherapy.

(h) Heart failure.

(i) Urinary incontinence.

(j) Dementia.

(k) Osteoporosis.

(*l*) Altered mental states.

(m) Physical and chemical restraints.

(n) Culture-change principles, person-centered caring, and self-directed care.

(26) The department shall biennially review and update all

clinical process guidelines as needed and shall continue to develop and implement clinical process guidelines for topics that have not been developed from the list in subsection (25) and other topics identified as a result of the meetings required in subsection (24). The department shall consider recommendations from an advisory workgroup created under subsection (24) on clinical process guidelines. The department shall include training on new and revised clinical process guidelines in the joint provider and surveyor training sessions as those clinical process guidelines are developed and revised.

(27) ~~Beginning November 1, 2012, representatives~~ **REPRESENTATIVES** from each nursing home provider organization that does not own or operate a nursing home representing 30 or more nursing homes statewide and the state long-term care ombudsman or his or her designee shall be permanent members of any clinical advisory workgroup created under subsection (24). The department shall issue survey certification memorandums to providers to announce or clarify changes in the interpretation of regulations.

(28) The department shall maintain the process by which the **DEPARTMENT** director ~~of the division of nursing home monitoring~~ or his or her designee ~~or the director of the division of operations or his or her designee~~ reviews and authorizes the issuance of a citation for immediate jeopardy or substandard quality of care before the statement of deficiencies is made final. The review shall be to assure that the applicable concepts, clinical process guidelines, and other tools contained in subsections (25) to (27) are being used consistently, accurately, and effectively. As used

in this subsection, "immediate jeopardy" and "substandard quality of care" mean those terms as defined by the federal ~~centers for medicare and medicaid services.~~**CENTERS FOR MEDICARE AND MEDICAID SERVICES.**

(29) Upon availability of funds, the department shall give grants, awards, or other recognition to nursing homes to encourage the rapid implementation or maintenance of the clinical process guidelines adopted under subsection (25).

(30) The department shall instruct and train the surveyors in the clinical process guidelines adopted under subsection (25) in citing deficiencies.

(31) A nursing home shall post the nursing home's survey report in a conspicuous place within the nursing home for public review.

(32) Nothing in this ~~amendatory act shall be construed to limit~~ **SECTION LIMITS** the requirements of related state and federal law.

(33) As used in this section:

(a) "Consecutive days" means calendar days, but does not include Saturday, Sunday, or state- or federally-recognized holidays.

(b) "Form CMS-2567" means the federal ~~centers for medicare and medicaid services'~~ **CENTERS FOR MEDICARE AND MEDICAID SERVICES'** form for the statement of deficiencies and plan of correction or a successor form serving the same purpose.

(c) "Title XVIII" means title XVIII of the social security act, 42 USC 1395 to 1395kkk.

(d) "Title XIX" means title XIX of the social security act, 42 USC 1396 to 1396w-5.

Sec. 20161. (1) The department shall assess fees and other assessments for health facility and agency licenses and certificates of need on an annual basis as provided in this article. ~~Except~~ **UNTIL OCTOBER 1, 2019, EXCEPT** as otherwise provided in this article, fees and assessments shall be paid as provided in the following schedule:

(a) Freestanding surgical outpatient facilities.....	~~$238.00~~ **$500.00** per facility **LICENSE**.
(b) Hospitals.....	~~$8.28~~ **$500.00 PER FACILITY LICENSE AND $10.00** per licensed bed.
(c) Nursing homes, county medical care facilities, and hospital long-term care units.....	~~$2.20~~ **$500.00 PER FACILITY LICENSE AND $3.00** per licensed bed **OVER 100 LICENSED BEDS**.
(d) Homes for the aged.....	$6.27 per licensed bed.
~~(e) Clinical laboratories.....~~	~~$475.00 per laboratory.~~
(E) HOSPICE AGENCIES.....	**$500.00 PER AGENCY LICENSE.**
(f) Hospice residences.....	~~$200.00~~ **$500.00** per **FACILITY** ~~survey,~~ **LICENSE** and ~~$20.00~~ **$5.00** per licensed bed.

