Missouri Board of Pharmacy  
Hospital Advisory Committee Meeting  

August 7, 2017  
10:00 a.m.  
Missouri Division of Professional Registration  
3605 Missouri Boulevard  
Jefferson City, MO 65109  

Notice is hereby given that the Missouri Board of Pharmacy's Hospital Advisory Committee will be meeting at 10:00 a.m. on August 7, 2017. A tentative agenda is attached. If any member of the public wishes to attend the meeting by participating in the conference call, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Boulevard, Jefferson City, Missouri at 10:00 a.m. on August 7, 2017.  

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy's Hospital Advisory Committee is authorized to close meetings, records and votes pursuant to Section 610.021(1). The Committee may go into closed session at any time during the meeting. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.  

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.  

Please see the attached tentative agenda for this meeting.
TENTATIVE AGENDA

Missouri Board of Pharmacy
Hospital Advisory Committee Meeting

August 7, 2017
10:00 a.m.
Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

1. Welcome & Introductions
2. Approval of Minutes
   a. March 9, 2017
   b. May 4, 2017
3. Board of Pharmacy Updates
4. Emergency/Amendment Class-J Shared Services Rule Revision (20 CSR 2220-2.650)
5. Department of Health Updates
6. Review of Outstanding Issues
7. Review of New 2017 Legislation
   a. SB 501
   b. SB 50
   c. SB 139
8. Strategic Review of Committee Operations
   a. SWOT Analysis
   b. Membership Tenure
   c. Meeting Frequency/Format
   d. Scope of Authority
   e. Future Topics
9. 2018 Proposed Legislation
   a. Practice Advancement
   b. Pharmacy Technician Training/Education
10. Election of Officer
11. Future Agenda Meeting/Schedule
12. Public Questions/Comments
13. Adjournment
The Missouri Hospital Advisory Committee met in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed.

**Committee Members Present**
Bert McClary, R.Ph., Chairman  
James Gray, R.Ph., Member (*via telephone*)  
Colby Grove, R.Ph., Member (*via telephone*)  
Neil Schmidt, R.Ph., Member  
Greg Teale, R.Ph., Member

**Staff Present**
Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector  
Katie DeBold, Inspector

**Others Present**
William Koebel, Missouri Department of Health and Senior Services  
Sarah Willson, Missouri Hospital Association  
David Wolfrath, MSHP

Chairman McClary opened the meeting at approximately 10:02 a.m. and roll-call was taken.

**Agenda Item # 2 (Board Updates):** Kimberly Grinston reported the Board is in the process of reviewing multiple rules that may be of interest to the Committee, including, the automated dispensing rule, the Class-N: Automated Dispensing System (Health Care Facility) rule and the Class-O: Automated Dispensing System (Ambulatory Care) rule. Committee feedback has been requested.

Neil Schmidt asked about the status of the PDMP legislation. Ms. Grinston indicated the current proposals have language that may be problematic for implementation, however, the local jurisdictions are moving forward with a municipal.

**Agenda Item # 3 (DHSS Updates):** William Koebel reported the moratorium on DHSS rules has ended; the proposed hospital rules will be resubmitted for approval under the
new criteria announced by the Governor’s office. Sarah Willson asked how the rule process has changed. Mr. Koebel indicated there is now an extended questionnaire that must be completed. Committee discussion held; the Committee expressed strong support for filing the revised hospital rules as soon as possible.

**Agenda Item # 4 (Approval of Minutes):** The January 13, 2017, minutes included in the agenda were presented for approval. A motion was made by Greg Teale, seconded by Neil Schmidt, to approve the January 13, 2017, minutes. The motion passed 3:0:0:3 with roll call vote as follows:

- James Gray – absent
- Colby Grove - yes
- Neil Schmidt- yes
- Greg Teale – yes
- Daniel Good – absent
- Kevin Kinkade - absent

**Agenda Item # 5 (Class-B Concept Draft):** Ms. Grinston asked for comments on the Class-B rule concept draft. Mrs. Grinston advised the language is not an official staff or Board recommendation but was intended to guide the Board in drafting future rule requirements. The following Committee discussion was held:

- Ms. Grinston indicated the definition of a dually operated pharmacy was mistakenly removed and would be added in.
- Mr. McClary suggested referencing licensed health care “practitioners” instead of “professionals.” Sarah Willson noted the current trend is to not use the word “provider” while Neil Schmidt noted the Joint Commission uses the term “licensed independent professional.” Committee members suggested specifically referencing advanced practice registered nurses and/or “individuals authorized to prescribe or administer medication.” Discussion held; Committee consensus to reference “licensed healthcare professional.”
- Discussion was held on section (2)’s definition of the pharmacy permit area. Neil Schmidt and Bert McClary asked if the language would allow licensure of a satellite pharmacy under a single permit. Bert McClary noted hospitals may not be aware of the notification requirement for pharmacy remodeling. The Committee questioned the draft language for Class-B pharmacies sharing space with a DHSS hospital pharmacy and asked if there was a difference between “commingled” and “shared inventory.” In lieu of referencing commingled/shared inventories, Sarah Willson suggested amending the language to provide that entities choosing to share inventories must maintain records of all medication transactions. Committee consensus to tentatively revise the language as suggested and review at a future meeting. Bert McClary noted there is difference between a shared site and shared inventory and suggested the Committee use caution when referencing these concepts.
- Kimberly Grinston noted the Board’s medication therapy services (MTS) rule will be revised separately and advised against including MTS changes in the Class-B rule for consistency purposes.

**COMMITTEE MEMBER JAMES GRAY JOINED THE MEETING VIA CONFERENCE CALL AT 10:51 A.M.**
• (Class-B Discussion Continued): Section (3)(A)- Ms. Grinston asked if a sink or water supply should be required. James Gray noted there may be instances where the sink or water may be directly across the hall and not in the actual patient care area for logistical or sanitation purposes. Mr. Gray noted some Class-B pharmacies may only be dispensing prepackaged medication that is already labeled. David Wolfrath noted some compounding areas may not have hot and cold water in the actual room. Committee consensus to revise the language to accommodate Class-B pharmacies that do not have an in-room sink but have a water supply available. William Koebel also suggested removing the word “appropriate” because it is ambiguous and may present legal concerns.

• Section (3)(B): Greg Teale asked how “open to the public” is defined; Mr. McClary asked if the term would include employee prescriptions. Committee discussion held; Consensus to remove “open to the public.” Kimberly Grinston discussed possibly addressing this issue in the general pharmacy standards rule, 20 CSR 2220-2.100.

• Section (4)(A)- Committee discussion held; Consensus to amend l. 62 to provide “Medication given to a Missouri licensed healthcare practitioner for use or administration to a patient onsite of a Class-B pharmacy….”

• Section (4)(B)- Committee discussion held; Committee consensus to include the following labeling language: “Medication will not be considered to have been dispensed for offsite use/administration if administration is initiated onsite but continued offsite via an external or implanted medical delivery device that is programmed by a healthcare professional.”

• Section (5): Tom Glenski noted the language conflicts with DHSS’ current rule/interpretation which allows nurses to access a pharmacy to prepare medication for take-home use when pharmacy services are not available. Mr. Glenski noted section (5) would prohibit the medication from being sent home. Committee discussion held; Sarah Willson suggested amending the opening paragraph of section (5) to provide “Except as otherwise authorized by DHSS…..”

• Section (5)(C): Kimberly Grinston asked if the dually operated pharmacy language should be removed. Discussion held; Committee consensus to make the section applicable to all Class-B pharmacies. Greg Teale suggested the rule clearly state that the pharmacist-in-charge has authority to allow or restrict access; Sarah Willson questioned if pharmacy access needed to be separately identified in the rule. Tom Glenski noted the Board’s pharmacist-in-charge rule already provides the PIC is responsible for determining pharmacy access.

• Section (5)(A)(3): Tom Glenski noted the verification and labeling requirements would apply to any filled prescription, including, prescriptions filled for patient use. Mr. Glenski noted this would be an expansion of current Board policy.
James Gray suggested amending the section to address medication for onsite administration.

Committee consensus to revise as suggested and review changes at future meeting.

**Agenda Item # 5 (Review of Class-B Guidance Document):** The following discussion was held:

1. Chairman McClary asked if the proposed language would allow a pharmacist to initiate medication therapy services (MTS) based on a protocol approved by the clinical care committee without an individual prescription order. Committee discussion held. Tom Glenski indicated the Board has informally suggested a separate prescription may not be required. Kimberly Grinston noted this is an open legal question that would need to be officially addressed by the Board.

2. Neil Schmidt suggested the language clearly indicate the guidance is only applicable to pharmacy/medication therapy services under the Board’s jurisdiction. James Gray agreed, however, Mr. McClary noted legal questions still exist on the scope/applicability of the Board’s MTS rules. Ms. Grinston reported the Board’s general counsel indicated it may be inappropriate for him to advise the Committee because of a possible conflict of interest. Ms. Grinston will talk with the Division’s legal counsel for further legal guidance. Committee consensus to seek legal clarification and clarify the guidance document as appropriate.

3. Chairman McClary asked for legal clarification on whether a MTS protocol can be initiated by a nurse. Mr. McClary also asked for legal guidance on whether the Board’s MTS rules would apply if a pharmacist operating under DHSS’ jurisdiction modifies medication that will be eventually dispensed as a prescription. Ms. Grinston asked if the question is under DHSS’ jurisdiction. Mr. Teale indicated clarification is important for hospitals like his that are primarily operating under DHSS’ jurisdiction but also providing pharmacy services under the Board’s jurisdiction (e.g., infusion centers).

4. Mr. Teale suggested the guidance document emphasize that a Class-B pharmacy permit is required if technicians will be used to assist in non-dispensing functions. Mr. Teale further asked if the distribution chart would be included in the final document; Kimberly Grinston indicated the chart became too difficult to follow after the additions added at the last Committee meeting and would be removed.

5. Kimberly Grinston noted Board member Barbara Bilek suggested alternative language for addressing medication that will be initially administered onsite but continued offsite via a pump or other implantable device. Greg Teale commented that not all administration devices are “locked”. Neil Schmidt asked how the language would apply to an insulin pump. Committee discussion held; Consensus to revise the proposed language to provide: “The Board will not consider medication to have been given to the patient for offsite use/administration if medication administration is initiated onsite but continued offsite via a programmed external or implanted medical delivery device.”

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McClary advised this language should be consistent throughout the guidance document.

COLBY GROVE LEFT THE CONFERENCE CALL AT 11:45 A.M.

**Agenda Item # 6 (Missouri MTS Rule):** The following Committee discussion was held:

- Bert McClary reported an informal group recently met to discuss the expansion of pharmacy practice, including, pharmacist MTS activities. The initial meeting representatives from MSHP and MPA; Tom Glenski and Christian Tadrus also attended on behalf of the Board for informational purposes. Mr. McClary reported the group discussed legislative options that included: (1) removing the individual patient prescription requirement for MTS services and (2) allowing modification of controlled substances. Mr. McClary reported draft language has been circulated; MPA offered to assist with the legislative process and will be discussing the proposal at their upcoming meeting. Mr. McClary noted the draft language might be added to an existing bill or filed as an independent bill during the current session.

- 20 CSR 2220-6.060: Bert McClary suggested defining a “health care entity” as a hospital clinic or facility as defined by 338.165, RSMo. Mr. McClary also suggested clarifying what it means to create a prescription. Specifically, Mr. McClary suggested amending the rule to clearly provide that a pharmacist can phone-in or send an electronic prescription but cannot create a prescription in their own name.

- 20 CSR 2220-6.080: The following Committee discussion was held:
  a. Section (1)(B): Bert McClary suggested revising this section to provide the protocol must be with an “authorized” physician to clarify that the physician must still meet minimum criteria.
  b. Section (2)(A): Bert McClary suggested simplifying the language and removing redundant references. Mr. McClary also suggested using “medication therapy services” in lieu of a medication therapy plan unless required by statute.
  c. Greg Teale questioned the requirement for a physician order and commented a separate physician order is not always issued in hospitals. Committee discussion held; Consensus to recommend modifying the statute to accommodate actual practice and allow seamless patient care.
  d. Section (3)(A): Bert McClary asked if “current and unrestricted” is necessary and noted some license restrictions may not relate to MTS. Consensus to modify or clarify as suggested.
  e. Section (3)(D): Bert McClary suggested allowing the review of pharmacist MTS activities by the “medical staff committee” as referenced in 338.165, RSMo. Committee discussion held. Greg Teale asked how the 50-mile rule is enforced/interpreted and questioned if the rule accommodates newer telepharmacy/telemedicine practices. Kimberly Grinston noted the 50-mile rule was requested by the Board of Healing Arts. Discussion held;
Consensus to clarify the 50-mile requirement in a Board guidance document.

f. Section (4)(C): Bert McClary asked if the list of MT services should include all of the items currently included in the rule; Mr. McClary noted many of the items listed in this section may be performed without an MTS certificate with the exception of initiating or modifying drug therapy. Mr. McClary further suggested amending the rule to provide the protocol “shall” include initiating or modifying drug therapy. Mr. Glenski noted not all pharmacists may be authorized to initiate therapy. Greg Teale commented section (4) may be confusing for pharmacists practicing across state lines. Committee consensus to remove redundant references and return for future Board review.

g. Section (5)(C): Greg Teale noted this section is imperative for hospitals.

h. Section (6): Bert McClary suggested defining what it means to “create” a prescription in this section. Greg Teale indicated the individual prescription requirement is burdensome for care centers such as infusion clinics.

i. Section (7): Bert McClary suggested clarifying that the pharmacist is responsible for records but the records do not have to be kept in the pharmacy. Greg Teale asked where records would be stored if the pharmacist leaves employment; Tom Glenski indicated the Board would first ask the pharmacist but would still be able to access records held at the pharmacy.

j. Section (11): Bert McClary suggested correcting the rule to reference the administration of medication “by prescription order” and not “by protocol.”

Committee Consensus to revise as suggested and review changes at future meeting.

**Agenda Item # 7 (Automated Distribution Cabinet):** The following Committee discussion was held:

- Committee discussion was held on how the language would affect or coincide with DEA and BNDD requirements for controlled substances. Bert McClary noted DEA originally did not have a rule governing transfers of controlled substances to an automated distribution machine and instead left the issue to the states. Approximately 10 years later, questions were raised regarding transferring controlled substances to another registration. Mr. McClary noted DEA still considers these medications as the pharmacy’s stock but allowed states to set requirements. However, DEA only allowed the practice for long-term care emergency kits. Discussion held; Committee consensus the rule would still be beneficial even if limited to non-contrrolleds.

- Tom Glenski asked how the rule would affect places that may use a secure bag to dispense medication instead of an actual “automated cabinet.” Bert McClary commented the automated cabinet language might be limiting and noted facilities may not purchase a machine for a small number of drugs. Greg Teale commented facilities may not be able to justify an expensive automated cabinet.
in areas like a gastrointestinal lab and may instead use a locked cabinet with some type of signature log. Discussion held. Bert McClary suggested referencing a substantially constructed container similar to DEA. Committee consensus to expand the language to include other non-automated secure cabinets/devices.

- Greg Teale questioned how the Board would define an area “not accessible to the public” and asked if hospitals would comply with the rule if the automated cabinet is in an area that patients may pass or walk through. Neil Schmidt asked if an InstaMed machine in an emergency department would be non-compliant. Tom Glenski noted the goal was to address security issues and to prohibit blatant practices like putting a tackle box on the counter.

Committee consensus to review recommended changes at a future meeting.

**Agenda Item # 9 (Remote Supervision of Pharmacy Technicians):** Kimberly Grinston and Bert McClary noted this issue is still under discussion by the Board and will be discussed at the upcoming April meeting. Greg Teale commented electronic supervision/verification has become more prevalent in hospitals especially in light of new USP Chapter 800 standards. Committee discussion held; Consensus to reconsider after the Board’s April meeting.

**Agenda Item # 10 (Future Agenda Items and Topics):** Discussion held; Consensus to review the Class-B, Class-N, Class-O and MTS revisions at a future meeting along with any updates from the Pharmacy Technician Working Group's proposal. Sarah Willson asked if the Board needed additional information on automated systems commonly used in hospitals; Committee consensus to provide suggested vendors to the Board office before the April meeting. Further consensus to poll members to determine availability for an April or May meeting.

THE HOSPITAL ADVISORY COMMITTEE ADJOURNED BY CONSENSUS AT 2:35 P.M.

KIMBERLY A. GRINSTON  
EXECUTIVE DIRECTOR

Date Approved:
The Missouri Hospital Advisory Committee met in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed.

**Committee Members Present**
Bert McClary, R.Ph., Chairman  
Daniel Good, R.Ph., Member  
James Gray, R.Ph., Member *(via telephone)*  
Colby Grove, R.Ph., Member *(via telephone)*  
Neil Schmidt, R.Ph., Member  
Greg Teale, R.Ph., Member

**Staff Present**
Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector  
Katie DeBold, Inspector

**Others Present**
Julie Creach, Missouri Department of Health and Senior Services (DHSS)  
Sarah Willson, Missouri Hospital Association (MHA)  
David Wolfrath, MSHP

Chairman McClary opened the meeting at approximately 10:02 a.m. and roll-call was taken.

**Agenda Item # 2 (Board Updates):** Kimberly Grinston reported the Board is in the process of reviewing all of its rule and noted rules specifically referred for Committee suggestions/input are included in the agenda.

**Agenda Item # 3 (DHSS Updates):** Julie Creach reported DHSS is also reviewing its rules; the hospital pharmacy rules are in the resubmission process for approval by the new administration. Ms. Creach reported DHSS’ budget will likely be approved by the legislature shortly.
Agenda Item # 4 (Class-J Shared Services Rule): The following Committee discussion was held:

- Neal Schmidt asked how the proposed changes would affect compounding pharmacies providing medication for another pharmacy. Tom Glenski noted section (2) would accommodate the practice but would prohibit the medication from being sent home with the patient without a Class-J permit.

- Section (2): Greg Teale asked if medication would need to be treated as a prescription if manipulated. Tom Glenski replied pharmacies would be required to treat the vial the same as if it came from a wholesaler which would include complying with relabeling requirements. Mr. Glenski further noted the Board’s requirement would not apply to in-patient dispensing under DHSS’ jurisdiction. James Gray questioned if the new language complies with the federal Drug Quality and Security Act.

- James Gray suggested the rule address return-to-stock items for hospital systems and allow medication that has been properly stored to be relabeled for patient use. Mr. Gray indicated it would be helpful for pharmacies in a hospital system to transport medication among the system instead of wasting it. Discussion held; Committee consensus that a return-to-stock allowance would be helpful for all hospitals. Tom Glenski commented DHSS has jurisdiction over how a hospital handles medication once received. Committee consensus to discuss at a later meeting; Bert McClary cautioned the rule should prohibit staff from arbitrarily using a patient’s medication for other patients.

AGENDA ITEM # 5 (20 CSR 2220-6.040): The following Committee discussion was held:

- Section (3)(C): Greg Teale suggested amending the rule to recognize administration training provided by a hospital or hospital related system. Mr. Teale noted pharmacist training requirements are stricter than training requirements for nurses and other healthcare practitioners. Discussion held; Committee members supported allowing alternative pharmacist training programs and noted most schools of pharmacy now require some form of administration training. Kimberly Grinston noted administration training may still be voluntary at some pharmacy schools and asked if a standard hospital pharmacist administration training program currently exists. Neal Schmidt commented St. Louis College of Pharmacy currently requires administration training; Greg Teale indicated pharmacist training would be handled via their nursing education program. Committee consensus to explore alternative training options to allow pharmacists to function at maximum capacity. Daniel Good asked if the rule should be amended to allow delegation to a technician if the technician rule is changed by the Board. Consensus to prohibit delegation “except as otherwise provided by rule.”
• Section (4): Greg Teale recommended adding “shall administer” to this section. Discussion was held on policy and procedure requirements; Tom Glenski noted the Board recently voted to remove the mandatory pharmacist-in-charge review and instead require that policies and procedures must be current and accurate. James Gray suggested requiring licensees to “follow” policies and procedures instead of just maintaining them.

• Section (4)(E): Greg Teale asked if the requirement that a patient be asked to remain in the pharmacy after vaccination is applicable to this rule. Kimberly Grinston explained the requirement is statutory, however, pending legislation would limit the language to immunizations by protocol. Bert McClary suggested addressing vaccines that are not given in a pharmacy.

• Section (5)(A): Bert McClary suggested adding that prescriptions for medication modifications/implementation must be in the name of an authorized practitioner instead of an “authorized prescriber.” Kimberly Grinston reported an authorized practitioner is not defined and suggested the Board of Healing Arts may have concerns with the Board of Pharmacy defining who is an authorized practitioner. Discussion held. Tom Glenski noted § 338.165 and § 338.059, RSMo, references an authorized prescriber.

• Section (6)(A): Greg Teale commented pharmacists practicing in care settings like the emergency department would have most of the documentation required by this section recorded in the hospital’s medical record. Mr. Teale questioned if a separate record was necessary for items already recorded and retrievable in another system. Mr. Teale further commented hospitals may not record the manufacturer or the NDC in the same record although the information could likely be researched and retrieved. David Wolfrath and James Gray agreed; Mr. Gray further noted pharmacists assisting practitioner’s clinics may not control what is recorded in the clinic’s software system. Kimberly Grinston asked if the requirement is truly too burdensome. Sarah Willson questioned the need to impose a higher standard than current Joint Commission and CMS requirements. James Gray asked if the required information could be maintained in a common record as referenced in section (10)(A). Committee consensus to include language allowing a common record. Consensus to also remove the reference to biologics and instead require: “The manufacturer name, lot number and expiration date must be documented and recorded for vaccines.” It was further agreed to require documentation of: “the date, route, name, dose and anatomic site” of administration.

• Committee discussion was held on addressing or clarifying the lines between DHSS jurisdiction and Board jurisdiction. Sarah Willson indicated she doesn’t
know the current position of the MHA membership but noted MHA would be willing to discuss the issue with its membership.

- Section (7): Bert McClary suggested allowing documentation in a common record; Consensus to amend as suggested. Kimberly Grinston reported the Board is also considering allowing ShowMeVax reporting for vaccines.
- Section (10)(A): Bert McClary suggested this section was no longer necessary with the exception of (10)(A) that allows a common hospital record.

**AGENDA ITEM # 6 (Class-B Rule Concept Draft)**- Bert McClary noted the agenda included an older draft that does not have the latest suggestions. Consensus to table for review in June.

**AGENDA ITEM # 7 (Class-B Guidance Document)**- Kimberly Grinston reported the Board approved the draft guidance document and asked for final changes. Bert McClary asked if the document should be held pending the Class-J rule revision which the Board indicated may be promulgated as an emergency rule. Discussion held; Committee consensus not to hold the guidance document. Mr. McClary noted the Bureau of Hospital Standards should be referenced as the Division of Hospital Licensure.

**AGENDA ITEM # 8 (Class-N/Automated Distribution Draft)**- Bert McClary suggested broadening the rule to allow Class-B pharmacies to provide general floor stock with or without an automated cabinet. Mr. McClary noted for safety and accountability reasons, these medications should be controlled by the pharmacy even if done via a distribution process. Discussion held; Committee consensus to focus on a general distribution rule that would include both automated and non-automated distribution models. Consensus to revise and review at future meeting.

**AGENDA ITEM # 9 (Pharmacy Technician Working Group)**- Kimberly Grinston reported the Board voted to pursue technician legislation in 2018 based on the Working Group’s recommendations. Daniel Good asked if the Board would consider a proposal that would address expansion of technician authority just in hospital settings given that retail pharmacy has voiced objections to the technician proposal in the past. Discussion held; Committee consensus to ask interested hospitals/associations to submit letters to the Board in support of pursuing legislative action.

**AGENDA ITEM # 10 (Remote Technician Supervision)**- Bert McClary noted this topic was discussed during the pharmacy technician working group discussion. Daniel Good commented remote supervision or telepharmacy needs to be properly defined because the terms are used differently in various practice settings.

**AGENDA ITEM # 11 (Medication Therapy Services)**- Discussion held on possible rule changes; Bert McClary noted the rule would need to be modified if the advanced pharmacy practice suggestions are enacted. Greg Teale asked if the rule revision
should be postposed pending the outcome of the practice advancement legislative discussions. James Gray noted the Board of Healing Arts does not allow physicians in training to enter into a protocol which may be problematic. Further discussion was held on modifying the rule to remove the patient-specific order requirement; James Gray and Neal Schmidt suggested allowing pharmacists to initiate MTS as authorized by the hospital’s approved protocols. Tom Glenski noted the statute requires a patient-specific order for services under the Board’s jurisdiction. Further discussion held; Consensus to advise that the Board not open the rule at this time in light of potential practice changes and other priority rules under Board review.

AGENDA ITEM # 12 (Committee Operations)- Bert McClary asked for feedback on Committee operations and the current meeting schedule; Mr. McClary suggested meeting in-person every other month. James Gray agreed calls are not as productive unless there is a pressing issue. Mr. McClary informed the Committee he would like to step down as Chairman due to personal travel and other activities. Mr. McClary also noted it would be appropriate for others to participate in the leadership and direction of the Committee. Committee consensus to discuss a replacement Chairman in July. Neil Schmidt announced he would be resigning from the Committee to spend additional time with family. Mr. Schmidt indicated David Wolfrath is his suggested replacement and is currently pending official appointment. Mr. Schmidt thanked the Committee and offered to assist in the future. Mr. McClary asked if the Committee would be interested in doing a strategic review of the Committee’s operations; Daniel Good suggested doing a brief SWOT analysis at the next meeting. Discussion held; Consensus to include a strategic planning/ review item on the agenda after Mr. Wolfrath is appointed.

AGENDA ITEM # 12 (Long-Term Care Working Group)- Kimberly Grinston reported the Board President has appointed working group members. Bert McClary suggested the Working Group consider state and federal compliance requirements affecting long-term care, including, CMS and DHSS requirements. Greg Teale noted health systems are starting to purchase more long-term care facilities to improve transitions of care and that pharmacists will be asked to assume additional duties in these facilities such as medication handling and anti-microbial stewardship. Mr. Teale further commented long-term care pharmacy issues may need to be addressed sooner than anticipated given industry expansion.