(g) Subject to subsection

~~(13),~~ **(11),** quality assurance assessment for nursing homes and hospital long-term care units.....an amount resulting in not more than 6% of total industry revenues.

(h) Subject to subsection ~~(14),~~ **(12),** quality assurance assessment for hospitals.....at a fixed or variable rate that generates funds not more than the maximum allowable under the federal matching requirements, after consideration for the amounts in subsection ~~(14)(a)~~ **(12)(A)** and (i).

(I) INITIAL LICENSURE APPLICATION FEE FOR SUBDIVISIONS (A), (B), (C), (E), AND (F).....$2,000.00 PER INITIAL LICENSE.

(2) If a hospital requests the department to conduct a certification survey for purposes of title XVIII or title XIX of the social security act, the hospital shall pay a license fee surcharge of $23.00 per bed. As used in this subsection, "title XVIII" and "title XIX" mean those terms as defined in section 20155.

(3) All of the following apply to the assessment under this

section for certificates of need:

(a) The base fee for a certificate of need is $3,000.00 for each application. For a project requiring a projected capital expenditure of more than $500,000.00 but less than $4,000,000.00, an additional fee of $5,000.00 is added to the base fee. For a project requiring a projected capital expenditure of $4,000,000.00 or more but less than $10,000,000.00, an additional fee of $8,000.00 is added to the base fee. For a project requiring a projected capital expenditure of $10,000,000.00 or more, an additional fee of $12,000.00 is added to the base fee.

(b) In addition to the fees under subdivision (a), the applicant shall pay $3,000.00 for any designated complex project including a project scheduled for comparative review or for a consolidated licensed health facility application for acquisition or replacement.

(c) If required by the department, the applicant shall pay $1,000.00 for a certificate of need application that receives expedited processing at the request of the applicant.

(d) The department shall charge a fee of $500.00 to review any letter of intent requesting or resulting in a waiver from certificate of need review and any amendment request to an approved certificate of need.

(e) A health facility or agency that offers certificate of need covered clinical services shall pay $100.00 for each certificate of need approved covered clinical service as part of the certificate of need annual survey at the time of submission of the survey data.

(f) The department ~~of community health~~ shall use the fees collected under this subsection only to fund the certificate of need program. Funds remaining in the certificate of need program at the end of the fiscal year shall not lapse to the general fund but shall remain available to fund the certificate of need program in subsequent years.

(4) ~~If licensure is for more than 1 year, the fees described in subsection (1) are multiplied by the number of years for which the license is issued, and the total amount of the fees shall be collected in the year in which the license is issued.~~**A LICENSE ISSUED UNDER THIS PART IS EFFECTIVE FOR NO LONGER THAN 1 YEAR AFTER THE DATE OF ISSUANCE.**

(5) Fees described in this section are payable to the department at the time an application for a license, permit, or certificate is submitted. If an application for a license, permit, or certificate is denied or if a license, permit, or certificate is revoked before its expiration date, the department shall not refund fees paid to the department.

(6) The fee for a provisional license or temporary permit is the same as for a license. A license may be issued at the expiration date of a temporary permit without an additional fee for the balance of the period for which the fee was paid if the requirements for licensure are met.

~~(7) The department may charge a fee to recover the cost of purchase or production and distribution of proficiency evaluation samples that are supplied to clinical laboratories under section 20521(3).~~

~~(8) In addition to the fees imposed under subsection (1), a clinical laboratory shall submit a fee of $25.00 to the department for each reissuance during the licensure period of the clinical laboratory's license.~~

(7) ~~(9)~~ The cost of licensure activities shall be supported by license fees.

(8) ~~(10)~~ The application fee for a waiver under section 21564 is $200.00 plus $40.00 per hour for the professional services and travel expenses directly related to processing the application. The travel expenses shall be calculated in accordance with the state standardized travel regulations of the department of technology, management, and budget in effect at the time of the travel.

(9) ~~(11)~~ An applicant for licensure or renewal of licensure under part 209 shall pay the applicable fees set forth in part 209.