AGENDA ITEM # 13 (Future Meeting Dates/Topics)- Greg Teale asked if the Committee should discuss the Board’s sterile compounding rule. Tom Glenski reported the Board reconvened the sterile compounding sub-committee to take comments and make suggestions on the rule. Discussion held; Consensus not to submit formal Committee recommendations at this time but to contact interested parties to submit individual comments if desired. Further discussion held on future meeting dates; Consensus to meet on July 17, 2017.

THE HOSPITAL ADVISORY COMMITTEE ADJOURNED BY CONSENSUS AT 3:03 P.M.
20 CSR 2220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy

PURPOSE: This rule is being amended to accommodate pharmacies dispensing medication to another pharmacy for administration by a licensed healthcare professional.

EMERGENCY STATEMENT: The current rule establishes mandatory requirements for pharmacies engaged in Class-J Shared Services pharmacies. The Board currently issues sixteen (16) classes of pharmacy permits (Class-A to Class-P). Pharmacies are required to have a pharmacy permit for each type of pharmacy service performed. As a result, many pharmacies have multiple classes of licensure. A Class-J pharmacy permit is required for pharmacies filling, dispensing or transferring medication/filled prescriptions to another pharmacy for dispensing to the patient.

In April 2017, the Board received comments from Missouri hospitals and specialty pharmacies indicating the current Class-J requirements are detrimentally impacting patient care by effectively prohibiting the dispensing of medication to Missouri patients with complex, chronic or rare diseases who are participating in certain patient assistance programs. Specifically, Missouri hospital and specialty pharmacies reported that an increased number of patient assistance programs and third party payors now mandate that certain high risk, high-cost medications can only be prepared/dispensed by a specialty pharmacy and shipped to another licensed pharmacy where it has to be administered to the patient on-site of the receiving pharmacy by a healthcare provider. A number of these medications are reportedly high-cost items while others require specialized pharmacist training or expertise to prepare.

To ship medication to another pharmacy, both the specialty pharmacy and the receiving pharmacy are required to have a Class-J Shared Services permit. A number of hospital/specialty pharmacies have indicated they are unable to apply for a Class-J permit primarily because of the rule's requirements that Class-J pharmacies: (1) have the same owner or have a pre-existing contract for shared services and (2) share a common electronic database that provides real-time, online access. Specifically, specialty/hospital pharmacies reported the patient may require medication before a contract can be negotiated with the corresponding pharmacy. In some instances, the receiving pharmacy may be unknown or have no business relationship with the specialty pharmacy until medication is required. In other instances, expensive software purchases would be required to render the electronic systems accessible or compliant.
Due to the Class-J licensing requirements, patients have been unable to procure medication provided by certain assistance programs from designated hospital/specialty pharmacies located throughout the state. In some instances, patients have reportedly been turned away or denied medication because the participating pharmacies could not obtain a Class-J permit. The Board was informed Missouri cancer patients have been particularly impacted and denied/delayed medication services. Significantly, some of the medications discussed with the Board are not dispensed by community/ambulatory pharmacies due, in part, to the required expertise, equipment and training needed to compound these preparations and/or due to the related medication costs which can reportedly exceed $100,000 per year in some cases.

After the April 2017 meeting the Board formed a sub-committee to immediately review and draft proposed revisions to the current rule. As part of this process, the Board consulted with hospital and specialty pharmacy advocates to draft language that would allow shipment of patient medication between licensed pharmacies without a Class-J pharmacy permit while maintaining appropriate safeguards to protect patient health. The Board also consulted with the statutorily authorized Missouri Hospital Advisory Committee in June of 2017. The Board is proposing this emergency amendment to allow continued dispensing to lower-income, uninsured Missouri patients by modifying Class-J licensing requirements for pharmacies transferring medication that will be administered onsite of the pharmacy by a healthcare practitioner. Significantly, the Class-J permit is an additional class of licensure. Pharmacies engaged in the affected conduct would still be required to hold a Board pharmacy permit in another classification.

Absent an amendment, the Board’s rule would significantly and adversely affect patient health and patient access to care by prohibiting pharmacies unable to qualify for a Class-J Shared Services pharmacy permit from dispensing designated medication to lower-income/uninsured patients participating in patient assistance programs. Once again, some of these medications may be unavailable from a traditional retail pharmacy and/or otherwise unaffordable for the targeted patient population.

As a result, the Missouri State Board of Pharmacy finds there is an immediate danger to the public health, safety and/or welfare and a compelling governmental interest that requires this emergency action. A proposed rule, which covers the same material, is published in this issue of the Missouri Register. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Missouri State Board of Pharmacy believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed__________, effective __________ and expires __________.

PURPOSE: The purpose of this rule is to establish minimum standards of operation for Class J: Shared Services Pharmacy, in compliance with House Bill 567 of the 91st General Assembly.
(1) Class J: Shared Services: Shared Service Pharmacy is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

(A) A pharmacy may perform or outsource centralized prescription processing services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;
2. Maintain separate licenses for each location involved in providing shared services; and
3. Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order. Either share a common database or allow access to each pharmacy's electronic medication or prescription records. The access must provide real-time online access to the patient's complete profile for the pharmacies involved.

(B) There must be record keeping systems between shared service pharmacies with real time on-line access to shared services by both pharmacies. Transfer of prescription information between two (2) pharmacies that are accessing the same real-time, on-line database pursuant to the operation of a shared service pharmacy operation shall not be considered a prescription transfer and, therefore, is not subject to the requirements of 4 CSR 220-2.120.

(C) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review upon request and that includes, but is not limited to, the following:

1. A description of how the parties will comply with federal and state laws and regulations;
2. The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;
3. The maintenance of a mechanism for tracking the prescription drug order during each step in the process;
4. The provision of adequate security to protect the confidentiality and integrity of patient information;
5. The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems.

(2) A Class J Shared services permit shall not be required if a completed and labeled prescription is delivered from a Missouri licensed pharmacy to another Missouri licensed pharmacy for administration by a pharmacist or other licensed health care professional to the patient on the same premises or physical location as the pharmacy.

(A) The exemption recognized in this subsection only applies if a completed and labeled prescription is delivered to the receiving pharmacy.
(B) If additional manipulation or compounding is required by the receiving pharmacy, receipt of a prescription or order is required and the receiving pharmacy must dispense the product as their own prescription/order. All prescription requirements, record keeping, compounding and labeling requirements must be met.
(C) The receiving pharmacy must maintain documentation of the medication received, the name and address of the pharmacy providing the medication, the date of receipt and the patient’s name.
(D) The receiving pharmacy is responsible for ensuring compliance with all applicable patient counseling requirements.
(E) For purposes of this rule, administration is defined as applying or introducing medication to the body of a patient, whether by injection, infusion, inhalation, ingestion or other means.
(F) Medication administered by a pharmacist must be performed in compliance with all applicable provisions of law.
(G) Notwithstanding any other provision of this rule, licensees shall comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security and record keeping requirements.


Title 20—DEPARTMENT OF
INSURANCE, FINANCIAL
INSTITUTIONS AND
PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED AMENDMENT

20 CSR 2220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy

PURPOSE: The Board is amending section (1)(A)3. of the rule and adding a new section (2) to (4) to update the rule, clarify database/contracting requirements and to accommodate pharmacies dispensing medication to another pharmacy for administration by a licensed healthcare professional.

PURPOSE: The purpose of this rule is to establish minimum standards of operation for Class J: Shared Services Pharmacy, in compliance with House Bill 567 of the 91st General Assembly standards for Class J: Shared Services pharmacies.

(1) Class J: Shared Services: [Shared Service Pharmacy is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.] A Class J Shared Services permit is required if two or more pharmacies are engaged in, or have an arrangement to provide, functions related to the practice of pharmacy for or on behalf of the other pharmacy. These functions may include, but are not limited to: prescription/order receipt, prescription/order clarification or modification, obtaining prescriber authorization, data entry, compounding, dispensing, pharmacist verification, patient counseling, patient profile maintenance, medication therapy services, medication administration, drug utilization review (DUR) and obtaining refill authorization. Both pharmacies participating in the shared services arrangement must have a Class J permit.

(A) [A pharmacy may perform or outsource centralized prescription processing services provided the parties] Pharmacies may perform Class-J Shared Services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities [and accountabilities] of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;

2. Maintain [separate licenses] a separate Class-J classification for each location involved in providing shared services; and

3. [Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order.] Either share a common database or allow access to each pharmacy’s electronic medication or prescription records. The access must provide real-time online access to the patient’s complete profile for the pharmacies involved.
(B) [There must be record keeping systems between shared service pharmacies with real time on-line access to shared services by both pharmacies. Transfer of prescription information between two (2) pharmacies that are accessing the same real-time, on-line database pursuant to the operation of a shared service pharmacy operation shall not be considered a prescription transfer and, therefore, is not subject to the requirements of 4 CSR 220-2.120.]

(C) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review upon request and that includes, but is not limited to, the following:

1. A description of how the parties will comply with federal and state laws and regulations;
2. The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;
3. The maintenance of a mechanism for tracking the prescription drug order during each step in the process;
4. The provision of adequate security to protect the confidentiality and integrity of patient information;
5. The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems.]

(B) Class-J pharmacies operating in compliance with this section are exempt from the requirements of 20 CSR 2220-2.120 and 20 CSR 2220-6.030(4) when transferring prescription information between themselves. A Class-J permit is not required to transfer an individual prescription as authorized by 20 CSR 2220-2.120 pursuant to a request by the patient or the patient’s authorized designee.

(C) The parties performing Class-J shared services shall maintain a detailed written description of authorized shared services that includes the name, address and permit number(s) of all pharmacies involved. The parties must maintain a current and accurate policy and procedure manual that includes, but is not limited to, the following:

1. Policies and procedures that identify the duties of each pharmacy, including, any functions identified in section (1);
2. A mechanism for tracking the prescription or medication order during each step in the process;
3. Security provisions for protecting the confidentiality and integrity of patient information;
4. Policies and procedures to ensure the safe and appropriate delivery of prescription drugs in compliance with 20 CSR 2200-2.013; and
5. A designation of the pharmacy responsible for offering patient counseling as required by 20 CSR 2220-2.190 and federal law. For purposes of § 338.059, RSMo, either the name and address of the pharmacy responsible for offering patient counseling or the pharmacy responsible for dispensing to the patient may be listed on the label as designated by the pharmacies by contract.

(D) Each pharmacy involved in a Class-J arrangement must maintain a quality assurance program that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of pharmacy services and resolve identified problems;
(E) Compounding may only be performed pursuant to a Class-J pharmacy arrangement pursuant to a patient-specific prescription or in anticipation of a patient-specific prescription as authorized by 20 CSR 2220-2.200 and the rules of the Board.

(F) A Class-J permit is not required for pharmacists performing non-dispensing activities authorized by 20 CSR 2220-6.050 outside of a licensed pharmacy.

(2) A Class J Shared services permit shall not be required if a completed and labeled prescription is delivered from a Missouri licensed pharmacy to another Missouri licensed pharmacy for administration by a pharmacist or other licensed health care professional to the patient on the same premises or physical location as the pharmacy.
   (A) The exemption recognized in this subsection only applies if a completed and labeled prescription is delivered to the receiving pharmacy.
   (B) If additional manipulation or compounding is required by the receiving pharmacy, receipt of a prescription or order is required and the receiving pharmacy must dispense the product as their own prescription/order. All prescription requirements, record keeping, compounding and labeling requirements must be met.
   (C) The receiving pharmacy must maintain documentation of the medication received, the name and address of the pharmacy providing the medication, the date of receipt and the patient's name.
   (D) The receiving pharmacy is responsible for ensuring compliance with all applicable patient counseling requirements.
   (E) For purposes of this rule, administration is defined as applying or introducing medication to the body of a patient, whether by injection, infusion, inhalation, ingestion or other means.
   (F) Medication administered by a pharmacist must be performed in compliance with all applicable provisions of law.
   (G) Notwithstanding any other provision of this rule, licensees shall comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security and record keeping requirements.

(3) A pharmacy participating in Class-J shared services with a pharmacy that is not under common ownership must notify patients that his/her prescription or medication order may be filled or compounded by another pharmacy.

(4) All records required by this rule, including, all policy and procedure manuals, contracts, quality assurance documentation, or other agreements must be maintained for two (2) years and must be made available to the Board or its representative upon request.