(10) ~~(12)~~ Except as otherwise provided in this section, the fees and assessments collected under this section shall be deposited in the state treasury, to the credit of the general fund. The department may use the unreserved fund balance in fees and assessments for the criminal history check program required under this article.

(11) ~~(13)~~ The quality assurance assessment collected under subsection (1)(g) and all federal matching funds attributed to that assessment shall be used only for the following purposes and under the following specific circumstances:

(a) The quality assurance assessment and all federal

matching funds attributed to that assessment shall be used to finance ~~medicaid~~ **MEDICAID** nursing home reimbursement payments. Only licensed nursing homes and hospital long-term care units that are assessed the quality assurance assessment and participate in the ~~medicaid~~ **MEDICAID** program are eligible for increased per diem ~~medicaid~~ **MEDICAID** reimbursement rates under this subdivision. A nursing home or long-term care unit that is assessed the quality assurance assessment and that does not pay the assessment required under subsection (1)(g) in accordance with subdivision (c)(*i*) or in accordance with a written payment agreement with the state shall not receive the increased per diem ~~medicaid~~ **MEDICAID** reimbursement rates under this subdivision until all of its outstanding quality assurance assessments and any penalties assessed ~~pursuant to~~ **UNDER** subdivision (f) have been paid in full. ~~Nothing in this~~ **THIS** subdivision ~~shall be construed to~~ **DOES NOT** authorize or require the department to overspend tax revenue in violation of the management and budget act, 1984 PA 431, MCL 18.1101 to 18.1594.

(b) Except as otherwise provided under subdivision (c), beginning October 1, 2005, the quality assurance assessment is based on the total number of patient days of care each nursing home and hospital long-term care unit provided to ~~nonmedicare~~ **NON-MEDICARE** patients within the immediately preceding year and shall be assessed at a uniform rate on October 1, 2005 and subsequently on October 1 of each following year, and is payable on a quarterly basis, the first payment due 90 days after the date the assessment is assessed.

(c) Within 30 days after September 30, 2005, the department shall submit an application to the federal ~~centers for medicare and medicaid services~~ **CENTERS FOR MEDICARE AND MEDICAID SERVICES** to request a waiver ~~pursuant~~ **ACCORDING** to 42 CFR 433.68(e) to implement this subdivision as follows:

(*i*) If the waiver is approved, the quality assurance assessment rate for a nursing home or hospital long-term care unit with less than 40 licensed beds or with the maximum number, or more than the maximum number, of licensed beds necessary to secure federal approval of the application is $2.00 per ~~nonmedicare~~ **NON-MEDICARE** patient day of care provided within the immediately preceding year or a rate as otherwise altered on the application for the waiver to obtain federal approval. If the waiver is approved, for all other nursing homes and long-term care units the quality assurance assessment rate is to be calculated by dividing the total statewide maximum allowable assessment permitted under subsection (1)(g) less the total amount to be paid by the nursing homes and long-term care units with less than 40 or with the maximum number, or more than the maximum number, of licensed beds necessary to secure federal approval of the application by the total number of ~~nonmedicare~~ **NON-MEDICARE** patient days of care provided within the immediately preceding year by those nursing homes and long-term care units with more than 39, but less than the maximum number of licensed beds necessary to secure federal approval. The quality assurance assessment, as provided under this subparagraph, shall be assessed in the first quarter after federal approval of the

waiver and shall be subsequently assessed on October 1 of each following year, and is payable on a quarterly basis, the first payment due 90 days after the date the assessment is assessed.

(*ii*) If the waiver is approved, continuing care retirement centers are exempt from the quality assurance assessment if the continuing care retirement center requires each center resident to provide an initial life interest payment of $150,000.00, on average, per resident to ensure payment for that resident's residency and services and the continuing care retirement center utilizes all of the initial life interest payment before the resident becomes eligible for medical assistance under the state's ~~medicaid~~ **MEDICAID** plan. As used in this subparagraph, "continuing care retirement center" means a nursing care facility that provides independent living services, assisted living services, and nursing care and medical treatment services, in a campus-like setting that has shared facilities or common areas, or both.