FIRST REGULAR SESSION
[TRULY AGREED TO AND FINALLY PASSED]
CONFERENCE COMMITTEE SUBSTITUTE FOR
HOUSE COMMITTEE SUBSTITUTE FOR

SENATE BILL NO. 501
99TH GENERAL ASSEMBLY
2017

2231S.03T

AN ACT
To repeal sections 191.227, 195.206, 197.040, 197.050, 197.070, 197.071, 197.080, 197.100, 334.010, 334.036, 334.735, 337.010, 337.025, 338.010, and 345.051, RSMo, and to enact in lieu thereof twenty-four new sections relating to health care, with an effective date for certain sections.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 191.227, 195.206, 197.040, 197.050, 197.070, 197.071, 197.080, 197.100, 334.010, 334.036, 334.735, 337.010, 337.025, 338.010, and 345.051, RSMo, are repealed and twenty-four new sections enacted in lieu thereof, to be known as sections 191.227, 194.600, 195.205, 195.206, 196.990, 197.005, 197.040, 197.050, 197.070, 197.071, 197.080, 197.100, 198.053, 324.003, 334.010, 334.036, 334.735, 337.010, 337.025, 338.010, 345.051, 478.004, 487.200, and 1, to read as follows:

191.227. 1. All physicians, chiropractors, hospitals, dentists, and other duly licensed practitioners in this state, herein called "providers", shall, upon written request of a patient, or guardian or legally authorized representative of a patient, furnish a copy of his or her record of that patient's health history and treatment rendered to the person submitting a written request, except that such right shall be limited to access consistent with the patient's condition and sound therapeutic treatment as determined by the provider. Beginning August 28, 1994, such record shall be furnished within a reasonable time of the receipt of the request therefor and upon payment of a fee as provided in this section.

2. Health care providers may condition the furnishing of the patient's health care records to the patient, the patient's authorized representative or any other person or entity authorized by law to obtain or reproduce such records upon payment of a fee for:

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.
14 (1) (a) Search and retrieval, in an amount not more than twenty-two
twenty-four dollars and eighty-two cents plus copying in the
amount of fifty-three cents per page for the cost of supplies and
labor plus, if the health care provider has contracted for off-site records storage
and management, any additional labor costs of outside storage retrieval, not to
exceed twenty-one dollars and thirty-six cents, as adjusted annually pursuant to subsection 5 of this section; or

(b) The records shall be furnished electronically upon payment of the
search, retrieval, and copying fees set under this section at the time of the
request or one hundred eight dollars and eighty-eight cents total, whichever
is less, if such person:

a. Requests health records to be delivered electronically in a format of the
health care provider's choice;

b. The health care provider stores such records completely in an electronic
health record; and

c. The health care provider is capable of providing the requested records
and affidavit, if requested, in an electronic format;

(2) Postage, to include packaging and delivery cost; and

(3) Notary fee, not to exceed two dollars, if requested.

3. Notwithstanding provisions of this section to the contrary, providers
may charge for the reasonable cost of all duplications of health care record
material or information which cannot routinely be copied or duplicated on a
standard commercial photocopy machine.

4. The transfer of the patient's record done in good faith shall not render
the provider liable to the patient or any other person for any consequences which
resulted or may result from disclosure of the patient's record as required by this
section.

5. Effective February first of each year, the fees listed in subsection 2 of
this section shall be increased or decreased annually based on the annual
percentage change in the unadjusted, U.S. city average, annual average inflation
rate of the medical care component of the Consumer Price Index for All Urban
Consumers (CPI-U). The current reference base of the index, as published by the
Bureau of Labor Statistics of the United States Department of Labor, shall be
used as the reference base. For purposes of this subsection, the annual average
inflation rate shall be based on a twelve-month calendar year beginning in
January and ending in December of each preceding calendar year. The
department of health and senior services shall report the annual adjustment and
the adjusted fees authorized in this section on the department's internet website.
6. A health care provider may disclose a deceased patient's health care records or payment records to the executor or administrator of the deceased person's estate, or pursuant to a valid, unrevoked power of attorney for health care that specifically directs that the deceased person's health care records be released to the agent after death. If an executor, administrator, or agent has not been appointed, the deceased prior to death did not specifically object to disclosure of his or her records in writing, and such disclosure is not inconsistent with any prior expressed preference of the deceased that is known to the health care provider, a deceased patient's health care records may be released upon written request of a person who is deemed as the personal representative of the deceased person under this subsection. Priority shall be given to the deceased patient's spouse and the records shall be released on the affidavit of the surviving spouse that he or she is the surviving spouse. If there is no surviving spouse, the health care records may be released to one of the following persons:

(1) The acting trustee of a trust created by the deceased patient either alone or with the deceased patient's spouse;
(2) An adult child of the deceased patient on the affidavit of the adult child that he or she is the adult child of the deceased;
(3) A parent of the deceased patient on the affidavit of the parent that he or she is the parent of the deceased;
(4) An adult brother or sister of the deceased patient on the affidavit of the adult brother or sister that he or she is the adult brother or sister of the deceased;
(5) A guardian or conservator of the deceased patient at the time of the patient's death on the affidavit of the guardian or conservator that he or she is the guardian or conservator of the deceased; or
(6) A guardian ad litem of the deceased's minor child based on the affidavit of the guardian that he or she is the guardian ad litem of the minor child of the deceased.

194.600. 1. As used in this section, the following terms mean:
(1) "Adult", an individual who is eighteen years of age or older;
(2) "Advance health care directive", a power of attorney for health care or a declaration signed or authorized by an adult, containing the person's direction concerning a health care decision;
(3) "Declaration", a record, including but not limited to a living
will or a do-not-resuscitate order, signed by an adult specifying the circumstances under which a life support system may be withheld or withdrawn;

(4) "Department", the department of health and senior services;

(5) "Health care decision", any decision regarding the health care of the person;

(6) "Intake point", any licensed health care provider or licensed attorney.

2. The department shall issue a request for proposals and contract with a third party for the establishment of a secure online central registry for individuals to be known as the "Advance Health Care Directives Registry" to store advance health care directives and to give authorized health care providers access to such directives.

3. An adult declarant may submit an advance health care directive or declaration and the revocations of such documents to the registry established under subsection 2 of this section.

4. Any document and any revocation of a document submitted for filing in the registry shall be submitted electronically at an intake point and signed electronically with a unique identifier, such as a social security number, a driver's license number, or another unique government-issued identifier. The electronic submission of the document shall be accompanied by a fee not to exceed ten dollars.

5. All data and information contained in the registry shall remain confidential and shall be exempt from the provisions of chapter 610.

6. The third party awarded a contract pursuant to subsection 2 of this section shall be solely responsible for all issues applicable to the registry, including, but not limited to, the development and operation of the registry; educating the general public, licensed health care providers, and legal professionals about the registry; responding to questions; providing technical assistance to users; and collection of user fees not to exceed ten dollars.

7. The department may promulgate rules to carry out the provisions of this section which may include, but not be limited to:

   (1) A determination of who may access the registry, including physicians, other licensed health care providers, the declarant, and his or her legal representatives or designees; and

   (2) A means for the contracting third party to annually remind registry users of which documents they have registered.
8. Any rule or portion of a rule, as that term is defined in section 536.010 that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2017, shall be invalid and void.

9. Failure to register a document with the registry maintained under this section shall not affect the document's validity. Failure to notify the registry of the revocation of a document previously filed with the registry shall not affect the validity of a revocation that meets the statutory requirements for such revocation to be valid.

195.205. 1. For purposes of this section, the following terms shall mean:

(1) "Drug or alcohol overdose", a condition including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, mania, or death which is the result of consumption or use of a controlled substance or alcohol or a substance with which the controlled substance or alcohol was combined, or that a person would reasonably believe to be a drug or alcohol overdose that requires medical assistance;

(2) "Medical assistance", includes, but is not limited to, reporting a drug or alcohol overdose or other medical emergency to law enforcement, the 911 system, a poison control center, or a medical provider; assisting someone so reporting; or providing care to someone who is experiencing a drug or alcohol overdose or other medical emergency while awaiting the arrival of medical assistance.

2. A person who, in good faith, seeks or obtains medical assistance for someone who is experiencing a drug or alcohol overdose or other medical emergency or a person experiencing a drug or alcohol overdose or other medical emergency who seeks medical assistance for himself or herself or is the subject of a good faith request shall not be arrested, charged, prosecuted, convicted, or have his or her property subject to civil forfeiture or otherwise be penalized for the following if the evidence for the arrest, charge, prosecution, conviction, seizure, or penalty was gained as a result of seeking or obtaining medical
assistance:
(1) Committing a prohibited act under sections 579.015, 579.074, 579.078, or 579.105;
(2) Committing a prohibited act under sections 311.310, 311.320, or 311.325;
(3) Violating a restraining order; or
(4) Violating probation or parole.
3. (1) This section shall not prohibit a police officer from arresting a person for an outstanding warrant under subsection 1 of section 221.510.
(2) This section shall not prohibit a person from being arrested, charged, or prosecuted based on an offense other than an offense under subsection 2 of this section, whether the offense arises from the same circumstances as the seeking of medical assistance.
(3) The protection of prosecution under this section for possession offenses shall not be grounds for suppression of evidence or dismissal in charges unrelated to this section.
4. Any police officer who is in contact with any person or persons in need of emergency medical assistance under this section shall provide appropriate information and resources for substance-related assistance.

195.206. 1. As used in this section, the following terms shall mean:
(1) "[Emergency] Opioid antagonist", naloxone hydrochloride that blocks the effects of an opioid overdose that is administered in a manner approved by the United States Food and Drug Administration or any accepted medical practice method of administering;
(2) "Opioid-related drug overdose", a condition including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of an opioid or other substance with which an opioid was combined or a condition that a layperson would reasonably believe to be an opioid-related drug overdose that requires medical assistance.
2. Notwithstanding any other law or regulation to the contrary:
(1) The director of the department of health and senior services, if a licensed physician, may issue a statewide standing order for an opioid antagonist;
(2) In the alternative, the department may employ or contract with a licensed physician who may issue a statewide standing order for an opioid antagonist with the express written consent of the
department director.

3. Notwithstanding any other law or regulation to the contrary, any licensed pharmacist in Missouri may sell and dispense an opioid antagonist under physician protocol or under a statewide standing order issued under subsection 2 of this section.

[3.] 4. A licensed pharmacist who, acting in good faith and with reasonable care, sells or dispenses an opioid antagonist and appropriate device to administer the drug, and the protocol physician, shall not be subject to any criminal or civil liability or any professional disciplinary action for prescribing or dispensing the opioid antagonist or any outcome resulting from the administration of the opioid antagonist. A physician issuing a statewide standing order under subsection 2 of this section shall not be subject to any criminal or civil liability or any professional disciplinary action for issuing the standing order or for any outcome related to the order or the administration of the opioid antagonist.

[4.] 5. Notwithstanding any other law or regulation to the contrary, it shall be permissible for any person to possess an opioid antagonist.

[5.] 6. Any person who administers an opioid antagonist to another person shall, immediately after administering the drug, contact emergency personnel. Any person who, acting in good faith and with reasonable care, administers an opioid antagonist to another person whom the person believes to be suffering an opioid-related overdose shall be immune from criminal prosecution, disciplinary actions from his or her professional licensing board, and civil liability due to the administration of the opioid antagonist.

196.990. 1. As used in this section, the following terms shall mean:

(1) "Administer", the direct application of an epinephrine auto-injector to the body of an individual;

(2) "Authorized entity", any entity or organization at or in connection with which allergens capable of causing anaphylaxis may be present including, but not limited to, restaurants, recreation camps, youth sports leagues, amusement parks, and sports arenas. "Authorized entity" shall not include any public school or public charter school;

(3) "Epinephrine auto-injector", a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body;

(4) "Physician", a physician licensed in this state under chapter 334;
(5) "Provide", the supply of one or more epinephrine auto-injectors to an individual;

(6) "Self-administration", a person's discretionary use of an epinephrine auto-injector.

2. A physician may prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with this section, and pharmacists, physicians, and other persons authorized to dispense prescription medications may dispense epinephrine auto-injectors under a prescription issued in the name of an authorized entity.

3. An authorized entity may acquire and stock a supply of epinephrine auto-injectors under a prescription issued in accordance with this section. Such epinephrine auto-injectors shall be stored in a location readily accessible in an emergency and in accordance with the epinephrine auto-injector's instructions for use and any additional requirements established by the department of health and senior services by rule. An authorized entity shall designate employees or agents who have completed the training required under this section to be responsible for the storage, maintenance, and general oversight of epinephrine auto-injectors acquired by the authorized entity.

4. An authorized entity that acquires a supply of epinephrine auto-injectors under a prescription issued in accordance with this section shall ensure that:

(1) Expected epinephrine auto-injector users receive training in recognizing symptoms of severe allergic reactions including anaphylaxis and the use of epinephrine auto-injectors from a nationally recognized organization experienced in training laypersons in emergency health treatment or another entity or person approved by the department of health and senior services;

(2) All epinephrine auto-injectors are maintained and stored according to the epinephrine auto-injector's instructions for use;

(3) Any person who provides or administers an epinephrine auto-injector to an individual who the person believes in good faith is experiencing anaphylaxis activates the emergency medical services system as soon as possible; and

(4) A proper review of all situations in which an epinephrine auto-injector is used to render emergency care is conducted.

5. Any authorized entity that acquires a supply of epinephrine auto-injectors under a prescription issued in accordance with this section shall notify the emergency communications district or the
ambulance dispatch center of the primary provider of emergency medical services where the epinephrine auto-injectors are to be located within the entity's facility.