(d) Beginning May 10, 2002, the department ~~of community health~~ shall increase the per diem nursing home ~~medicaid~~ **MEDICAID** reimbursement rates for the balance of that year. For each subsequent year in which the quality assurance assessment is assessed and collected, the department ~~of community health~~ shall maintain the ~~medicaid~~ **MEDICAID** nursing home reimbursement payment increase financed by the quality assurance assessment.

(e) The department ~~of community health~~ shall implement this section in a manner that complies with federal requirements necessary to ~~assure~~ **ENSURE** that the quality assurance assessment

qualifies for federal matching funds.

(f) If a nursing home or a hospital long-term care unit fails to pay the assessment required by subsection (1)(g), the department ~~of community health~~ may assess the nursing home or hospital long-term care unit a penalty of 5% of the assessment for each month that the assessment and penalty are not paid up to a maximum of 50% of the assessment. The department ~~of community health~~ may also refer for collection to the department of treasury past due amounts consistent with section 13 of 1941 PA 122, MCL 205.13.

(g) The ~~medicaid~~ **MEDICAID** nursing home quality assurance assessment fund is established in the state treasury. The department ~~of community health~~ shall deposit the revenue raised through the quality assurance assessment with the state treasurer for deposit in the ~~medicaid~~ **MEDICAID** nursing home quality assurance assessment fund.

(h) The department ~~of community health~~ shall not implement this subsection in a manner that conflicts with 42 USC 1396b(w).

(i) The quality assurance assessment collected under subsection (1)(g) shall be prorated on a quarterly basis for any licensed beds added to or subtracted from a nursing home or hospital long-term care unit since the immediately preceding July 1. Any adjustments in payments are due on the next quarterly installment due date.

(j) In each fiscal year governed by this subsection, ~~medicaid~~ **MEDICAID** reimbursement rates shall not be reduced below the ~~medicaid~~ **MEDICAID** reimbursement rates in effect on April 1,

2002 as a direct result of the quality assurance assessment collected under subsection (1)(g).

(k) The state retention amount of the quality assurance assessment collected ~~pursuant to~~ **UNDER** subsection (1)(g) shall be equal to 13.2% of the federal funds generated by the nursing homes and hospital long-term care units quality assurance assessment, including the state retention amount. The state retention amount shall be appropriated each fiscal year to the department ~~of community health~~ to support ~~medicaid~~ **MEDICAID** expenditures for long-term care services. These funds shall offset an identical amount of general fund/general purpose revenue originally appropriated for that purpose.

(*l*) Beginning October 1, ~~2015,~~ **2019,** the department shall no longer assess or collect the quality assurance assessment or apply for federal matching funds. The quality assurance assessment collected under subsection (1)(g) shall no longer be assessed or collected after September 30, 2011, in the event that the quality assurance assessment is not eligible for federal matching funds. Any portion of the quality assurance assessment collected from a nursing home or hospital long-term care unit that is not eligible for federal matching funds shall be returned to the nursing home or hospital long-term care unit.

(12) ~~(14)~~ The quality assurance dedication is an earmarked assessment collected under subsection (1)(h). That assessment and all federal matching funds attributed to that assessment shall be used only for the following purpose and under the following specific circumstances:

(a) To maintain the increased ~~medicaid~~ **MEDICAID** reimbursement rate increases as provided for in subdivision (c).

(b) The quality assurance assessment shall be assessed on all net patient revenue, before deduction of expenses, less ~~medicare~~ **MEDICARE** net revenue, as reported in the most recently available ~~medicare~~ **MEDICARE** cost report and is payable on a quarterly basis, the first payment due 90 days after the date the assessment is assessed. As used in this subdivision, ~~"medicare~~ **"MEDICARE** net revenue" includes ~~medicare~~ **MEDICARE** payments and amounts collected for coinsurance and deductibles.