6. No person shall provide or administer an epinephrine auto-injector to any individual who is under eighteen years of age without the verbal consent of a parent or guardian who is present at the time when provision or administration of the epinephrine auto-injector is needed. Provided, however, that a person may provide or administer an epinephrine auto-injector to such an individual without the consent of a parent or guardian if the parent or guardian is not physically present and the person reasonably believes the individual shall be in imminent danger without the provision or administration of the epinephrine auto-injector.

7. The following persons and entities shall not be liable for any injuries or related damages that result from the administration or self-administration of an epinephrine auto-injector in accordance with this section that may constitute ordinary negligence:

(1) An authorized entity that possesses and makes available epinephrine auto-injectors and its employees, agents, and other trained persons;

(2) Any person who uses an epinephrine auto-injector made available under this section;

(3) A physician that prescribes epinephrine auto-injectors to an authorized entity; or

(4) Any person or entity that conducts the training described in this section.

Such immunity does not apply to acts or omissions constituting a reckless disregard for the safety of others or willful or wanton conduct. The administration of an epinephrine auto-injector in accordance with this section shall not be considered the practice of medicine. The immunity from liability provided under this subsection is in addition to and not in lieu of that provided under section 537.037. An authorized entity located in this state shall not be liable for any injuries or related damages that result from the provision or administration of an epinephrine auto-injector by its employees or agents outside of this state if the entity or its employee or agent are not liable for such injuries or related damages under the laws of the state in which such provision or administration occurred. No trained person who is in compliance with this section and who in good faith and
exercising reasonable care fails to administer an epinephrine auto-injector shall be liable for such failure.

8. All basic life support ambulances and stretcher vans operated in the state shall be equipped with epinephrine auto-injectors and be staffed by at least one individual trained in the use of epinephrine auto-injectors.

9. The provisions of this section shall apply in all counties within the state and any city not within a county.

10. Nothing in this section shall be construed as superseding the provisions of section 167.630.

197.005. 1. As used in this section, the term "Medicare conditions of participation" shall mean federal regulatory standards established under Title XVIII of the Social Security Act and defined in 42 CFR 482, as amended, for hospitals and 42 CFR 485, as amended, for hospitals designated as critical access hospitals under 42 U.S.C. Section 1395i-4.

2. To minimize the administrative cost of enforcing and complying with duplicative regulatory standards, on and after July 1, 2018, compliance with Medicare conditions of participation shall be deemed to constitute compliance with the standards for hospital licensure under sections 197.010 to 197.120 and regulations promulgated thereunder.

3. Nothing in this section shall preclude the department of health and senior services from promulgating regulations effective on or after July 1, 2018, to define separate regulatory standards that do not duplicate or contradict the Medicare conditions of participation, with specific state statutory authorization to create separate regulatory standards.

4. Regulations promulgated by the department of health and senior services to establish and enforce hospital licensure regulations under this chapter that duplicate or conflict with the Medicare conditions of participation shall lapse and expire on and after July 1, 2018.

197.040. After ninety days from the date this law becomes effective, no person or governmental unit, acting severally or jointly with any other person or governmental unit, shall establish, conduct or maintain a hospital in this state without a license under this law and section 197.005 issued by the department of health and senior services.

197.050. Application for a license shall be made to the department of health and senior services upon forms provided by it and shall contain such
information as the department of health and senior services requires, which may include affirmative evidence of ability to comply with such reasonable standards, rules and regulations as are lawfully prescribed hereunder in compliance with section 197.005. Until June 30, 1989, each application for a license, except applications from governmental units, shall be accompanied by an annual license fee of two hundred dollars plus two dollars per bed for the first one hundred beds and one dollar per bed for each additional bed. Beginning July 1, 1989, each application for a license, except applications from governmental units, shall be accompanied by an annual license fee of two hundred fifty dollars plus three dollars per bed for the first four hundred beds and two dollars per bed for each additional bed. All license fees shall be paid to the director of revenue and deposited in the state treasury to the credit of the general revenue fund.

197.070. The department of health and senior services may deny, suspend or revoke a license in any case in which it finds that there has been a substantial failure to comply with the requirements established under this law and section 197.005.

197.071. Any person aggrieved by an official action of the department of health and senior services affecting the licensed status of a person under the provisions of sections [197.010] 197.005 to 197.120, including the refusal to grant, the grant, the revocation, the suspension, or the failure to renew a license, may seek a determination thereon by the administrative hearing commission pursuant to the provisions of section 621.045, and it shall not be a condition to such determination that the person aggrieved seek a reconsideration, a rehearing, or exhaust any other procedure within the department of health and senior services.

197.080. 1. The department of health and senior services, with the advice of the state advisory council and pursuant to the provisions of this section, section 197.005, and chapter 536, shall adopt, amend, promulgate and enforce such rules, regulations and standards with respect to all hospitals or different types of hospitals to be licensed hereunder as may be designed to further the accomplishment of the purposes of this law in promoting safe and adequate treatment of individuals in hospitals in the interest of public health, safety and welfare. No rule or portion of a rule promulgated under the authority of sections 197.010 to 197.280 shall become effective unless it has been promulgated pursuant to the provisions of section 536.024.

2. The department shall review and revise regulations governing hospital licensure and enforcement to promote hospital and regulatory efficiencies [and]. The department shall eliminate all duplicative regulations and
inspections by or on behalf of state agencies and the Centers for Medicare and
Medicaid Services (CMS). The hospital licensure regulations adopted under this
section shall incorporate standards which shall include, but not be
limited to, the following:

(1) Each citation or finding of a regulatory deficiency shall refer to the
specific written regulation, any state associated written interpretive guidance
developed by the department and any publicly available, professionally recognized
standards of care that are the basis of the citation or finding;

(2) Subject to appropriations, the department shall ensure that its
hospital licensure regulatory standards are consistent with and do not contradict
the CMS Conditions of Participation (COP) and associated interpretive
guidance. However, this shall not preclude the department from enforcing
standards produced by the department which exceed the federal CMS' COP and
associated interpretive guidance, so long as such standards produced by the
department promote a higher degree of patient safety and do not contradict the
federal CMS' COP and associated interpretive guidance;

(3) The department shall establish and publish guidelines for complaint
investigation, including but not limited to:

(a) The department's process for reviewing and determining which
complaints warrant an on-site investigation based on a preliminary review of
available information from the complainant, other appropriate sources, and when
not prohibited by CMS, the hospital. For purposes of providing hospitals with
information necessary to improve processes and patient care, the number and
nature of complaints filed and the recommended actions by the department and,
as appropriate CMS, shall be disclosed upon request to hospitals so long as the
otherwise confidential identity of the complainant or the patient for whom the
complaint was filed is not disclosed;

(b) A departmental investigation of a complaint shall be focused on the
specific regulatory standard and departmental written interpretive guidance and
publicly available professionally recognized standard of care related to the
complaint. During the course of any complaint investigation, the department
shall cite any serious and immediate threat discovered that may potentially
jeopardize the health and safety of patients;

(c) A hospital shall be provided with a report of all complaints made
against the hospital. Such report shall include the nature of the complaint, the
date of the complaint, the department conclusions regarding the complaint, the
number of investigators and days of investigation resulting from each complaint;

(4) Hospitals and hospital personnel shall have the opportunity to
participate in annual continuing training sessions when such training is provided
to state licensure surveyors with prior approval from the department director and
CMS when appropriate. Hospitals and hospital personnel shall assume all costs
associated with facilitating the training sessions and use of curriculum materials,
including but not limited to the location for training, food, and printing costs;
(5) Time lines for the department to provide responses to hospitals
regarding the status and outcome of pending investigations and regulatory
actions and questions about interpretations of regulations shall be identical to,
to the extent practicable, the time lines established for the federal hospital
certification and enforcement system in the CMS State Operations Manual, as
amended. These time lines shall be the guide for the department to
follow. Every reasonable attempt shall be made to meet the time lines. However,
failure to meet the established time lines shall in no way prevent the department
from performing any necessary inspections to ensure the health and safety of
patients.

3. Any rule or portion of a rule, as that term is defined in section 536.010,
that is created under the authority delegated in this section shall become effective
only if it complies with and is subject to all of the provisions of chapter 536 and,
if applicable, section 536.028. This section and chapter 536 are nonseverable and
if any of the powers vested with the general assembly pursuant to chapter 536 to
review, to delay the effective date, or to disapprove and annul a rule are
subsequently held unconstitutional, then the grant of rulemaking authority and
any rule proposed or adopted after August 28, 2013, shall be invalid and void.

197.100. 1. Any provision of chapter 198 and chapter 338 to the contrary
notwithstanding, the department of health and senior services shall have sole
authority, and responsibility for inspection and licensure of hospitals in this state
including, but not limited to, all parts, services, functions, support functions and
activities which contribute directly or indirectly to patient care of any kind
whatsoever. The department of health and senior services shall annually inspect
each licensed hospital and shall make any other inspections and investigations
as it deems necessary for good cause shown. The department of health and senior
services shall accept reports of hospital inspections from or on behalf of
governmental agencies, the joint commission, and the American Osteopathic
Association Healthcare Facilities Accreditation Program, provided the
accreditation inspection was conducted within one year of the date of license
renewal. Prior to granting acceptance of any other accrediting organization
reports in lieu of the required licensure survey, the accrediting organization’s
survey process must be deemed appropriate and found to be comparable to the
department’s licensure survey. It shall be the accrediting organization’s responsibility to provide the department any and all information necessary to determine if the accrediting organization’s survey process is comparable and fully meets the intent of the licensure regulations. The department of health and senior services shall attempt to schedule inspections and evaluations required by this section so as not to cause a hospital to be subject to more than one inspection in any twelve-month period from the department of health and senior services or any agency or accreditation organization the reports of which are accepted for licensure purposes pursuant to this section, except for good cause shown.

2. Other provisions of law to the contrary notwithstanding, the department of health and senior services shall be the only state agency to determine life safety and building codes for hospitals defined or licensed pursuant to the provisions of this chapter, including but not limited to sprinkler systems, smoke detection devices and other fire safety-related matters so long as any new standards shall apply only to new construction.

198.053. No later than October first of each year, in accordance with the latest recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, each assisted living facility, as such term is defined in section 198.006, shall notify residents and staff where in the facility that the latest edition of the Vaccine Informational Sheet published by the Centers for Disease Control and Prevention has been posted. Nothing in this section shall be construed to require any assisted living facility to provide or pay for any vaccination against influenza, allow the department of health to promulgate any rules to implement this section, or cite any facility for acting in good faith to post the Vaccine Informational Sheet.

324.003. Notwithstanding any other provision of law or administrative rule to the contrary, the division of professional registration and its component boards, committees, offices, and commissions shall permit:

(1) Any licensee to submit payment for fees so established in the form of personal check, money order, cashier’s check, credit card, or electronic check as defined by section 407.432;

(2) Any applicant or licensee to apply for licensure or renew their license in writing or electronically; and

(3) Any licensee to make requests of their license-granting board or commission for extensions of time to complete continuing education, notify their license-granting board or commission of changes to name,
business name, home address, or work address, and provide any other items required as part of licensure to their licensure board in writing or electronically.

334.010. 1. It shall be unlawful for any person not now a registered physician within the meaning of the law to practice medicine or surgery in any of its departments, to engage in the practice of medicine across state lines or to profess to cure and attempt to treat the sick and others afflicted with bodily or mental infirmities, or engage in the practice of midwifery in this state, except as herein provided.

2. For the purposes of this chapter, the "practice of medicine across state lines" shall mean:

   (1) The rendering of a written or otherwise documented medical opinion concerning the diagnosis or treatment of a patient within this state by a physician located outside this state as a result of transmission of individual patient data by electronic or other means from within this state to such physician or physician's agent; or

   (2) The rendering of treatment to a patient within this state by a physician located outside this state as a result of transmission of individual patient data by electronic or other means from within this state to such physician or physician's agent.

3. A physician located outside of this state shall not be required to obtain a license when:

   (1) In consultation with a physician licensed to practice medicine in this state; and

   (2) The physician licensed in this state retains ultimate authority and responsibility for the diagnosis or diagnoses and treatment in the care of the patient located within this state; or

   (3) Evaluating a patient or rendering an oral, written or otherwise documented medical opinion, or when providing testimony or records for the purpose of any civil or criminal action before any judicial or administrative proceeding of this state or other forum in this state; or

   (4) Participating in a utilization review pursuant to section 376.1350.

4. This section shall not apply to a person who holds a current, unrestricted license to practice medicine in another state when the person, under a written agreement with an athletic team located in the state in which the person is licensed, provides sports-related medical services to any of the following individuals if the team is traveling to or from, or participating in, a sporting event in this state:
(1) A member of an athletic team;
(2) A member of an athletic team's coaching, communications, equipment, or sports medicine staff;
(3) A member of a band, dance team, or cheerleading squad accompanying an athletic team; or
(4) An athletic team's mascot.

5. In providing sports-related medical services under subsection 4 of this section, the person shall not provide medical services at a health care facility, including a hospital, ambulatory surgical center, or any other facility in which medical care, diagnosis, or treatment is provided on an inpatient or outpatient basis.