(c) Beginning October 1, 2002, the department ~~of community health~~ shall increase the hospital ~~medicaid~~ **MEDICAID** reimbursement rates for the balance of that year. For each subsequent year in which the quality assurance assessment is assessed and collected, the department ~~of community health~~ shall maintain the hospital ~~medicaid~~ **MEDICAID** reimbursement rate increase financed by the quality assurance assessments.

(d) The department ~~of community health~~ shall implement this section in a manner that complies with federal requirements necessary to ~~assure~~ **ENSURE** that the quality assurance assessment qualifies for federal matching funds.

(e) If a hospital fails to pay the assessment required by subsection (1)(h), the department ~~of community health~~ may assess the hospital a penalty of 5% of the assessment for each month that the assessment and penalty are not paid up to a maximum of 50% of the assessment. The department ~~of community health~~ may also refer for collection to the department of treasury past due

amounts consistent with section 13 of 1941 PA 122, MCL 205.13.

(f) The hospital quality assurance assessment fund is established in the state treasury. The department ~~of community health~~ shall deposit the revenue raised through the quality assurance assessment with the state treasurer for deposit in the hospital quality assurance assessment fund.

(g) In each fiscal year governed by this subsection, the quality assurance assessment shall only be collected and expended if ~~medicaid~~ **MEDICAID** hospital inpatient DRG and outpatient reimbursement rates and disproportionate share hospital and graduate medical education payments are not below the level of rates and payments in effect on April 1, 2002 as a direct result of the quality assurance assessment collected under subsection (1)(h), except as provided in subdivision (h).

(h) The quality assurance assessment collected under subsection (1)(h) shall no longer be assessed or collected after September 30, 2011 in the event that the quality assurance assessment is not eligible for federal matching funds. Any portion of the quality assurance assessment collected from a hospital that is not eligible for federal matching funds shall be returned to the hospital.

(i) The state retention amount of the quality assurance assessment collected ~~pursuant to~~ **UNDER** subsection (1)(h) shall be equal to 13.2% of the federal funds generated by the hospital quality assurance assessment, including the state retention amount. **[IN THE FISCAL YEAR ENDING SEPTEMBER 30, 2016, THERE IS A 1-TIME ADDITIONAL RETENTION AMOUNT OF UP TO $92,856,100.00.]** The state retention percentage shall be applied proportionately to each hospital quality assurance assessment

program to determine the retention amount for each program. The state retention amount shall be appropriated each fiscal year to the department ~~of community health~~ to support ~~medicaid~~ **MEDICAID** expenditures for hospital services and therapy. These funds shall offset an identical amount of general fund/general purpose revenue originally appropriated for that purpose.

[(13) THE DEPARTMENT MAY ESTABLISH A QUALITY ASSURANCE ASSESSMENT TO INCREASE AMBULANCE REIMBURSEMENT AS FOLLOWS:

(A) THE QUALITY ASSURANCE ASSESSMENT AUTHORIZED UNDER THIS SUBSECTION SHALL BE USED TO PROVIDE REIMBURSEMENT TO MEDICAID AMBULANCE PROVIDERS. THE DEPARTMENT MAY PROMULGATE RULES TO PROVIDE THE STRUCTURE OF THE QUALITY ASSURANCE ASSESSMENT AUTHORIZED UNDER THIS SUBSECTION AND THE LEVEL OF THE ASSESSMENT.

(B) THE DEPARTMENT SHALL IMPLEMENT THIS SUBSECTION IN A MANNER THAT COMPLIES WITH FEDERAL REQUIREMENTS NECESSARY TO ENSURE THAT THE QUALITY ASSURANCE ASSESSMENT QUALIFIES FOR FEDERAL MATCHING FUNDS.

(C) THE TOTAL ANNUAL COLLECTIONS BY THE DEPARTMENT UNDER THIS SUBSECTION SHALL NOT EXCEED $6,000,000.00.

(D) THE QUALITY ASSURANCE ASSESSMENT AUTHORIZED UNDER THIS SUBSECTION SHALL NOT BE COLLECTED AFTER OCTOBER 1, 2018. THE QUALITY ASSURANCE ASSESSMENT AUTHORIZED UNDER THIS SUBSECTION SHALL NO LONGER BE COLLECTED OR ASSESSED IF THE QUALITY ASSURANCE ASSESSMENT AUTHORIZED UNDER THIS SUBSECTION IS NOT ELIGIBLE FOR FEDERAL MATCHING FUNDS.]