334.036. 1. For purposes of this section, the following terms shall mean:

(1) "Assistant physician", any medical school graduate who:
   (a) Is a resident and citizen of the United States or is a legal resident alien;
   (b) Has successfully completed Step 1 and Step 2 of the United States Medical Licensing Examination or the equivalent of such steps of any other board-approved medical licensing examination within the two-year period immediately preceding application for licensure as an assistant physician, but in no event more than three years after graduation from a medical college or osteopathic medical college;
   (c) Has not completed an approved postgraduate residency and has successfully completed Step 2 of the United States Medical Licensing Examination or the equivalent of such step of any other board-approved medical licensing examination within the immediately preceding two-year period unless when such two-year anniversary occurred he or she was serving as a resident physician in an accredited residency in the United States and continued to do so within thirty days prior to application for licensure as an assistant physician; and
   (d) Has proficiency in the English language.]

Any medical school graduate who could have applied for licensure and complied with the provisions of this subdivision at any time between August 28, 2014, and August 28, 2017, may apply for licensure and shall be deemed in compliance with the provisions of this subdivision;

(2) "Assistant physician collaborative practice arrangement", an agreement between a physician and an assistant physician that meets the requirements of this section and section 334.037;
(3) "Medical school graduate", any person who has graduated from a medical college or osteopathic medical college described in section 334.031.
2. (1) An assistant physician collaborative practice arrangement shall limit the assistant physician to providing only primary care services and only in medically underserved rural or urban areas of this state or in any pilot project areas established in which assistant physicians may practice.

(2) For a physician-assistant physician team working in a rural health clinic under the federal Rural Health Clinic Services Act, P.L. 95-210, as amended:

(a) An assistant physician shall be considered a physician assistant for purposes of regulations of the Centers for Medicare and Medicaid Services (CMS); and

(b) No supervision requirements in addition to the minimum federal law shall be required.

3. (1) For purposes of this section, the licensure of assistant physicians shall take place within processes established by rules of the state board of registration for the healing arts. The board of healing arts is authorized to establish rules under chapter 536 establishing licensure and renewal procedures, supervision, collaborative practice arrangements, fees, and addressing such other matters as are necessary to protect the public and discipline the profession. An application for licensure may be denied or the licensure of an assistant physician may be suspended or revoked by the board in the same manner and for violation of the standards as set forth by section 334.100, or such other standards of conduct set by the board by rule.

(2) Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly under chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2014, shall be invalid and void.

4. An assistant physician shall clearly identify himself or herself as an assistant physician and shall be permitted to use the terms "doctor", "Dr.", or "doc". No assistant physician shall practice or attempt to practice without an assistant physician collaborative practice arrangement, except as otherwise provided in this section and in an emergency situation.

5. The collaborating physician is responsible at all times for the oversight of the activities of and accepts responsibility for primary care services rendered
66 by the assistant physician.
67 6. The provisions of section 334.037 shall apply to all assistant physician
68 collaborative practice arrangements. To be eligible to practice as an assistant
69 physician, a licensed assistant physician shall enter into an assistant physician
70 collaborative practice arrangement within six months of his or her initial
71 licensure and shall not have more than a six-month time period between
72 collaborative practice arrangements during his or her licensure period. Any
73 renewal of licensure under this section shall include verification of actual practice
74 under a collaborative practice arrangement in accordance with this subsection
75 during the immediately preceding licensure period.

334.735. 1. As used in sections 334.735 to 334.749, the following terms
2 mean:
3 (1) "Applicant", any individual who seeks to become licensed as a
4 physician assistant;
5 (2) "Certification" or "registration", a process by a certifying entity that
6 grants recognition to applicants meeting predetermined qualifications specified
7 by such certifying entity;
8 (3) "Certifying entity", the nongovernmental agency or association which
9 certifies or registers individuals who have completed academic and training
10 requirements;
11 (4) "Department", the department of insurance, financial institutions and
12 professional registration or a designated agency thereof;
13 (5) "License", a document issued to an applicant by the board
14 acknowledging that the applicant is entitled to practice as a physician assistant;
15 (6) "Physician assistant", a person who has graduated from a physician
16 assistant program accredited by the American Medical Association's Committee
17 on Allied Health Education and Accreditation or by its successor agency, who has
18 passed the certifying examination administered by the National Commission on
19 Certification of Physician Assistants and has active certification by the National
20 Commission on Certification of Physician Assistants who provides health care
21 services delegated by a licensed physician. A person who has been employed as
22 a physician assistant for three years prior to August 28, 1989, who has passed the
23 National Commission on Certification of Physician Assistants examination, and
24 has active certification of the National Commission on Certification of Physician
25 Assistants;
26 (7) "Recognition", the formal process of becoming a certifying entity as
27 required by the provisions of sections 334.735 to 334.749;
28 (8) "Supervision", control exercised over a physician assistant working
with a supervising physician and oversight of the activities of and accepting responsibility for the physician assistant's delivery of care. The physician assistant shall only practice at a location where the physician routinely provides patient care, except existing patients of the supervising physician in the patient's home and correctional facilities. The supervising physician must be immediately available in person or via telecommunication during the time the physician assistant is providing patient care. Prior to commencing practice, the supervising physician and physician assistant shall attest on a form provided by the board that the physician shall provide supervision appropriate to the physician assistant's training and that the physician assistant shall not practice beyond the physician assistant's training and experience. Appropriate supervision shall require the supervising physician to be working within the same facility as the physician assistant for at least four hours within one calendar day for every fourteen days on which the physician assistant provides patient care as described in subsection 3 of this section. Only days in which the physician assistant provides patient care as described in subsection 3 of this section shall be counted toward the fourteen-day period. The requirement of appropriate supervision shall be applied so that no more than thirteen calendar days in which a physician assistant provides patient care shall pass between the physician's four hours working within the same facility. The board shall promulgate rules pursuant to chapter 536 for documentation of joint review of the physician assistant activity by the supervising physician and the physician assistant.

2. (1) A supervision agreement shall limit the physician assistant to practice only at locations described in subdivision (8) of subsection 1 of this section, where the supervising physician is no further than fifty miles by road using the most direct route available and where the location is not so situated as to create an impediment to effective intervention and supervision of patient care or adequate review of services.

(2) For a physician-physician assistant team working in a rural health clinic under the federal Rural Health Clinic Services Act, P.L. 95-210, as amended, no supervision requirements in addition to the minimum federal law shall be required.

3. The scope of practice of a physician assistant shall consist only of the following services and procedures:

(1) Taking patient histories;

(2) Performing physical examinations of a patient;

(3) Performing or assisting in the performance of routine office laboratory and patient screening procedures;
(4) Performing routine therapeutic procedures;
(5) Recording diagnostic impressions and evaluating situations calling for attention of a physician to institute treatment procedures;
(6) Instructing and counseling patients regarding mental and physical health using procedures reviewed and approved by a licensed physician;
(7) Assisting the supervising physician in institutional settings, including reviewing of treatment plans, ordering of tests and diagnostic laboratory and radiological services, and ordering of therapies, using procedures reviewed and approved by a licensed physician;
(8) Assisting in surgery;
(9) Performing such other tasks not prohibited by law under the supervision of a licensed physician as the physician's assistant has been trained and is proficient to perform; and
(10) Physician assistants shall not perform or prescribe abortions.

4. Physician assistants shall not prescribe nor dispense any drug, medicine, device or therapy unless pursuant to a physician supervision agreement in accordance with the law, nor prescribe lenses, prisms or contact lenses for the aid, relief or correction of vision or the measurement of visual power or visual efficiency of the human eye, nor administer or monitor general or regional block anesthesia during diagnostic tests, surgery or obstetric procedures. Prescribing and dispensing of drugs, medications, devices or therapies by a physician assistant shall be pursuant to a physician assistant supervision agreement which is specific to the clinical conditions treated by the supervising physician and the physician assistant shall be subject to the following:

(1) A physician assistant shall only prescribe controlled substances in accordance with section 334.747;
(2) The types of drugs, medications, devices or therapies prescribed or dispensed by a physician assistant shall be consistent with the scopes of practice of the physician assistant and the supervising physician;
(3) All prescriptions shall conform with state and federal laws and regulations and shall include the name, address and telephone number of the physician assistant and the supervising physician;
(4) A physician assistant, or advanced practice registered nurse as defined in section 335.016 may request, receive and sign for noncontrolled professional samples and may distribute professional samples to patients; and
(5) A physician assistant shall not prescribe any drugs, medicines, devices or therapies the supervising physician is not qualified or authorized to prescribe;
5. A physician assistant shall clearly identify himself or herself as a physician assistant and shall not use or permit to be used in the physician assistant's behalf the terms "doctor", "Dr." or "doc" nor hold himself or herself out in any way to be a physician or surgeon. No physician assistant shall practice or attempt to practice without physician supervision or in any location where the supervising physician is not immediately available for consultation, assistance and intervention, except as otherwise provided in this section, and in an emergency situation, nor shall any physician assistant bill a patient independently or directly for any services or procedure by the physician assistant; except that, nothing in this subsection shall be construed to prohibit a physician assistant from enrolling with the department of social services as a MO HealthNet or Medicaid provider while acting under a supervision agreement between the physician and physician assistant.

6. For purposes of this section, the licensing of physician assistants shall take place within processes established by the state board of registration for the healing arts through rule and regulation. The board of healing arts is authorized to establish rules pursuant to chapter 536 establishing licensing and renewal procedures, supervision, supervision agreements, fees, and addressing such other matters as are necessary to protect the public and discipline the profession. An application for licensing may be denied or the license of a physician assistant may be suspended or revoked by the board in the same manner and for violation of the standards as set forth by section 334.100, or such other standards of conduct set by the board by rule or regulation. Persons licensed pursuant to the provisions of chapter 335 shall not be required to be licensed as physician assistants. All applicants for physician assistant licensure who complete a physician assistant training program after January 1, 2008, shall have a master's degree from a physician assistant program.

7. "Physician assistant supervision agreement" means a written agreement, jointly agreed-upon protocols or standing order between a supervising physician and a physician assistant, which provides for the delegation of health care services from a supervising physician to a physician assistant and the review of such services. The agreement shall contain at least the following provisions:

   (1) Complete names, home and business addresses, zip codes, telephone numbers, and state license numbers of the supervising physician and the physician assistant;

   (2) A list of all offices or locations where the physician routinely provides
patient care, and in which of such offices or locations the supervising physician has authorized the physician assistant to practice;

(3) All specialty or board certifications of the supervising physician;

(4) The manner of supervision between the supervising physician and the physician assistant, including how the supervising physician and the physician assistant shall:

(a) Attest on a form provided by the board that the physician shall provide supervision appropriate to the physician assistant's training and experience and that the physician assistant shall not practice beyond the scope of the physician assistant's training and experience nor the supervising physician's capabilities and training; and

(b) Provide coverage during absence, incapacity, infirmity, or emergency by the supervising physician;

(5) The duration of the supervision agreement between the supervising physician and physician assistant; and

(6) A description of the time and manner of the supervising physician's review of the physician assistant's delivery of health care services. Such description shall include provisions that the supervising physician, or a designated supervising physician listed in the supervision agreement review a minimum of ten percent of the charts of the physician assistant's delivery of health care services every fourteen days.

8. When a physician assistant supervision agreement is utilized to provide health care services for conditions other than acute self-limited or well-defined problems, the supervising physician or other physician designated in the supervision agreement shall see the patient for evaluation and approve or formulate the plan of treatment for new or significantly changed conditions as soon as practical, but in no case more than two weeks after the patient has been seen by the physician assistant.

9. At all times the physician is responsible for the oversight of the activities of, and accepts responsibility for, health care services rendered by the physician assistant.

10. It is the responsibility of the supervising physician to determine and document the completion of at least a one-month period of time during which the licensed physician assistant shall practice with a supervising physician continuously present before practicing in a setting where a supervising physician is not continuously present.

11. No contract or other agreement shall require a physician to act as a supervising physician for a physician assistant against the physician's will. A
physician shall have the right to refuse to act as a supervising physician, without penalty, for a particular physician assistant. No contract or other agreement shall limit the supervising physician's ultimate authority over any protocols or standing orders or in the delegation of the physician's authority to any physician assistant, but this requirement shall not authorize a physician in implementing such protocols, standing orders, or delegation to violate applicable standards for safe medical practice established by the hospital's medical staff.

12. Physician assistants shall file with the board a copy of their supervising physician form.

13. No physician shall be designated to serve as supervising physician for more than three full-time equivalent licensed physician assistants. This limitation shall not apply to physician assistant agreements of hospital employees providing inpatient care service in hospitals as defined in chapter 197.

337.010. As used in sections 337.010 to 337.090 the following terms mean:

1. "Committee", the state committee of psychologists;

2. "Department", the department of insurance, financial institutions and professional registration;

3. "Division", the division of professional registration;

4. "Internship", any supervised hours that occur during a formal internship of twelve to twenty-four months after all academic course work toward a doctorate has been completed but prior to completion of the full degree. Internship is part of successful completion of a doctorate in psychology, and a person cannot earn his or her doctorate without completion of an internship;

5. "Licensed psychologist", any person who offers to render psychological services to individuals, groups, organizations, institutions, corporations, schools, government agencies or the general public for a fee, monetary or otherwise, implying that such person is trained, experienced and licensed to practice psychology and who holds a current and valid, whether temporary, provisional or permanent, license in this state to practice psychology;

6. "Postdoctoral experiences", experiences that follow the completion of a person's doctoral degree. Such person shall not be licensed until he or she satisfies additional supervised hours. Postdoctoral experiences shall include any supervised clinical activities following the completion of the doctoral degree;

7. "Predoctoral postinternship", any supervised hours that occur following completion of the internship but prior to completing the degree. Such person may continue to provide supervised clinical...
services even after his or her internship is completed and while still completing his or her doctoral degree requirements;

(8) "Preinternship", any supervised hours acquired as a student or in the course of seeking a doctorate in psychology but before the internship, which includes supervised practicum;

[[5] (9) "Provisional licensed psychologist", any person who is a graduate of a recognized educational institution with a doctoral degree in psychology as defined in section 337.025, and who otherwise meets all requirements to become a licensed psychologist except for passage of the licensing exams, oral examination and completion of the required period of postdegree supervised experience as specified in subsection 2 of section 337.025;

[[6] (10) "Recognized educational institution":

(a) A school, college, university or other institution of higher learning in the United States, which, at the time the applicant was enrolled and graduated, had a graduate program in psychology and was accredited by one of the regional accrediting associations approved by the Council on Postsecondary Accreditation;

or

(b) A school, college, university or other institution of higher learning outside the United States, which, at the time the applicant was enrolled and graduated, had a graduate program in psychology and maintained a standard of training substantially equivalent to the standards of training of those programs accredited by one of the regional accrediting associations approved by the Council of Postsecondary Accreditation;

[[7] (11) "Temporary license", a license which is issued to a person licensed as a psychologist in another jurisdiction, who has applied for licensure in this state either by reciprocity or endorsement of the score from the Examination for Professional Practice in Psychology, and who is awaiting either a final determination by the committee relative to such person's eligibility for licensure or who is awaiting the results of the jurisprudence examination or oral examination.

337.025. 1. The provisions of this section shall govern the education and experience requirements for initial licensure as a psychologist for the following persons:

(1) A person who has not matriculated in a graduate degree program which is primarily psychological in nature on or before August 28, 1990; and

(2) A person who is matriculated after August 28, 1990, in a graduate degree program designed to train professional psychologists.

2. Each applicant shall submit satisfactory evidence to the committee that
the applicant has received a doctoral degree in psychology from a recognized educational institution, and has had at least one year of satisfactory supervised professional experience in the field of psychology.

3. A doctoral degree in psychology is defined as:

(1) A program accredited, or provisionally accredited, by the American Psychological Association or the Canadian Psychological Association; or

(2) A program designated or approved, including provisional approval, by the [American] Association of State and Provincial Psychology Boards or the Council for the National Register of Health Service Providers in Psychology, or both; or

(3) A graduate program that meets all of the following criteria:

(a) The program, wherever it may be administratively housed, shall be clearly identified and labeled as a psychology program. Such a program shall specify in pertinent institutional catalogues and brochures its intent to educate and train professional psychologists;

(b) The psychology program shall stand as a recognizable, coherent organizational entity within the institution of higher education;

(c) There shall be a clear authority and primary responsibility for the core and specialty areas whether or not the program cuts across administrative lines;

(d) The program shall be an integrated, organized, sequence of study;

(e) There shall be an identifiable psychology faculty and a psychologist responsible for the program;

(f) The program shall have an identifiable body of students who are matriculated in that program for a degree;

(g) The program shall include a supervised practicum, internship, field, or laboratory training appropriate to the practice of psychology;

(h) The curriculum shall encompass a minimum of three academic years of full-time graduate study, with a minimum of one year’s residency at the educational institution granting the doctoral degree; and

(i) Require the completion by the applicant of a core program in psychology which shall be met by the completion and award of at least one three-semester-hour graduate credit course or a combination of graduate credit courses totaling three semester hours or five quarter hours in each of the following areas:

a. The biological bases of behavior such as courses in: physiological psychology, comparative psychology, neuropsychology, sensation and perception, psychopharmacology;

b. The cognitive-affective bases of behavior such as courses in: learning, thinking, motivation, emotion, and cognitive psychology;
c. The social bases of behavior such as courses in: social psychology, group processes/dynamics, interpersonal relationships, and organizational and systems theory;

d. Individual differences such as courses in: personality theory, human development, abnormal psychology, developmental psychology, child psychology, adolescent psychology, psychology of aging, and theories of personality;

e. The scientific methods and procedures of understanding, predicting and influencing human behavior such as courses in: statistics, experimental design, psychometrics, individual testing, group testing, and research design and methodology.

4. Acceptable supervised professional experience may be accrued through preinternship, internship, predoctoral postinternship, or postdoctoral experiences. The academic training director or the postdoctoral training supervisor shall attest to the hours accrued to meet the requirements of this section. Such hours shall consist of:

(1) A minimum of fifteen hundred hours of [professional] experience [obtained] in a successfully completed internship to be completed in not less than twelve nor more than twenty-four [consecutive calendar] months; and

(2) A minimum of two thousand hours of experience consisting of any combination of the following:

(a) Preinternship and predoctoral postinternship professional experience that occurs following the completion of the first year of the doctoral program or at any time while in a doctoral program after completion of a master's degree in psychology or equivalent as defined by rule by the committee;

(b) Up to seven hundred fifty hours obtained while on the internship under subdivision (1) of this subsection but beyond the fifteen hundred hours identified in subdivision (1) of this subsection; or

(c) Postdoctoral professional experience obtained in no more than twenty-four consecutive calendar months. In no case shall this experience be accumulated at a rate of [less than twenty hours per week nor] more than fifty hours per week. Postdoctoral supervised professional experience for prospective health service providers and other applicants shall involve and relate to the delivery of psychological [health] services. Postdoctoral supervised professional experience for other applicants shall be in accordance with professional requirements and relevant to the applicant's intended area of practice.
5. [Postdoctoral] Experience for those applicants who intend to seek health service provider certification and who have completed a program in one or more of the American Psychological Association designated health service provider delivery areas shall be obtained under the primary supervision of a licensed psychologist who is also a health service provider or who otherwise meets the requirements for health service provider certification. [Postdoctoral] Experience for those applicants who do not intend to seek health service provider certification shall be obtained under the primary supervision of a licensed psychologist or such other qualified mental health professional approved by the committee.

6. **For postinternship and postdoctoral hours,** the psychological activities of the applicant shall be performed pursuant to the primary supervisor's order, control, and full professional responsibility. The primary supervisor shall maintain a continuing relationship with the applicant and shall meet with the applicant a minimum of one hour per month in face-to-face individual supervision. Clinical supervision may be delegated by the primary supervisor to one or more secondary supervisors who are qualified psychologists. The secondary supervisors shall retain order, control, and full professional responsibility for the applicant's clinical work under their supervision and shall meet with the applicant a minimum of one hour per week in face-to-face individual supervision. If the primary supervisor is also the clinical supervisor, meetings shall be a minimum of one hour per week. Group supervision shall not be acceptable for supervised professional experience. The primary supervisor shall certify to the committee that the applicant has complied with these requirements and that the applicant has demonstrated ethical and competent practice of psychology. The changing by an agency of the primary supervisor during the course of the supervised experience shall not invalidate the supervised experience.

7. The committee by rule shall provide procedures for exceptions and variances from the requirements for once a week face-to-face supervision due to vacations, illness, pregnancy, and other good causes.

338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration
of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by rule or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of his or her own prescriptions.

2. Any pharmacist who accepts a prescription order for a medication therapeutic plan shall have a written protocol from the physician who refers the patient for medication therapy services. The written protocol and the prescription order for a medication therapeutic plan shall come from the physician only, and shall not come from a nurse engaged in a collaborative practice arrangement under section 334.104, or from a physician assistant engaged in a supervision agreement under section 334.735.

3. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

4. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such
drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

5. No health carrier as defined in chapter 376 shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication therapeutic services.

6. This section shall not be construed to allow a pharmacist to diagnose or independently prescribe pharmaceuticals.

7. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

8. The state board of pharmacy may grant a certificate of medication therapeutic plan authority to a licensed pharmacist who submits proof of successful completion of a board-approved course of academic clinical study beyond a bachelor of science in pharmacy, including but not limited to clinical assessment skills, from a nationally accredited college or university, or a certification of equivalence issued by a nationally recognized professional organization and approved by the board of pharmacy.

9. Any pharmacist who has received a certificate of medication therapeutic plan authority may engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a prescription order from a physician that is specific to each patient for care by a pharmacist.

10. Nothing in this section shall be construed to allow a pharmacist to
make a therapeutic substitution of a pharmaceutical prescribed by a physician
unless authorized by the written protocol or the physician's prescription order.

11. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or an equivalent title means a person who has received a doctor's degree in veterinary medicine from an accredited school of veterinary medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical Association (AVMA).

12. In addition to other requirements established by the joint promulgation of rules by the board of pharmacy and the state board of registration for the healing arts:

(1) A pharmacist shall administer vaccines by protocol in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC);

(2) A pharmacist who is administering a vaccine shall request a patient to remain in the pharmacy a safe amount of time after administering the vaccine to observe any adverse reactions. Such pharmacist shall have adopted emergency treatment protocols;

(3) In addition to other requirements by the board, a pharmacist shall receive additional training as required by the board and evidenced by receiving a certificate from the board upon completion, and shall display the certification in his or her pharmacy where vaccines are delivered.

13. A pharmacist shall provide a written report within fourteen days of administration of a vaccine to the patient's primary health care provider, if provided by the patient, containing:

(1) The identity of the patient;

(2) The identity of the vaccine or vaccines administered;

(3) The route of administration;

(4) The anatomic site of the administration;

(5) The dose administered; and

(6) The date of administration.

345.051. 1. Every person licensed or registered pursuant to the provisions of sections 345.010 to 345.080 shall renew the license or registration on or before the renewal date. Such renewal date shall be determined by the board, but shall be no less than three years. The application shall be made on a form furnished by the board. The application shall include, but not be limited to, disclosure of the applicant's full name and the applicant's office and residence...
addresses and the date and number of the applicant's license or registration, all final disciplinary actions taken against the applicant by any speech-language-hearing association or society, state, territory or federal agency or country and information concerning the applicant's current physical and mental fitness to practice.

2. A blank form for application for license or registration renewal shall be mailed to each person licensed or registered in this state at the person's last known office or residence address. The failure to mail the form of application or the failure to receive it does not, however, relieve any person of the duty to renew the license or registration and pay the fee required by sections 345.010 to 345.080 for failure to renew the license or registration.

3. An applicant for renewal of a license or registration under this section shall:
   (1) Submit an amount established by the board; and
   (2) Meet any other requirements the board establishes as conditions for license or registration renewal, including the demonstration of continued competence to practice the profession for which the license or registration is issued. A requirement of continued competence may include, but is not limited to, up to thirty hours triennially of continuing education, examination, self-evaluation, peer review, performance appraisal or practical simulation.

4. If a license or registration is suspended pursuant to section 345.065, the license or registration expires on the expiration date as established by the board for all licenses and registrations issued pursuant to sections 345.010 to 345.080. Such license or registration may be renewed but does not entitle the licensee to engage in the licensed or registered activity or in any other conduct or activity which violates the order of judgment by which the license or registration was suspended until such license or registration has been reinstated.

5. If a license or registration is revoked on disciplinary grounds pursuant to section 345.065, the license or registration expires on the expiration date as established by the board for all licenses and registrations issued pursuant to sections 345.010 to 345.080. Such license or registration may not be renewed. If a license or registration is reinstated after its expiration, the licensee, as a condition of reinstatement, shall pay a reinstatement fee that is equal to the renewal fee in effect on the last regular renewal date immediately preceding the date of reinstatement plus any late fee established by the board.

478.004. 1. As used in this section, "medication-assisted treatment" means the use of pharmacological medications, in combination with counseling and behavioral therapies, to provide a
whole patient approach to the treatment of substance use disorders.

2. If a drug court or veterans court participant requires treatment for opioid or other substance misuse or dependence, a drug court or veterans court shall not prohibit such participant from participating in and receiving medication-assisted treatment under the care of a physician licensed in this state to practice medicine. A drug court or veterans court participant shall not be required to refrain from using medication-assisted treatment as a term or condition of successful completion of the drug court program.

3. A drug court or veterans court participant assigned to a treatment program for opioid or other substance misuse or dependence shall not be in violation of the terms or conditions of the drug court or veterans court on the basis of his or her participation in medication-assisted treatment under the care of a physician licensed in this state to practice medicine.

487.200. 1. As used in this section, "medication-assisted treatment" means the use of pharmacological medications, in combination with counseling and behavioral therapies, to provide a whole patient approach to the treatment of substance use disorders.

2. If a family court participant requires treatment for opioid or other substance misuse or dependence, a family court shall not prohibit such participant from participating in and receiving medication-assisted treatment under the care of a physician licensed in this state to practice medicine. A family court participant shall not be required to refrain from using medication-assisted treatment as a term or condition of successful completion of the family court program.