(14)] ~~(15)~~ The quality assurance assessment provided for under this section is a tax that is levied on a health facility or agency.

(15)] ~~(16)~~ As used in this section, ~~"medicaid"~~ **"MEDICAID"** means that term as defined in section 22207.

Sec. 20501. (1) As used in this part, ~~:~~ **"LABORATORY" MEANS A FACILITY FOR THE BIOLOGICAL, MICROBIOLOGICAL, SEROLOGICAL, CHEMICAL, IMMUNOHEMATOLOGICAL, HEMATOLOGICAL, BIOPHYSICAL, CYTOLOGICAL, PATHOLOGICAL, OR OTHER EXAMINATION OF MATERIALS DERIVED FROM THE HUMAN BODY FOR THE PURPOSE OF PROVIDING INFORMATION FOR THE DIAGNOSIS, PREVENTION, OR TREATMENT OF ANY DISEASE OR IMPAIRMENT OF, OR THE ASSESSMENT OF THE HEALTH OF, HUMAN BEINGS.**

~~(a) "Laboratory director" means the individual responsible for administration of the technical and scientific operation of a clinical laboratory, including the supervision of procedures and reporting of findings.~~

~~(b) "Owner" means a person who owns and controls a clinical laboratory.~~

(2) In addition, article 1 contains general definitions and principles of construction applicable to all articles in this

code. ~~and part 201 contains definitions applicable to this part.~~

Sec. 20521. ~~(1) The owner, laboratory director, and governing body of a clinical laboratory are responsible for the operation of the clinical laboratory.~~

~~(2) The laboratory director is responsible for the making and keeping of an accurate record for each specimen examined and procedure followed.~~

~~(3) A clinical laboratory shall analyze test samples submitted by the department and report to the department on the results of the analyses, except that proficiency evaluation programs of recognized professional organizations may be acceptable to the department in lieu thereof. The analyses and reports may be considered by the department in taking action under section 20165 or 20525.~~**ONLY A PHYSICIAN, DENTIST, OR OTHER PERSON AUTHORIZED BY LAW CAN ORDER A LABORATORY TEST THAT HAS BEEN CLASSIFIED BY THE FOOD AND DRUG ADMINISTRATION AS MODERATE OR HIGH COMPLEXITY. A LABORATORY TEST THAT IS CLASSIFIED BY THE FOOD AND DRUG ADMINISTRATION AS WAIVED DOES NOT REQUIRE AN ORDER.**

Sec. 20551. (1) A laboratory or other place where live bacteria, fungi, mycoplasma, parasites, viruses, or other microorganisms of a pathogenic nature are handled, cultivated, sold, given away, or shipped from or to or where recombinant deoxyribonucleic acid research is done shall be registered with the department, and a registration number shall be issued to each place registered. An application for a registration number shall be made by the person in charge of the laboratory or other place where the pathogens are handled or where recombinant

deoxyribonucleic acid research is done. The registration number is valid for 1 year and may be renewed upon application to the department.

~~(2) A clinical laboratory licensed in microbiology under sections 20501 to 20525 is registered for purposes of this section and section 20552, and its license number shall be used as its registration number.~~

(2) ~~(3)~~ As used in ~~sections 20551~~ **THIS SECTION** and **SECTION** 20552, "handled", "cultivated", or "shipped" does not include the collection of specimens, the initial inoculation of specimens into transport media or culture media, or the shipment to registered laboratories, but does include any additional work performed on cultivated pathogenic microorganisms or any recombinant deoxyribonucleic acid research is done.

Enacting section 1. Sections 20511, 20515, and 20525 of the public health code, 1978 PA 368, MCL 333.20511, 333.20515, and 333.20525, are repealed.

[Enacting section 2. This amendatory act takes effect October 1, 2015.]