3. A family court participant assigned to a treatment program for opioid or other substance misuse or dependence shall not be in violation of the terms or conditions of the family court on the basis of his or her participation in medication-assisted treatment under the care of a physician licensed in this state to practice medicine.

Section 1. The Missouri board of pharmacy, in consultation with the Missouri department of health and senior services, shall be authorized to expend, allocate, or award funds appropriated to the board to private or public entities to develop a drug take-back program. Such program shall collect and dispose of Schedule II and III controlled substances, as described in section 195.017.

Section B. The enactment of section 197.005 and the repeal and reenactment of sections 197.040, 197.050, 197.070, 197.071, 197.080, and 197.100
3 of this act shall become effective on July 1, 2018.
AN ACT

To repeal sections 208.227, 208.790, 208.798, and 334.506, RSMo, and to enact in lieu thereof eight new sections relating to health care.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 208.227, 208.790, 208.798, and 334.506, RSMo, are repealed and eight new sections enacted in lieu thereof, to be known as sections 196.990, 208.227, 208.229, 208.790, 208.798, 334.506, 338.700, and 338.710, to read as follows:

196.990. 1. As used in this section, the following terms shall mean:

(1) "Administer", the direct application of an epinephrine auto-injector to the body of an individual;

(2) "Authorized entity", any entity or organization at or in connection with which allergens capable of causing anaphylaxis may be present including, but not limited to, restaurants, recreation camps, youth sports leagues, amusement parks, and sports arenas. "Authorized entity" shall not include any public school or public charter school;

(3) "Epinephrine auto-injector", a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body;

(4) "Physician", a physician licensed in this state under chapter 334;

EXPLANATION--Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.
(5) "Provide", the supply of one or more epinephrine auto-injectors to an individual;

(6) "Self-administration", a person's discretionary use of an epinephrine auto-injector.

2. A physician may prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with this section, and pharmacists, physicians, and other persons authorized to dispense prescription medications may dispense epinephrine auto-injectors under a prescription issued in the name of an authorized entity.

3. An authorized entity may acquire and stock a supply of epinephrine auto-injectors under a prescription issued in accordance with this section. Such epinephrine auto-injectors shall be stored in a location readily accessible in an emergency and in accordance with the epinephrine auto-injector's instructions for use and any additional requirements established by the department of health and senior services by rule. An authorized entity shall designate employees or agents who have completed the training required under this section to be responsible for the storage, maintenance, and general oversight of epinephrine auto-injectors acquired by the authorized entity.

4. An authorized entity that acquires a supply of epinephrine auto-injectors under a prescription issued in accordance with this section shall ensure that:

   (1) Expected epinephrine auto-injector users receive training in recognizing symptoms of severe allergic reactions including anaphylaxis and the use of epinephrine auto-injectors from a nationally recognized organization experienced in training laypersons in emergency health treatment or another entity or person approved by the department of health and senior services;

   (2) All epinephrine auto-injectors are maintained and stored according to the epinephrine auto-injector's instructions for use;

   (3) Any person who provides or administers an epinephrine auto-injector to an individual who the person believes in good faith is experiencing anaphylaxis activates the emergency medical services system as soon as possible; and

   (4) A proper review of all situations in which an epinephrine auto-injector is used to render emergency care is conducted.

5. Any authorized entity that acquires a supply of epinephrine auto-injectors under a prescription issued by a physician or another person authorized by the department of health and senior services shall ensure that:

   (1) The prescribed medications are dispensed in accordance with the prescription and the instructions for use;

   (2) The prescribed medications are stored in a location readily accessible in an emergency and in accordance with the prescribed medications' instructions for use and any additional requirements established by the department of health and senior services by rule; and

   (3) The authorized entity's employees or agents who have completed the training required under this section are responsible for the storage, maintenance, and general oversight of the prescribed medications acquired by the authorized entity.
auto-injectors under a prescription issued in accordance with this section shall notify the emergency communications district or the ambulance dispatch center of the primary provider of emergency medical services where the epinephrine auto-injectors are to be located within the entity's facility.

6. No person shall provide or administer an epinephrine auto-injector to any individual who is under eighteen years of age without the verbal consent of a parent or guardian who is present at the time when provision or administration of the epinephrine auto-injector is needed. Provided, however, that a person may provide or administer an epinephrine auto-injector to such an individual without the consent of a parent or guardian if the parent or guardian is not physically present and the person reasonably believes the individual shall be in imminent danger without the provision or administration of the epinephrine auto-injector.

7. The following persons and entities shall not be liable for any injuries or related damages that result from the administration or self-administration of an epinephrine auto-injector in accordance with this section that may constitute ordinary negligence:

(1) An authorized entity that possesses and makes available epinephrine auto-injectors and its employees, agents, and other trained persons;

(2) Any person who uses an epinephrine auto-injector made available under this section;

(3) A physician that prescribes epinephrine auto-injectors to an authorized entity; or

(4) Any person or entity that conducts the training described in this section.

Such immunity does not apply to acts or omissions constituting a reckless disregard for the safety of others or willful or wanton conduct. The administration of an epinephrine auto-injector in accordance with this section shall not be considered the practice of medicine. The immunity from liability provided under this subsection is in addition to and not in lieu of that provided under section 537.037. An authorized entity located in this state shall not be liable for any injuries or related damages that result from the provision or administration of an epinephrine auto-injector by its employees or
agents outside of this state if the entity or its employee or agent is not liable for such injuries or related damages under the laws of the state in which such provision or administration occurred. No trained person who is in compliance with this section and who in good faith and exercising reasonable care fails to administer an epinephrine auto-injector shall be liable for such failure.

8. All basic life support ambulances and stretcher vans operated in the state shall be equipped with epinephrine auto-injectors and be staffed by at least one individual trained in the use of epinephrine auto-injectors.

9. The provisions of this section shall apply in all counties within the state and any city not within a county.

10. Nothing in this section shall be construed as superseding the provisions of section 167.630.

208.227. [Fee for service eligible policies for prescribing psychotropic medications shall not include any new limits to initial access requirements, except dose optimization or new drug combinations consisting of one or more existing drug entities or preference algorithms for SSRI antidepressants, for persons with mental illness diagnosis, or other illnesses for which treatment with psychotropic medications are indicated and the drug has been approved by the federal Food and Drug Administration for at least one indication and is a recognized treatment in one of the standard reference compendia or in substantially accepted peer-reviewed medical literature and deemed medically appropriate for a diagnosis.] 1. No restrictions to access shall be imposed that preclude availability of any individual atypical antipsychotic monotherapy for the treatment of schizophrenia, bipolar disorder, or psychosis associated with severe depression. The division shall establish a pharmaceutical case management or polypharmacy program for high-risk MO HealthNet participants with numerous or multiple prescribed drugs. The division shall also establish a behavioral health pharmacy and opioid surveillance program to encourage the use of best medical evidence-supported prescription practices. The division shall communicate with providers, as such term is defined in section 208.164, whose prescribing practices deviate from or do not otherwise utilize best medical evidence-supported prescription practices. The communication may be telemetric, written, oral, or some combination thereof. These programs
shall be established and administered through processes established and supported under a memorandum of understanding between the department of mental health and the department of social services, or their successor entities.

2. The provisions of this section shall not prohibit the division from utilizing clinical edits to ensure clinical best practices including, but not limited to:

   (1) Drug safety and avoidance of harmful drug interactions;
   (2) Compliance with nationally recognized and juried clinical guidelines from national medical associations using medical evidence and emphasizing best practice principles;
   (3) Detection of patients receiving prescription drugs from multiple prescribers; and
   (4) Detection, prevention, and treatment of substance use disorders.

3. The division shall issue a provider update no less than twice annually to enumerate treatment and utilization principles for MO HealthNet providers including, but not limited to:

   (1) Treatment with antipsychotic drugs, as with any other form of treatment, should be individualized in order to optimize the patient's recovery and stability;
   (2) Treatment with antipsychotic drugs should be as effective, safe, and well-tolerated as supported by best medical evidence;
   (3) Treatment with antipsychotic drugs should consider the individual patient's needs, preferences, and vulnerabilities;
   (4) Treatment with antipsychotic drugs should support an improved quality of life for the patient;
   (5) Treatment choices should be informed by the best current medical evidence and should be updated consistent with evolving nationally recognized best practice guidelines; and
   (6) Cost considerations in the context of best practices, efficacy, and patient response to adverse drug reactions should guide antipsychotic medication policy and selection once the preceding principles have been maximally achieved.

4. If the division implements any new policy or clinical edit for an antipsychotic drug, the division shall continue to allow MO HealthNet participants access to any antipsychotic drug that they
utilize and on which they are stable or that they have successfully utilized previously. The division shall adhere to the following:

1. If an antipsychotic drug listed as "nonpreferred" is considered clinically appropriate for an individual patient based on the patient's previous response to the drug or other medical considerations, prior authorization procedures, as such term is defined in section 208.164, shall be simple and flexible;

2. If an antipsychotic drug listed as "nonpreferred" is known or found to be safe and effective for a given individual, the division shall not restrict the patient's access to that drug. Such nonpreferred drug shall, for that patient only and if that patient has been reasonably adherent to the prescribed therapy, be considered "preferred" in order to minimize the risk of relapse and to support continuity of care for the patient;

3. A patient shall not be required to change antipsychotic drugs due to changes in medication management policy, prior authorization, or a change in the payor responsible for the benefit; and

4. Patients transferring from state psychiatric hospitals to community-based settings, including patients previously found to be not guilty of a criminal offense by reason of insanity or who have previously been found to be incompetent to stand trial, shall be permitted to continue the medication regimen that aided the stability and recovery so that such patient was able to successfully transition to the community-based setting.

5. The division's medication policy and clinical edits shall provide MO HealthNet participants initial access to multiple Food and Drug Administration-approved antipsychotic drugs that have substantially the same clinical differences and adverse effects that are predictable across individual patients and whose manufacturers have entered into a federal rebate agreement with the Department of Health and Human Services. Clinical differences may include, but not be limited to, weight gain, extrapyramidal side effects, sedation, susceptibility to metabolic syndrome, other substantial adverse effects, the availability of long-acting formulations, and proven efficacy in the treatment of psychosis. The available drugs for an individual patient shall include, but not be limited to, the following categories:

1. At least one relatively weight-neutral atypical antipsychotic
medication;

(2) At least one long-acting injectable formulation of an atypical antipsychotic;

(3) Clozapine;

(4) At least one atypical antipsychotic medication with relatively potent sedative effects;

(5) At least one medium-potency typical antipsychotic medication;

(6) At least one long-acting injectable formulation of a high-potency typical antipsychotic medication;

(7) At least one high-potency typical antipsychotic medication;

and

(8) At least one low-potency typical antipsychotic medication.

6. Nothing in subsection 5 of this section shall be construed to require any of the following:

(1) Step therapy or a trial of a typical antipsychotic drug before permitting a patient access to an atypical drug or antipsychotic medication;

(2) A limit of one atypical antipsychotic drug as an open-access, first-choice agent; or

(3) A trial of one of the eight categories of drugs listed in subsection 5 of this section before having access to the other seven categories.

7. The department of social services may promulgate rules and regulations to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable, and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2017, shall be invalid and void.

8. The department shall submit such state plan amendments and waivers to the Centers for Medicare and Medicaid Services of the federal Department of Health and Human Services as the department
determines are necessary to implement the provisions of this section.

9. As used in this section, the following terms mean:

(1) "Division", the MO HealthNet division of the department of social services;

(2) "Reasonably adherent", a patient's adherence to taking medication on a prescribed schedule as measured by a medication position ratio of at least seventy-five percent;

(3) "Successfully utilized previously", a drug or drug regimen's provision of clinical stability in treating a patient's symptoms.

208.229. 1. Pharmaceutical manufacturers shall pay to the state, in accordance with 42 U.S.C. Section 1396r-8, rebates on eligible utilization of covered outpatient drugs dispensed to MO HealthNet participants under the MO HealthNet pharmacy program as follows:

(1) For single source drugs and innovator multiple source drugs, rebates shall reflect the manufacturer's best price, as defined by 42 CFR 447.505, as updated and amended, and set forth in 42 CFR 447.509, as updated and amended; and

(2) For single source drugs and innovator and noninnovator multiple source drugs, any additional rebates necessary to account for certain price increases in excess of inflation, as set forth in 42 CFR 447.509, as updated and amended.

2. For purposes of this section, the terms "innovator multiple source drug", "noninnovator multiple source drug", and "single source drug" shall have the same meanings as defined in 42 CFR 447.502, as updated and amended.

208.790. 1. The applicant shall have or intend to have a fixed place of residence in Missouri, with the present intent of maintaining a permanent home in Missouri for the indefinite future. The burden of establishing proof of residence within this state is on the applicant. The requirement also applies to persons residing in long-term care facilities located in the state of Missouri.

2. The department shall promulgate rules outlining standards for documenting proof of residence in Missouri. Documents used to show proof of residence shall include the applicant’s name and address in the state of Missouri.

3. Applicant household income limits for eligibility shall be subject to appropriations, but in no event shall applicants have household income that is greater than one hundred eighty-five percent of the federal poverty level for the applicable family size for the applicable year as converted to the MAGI equivalent
net income standard. **The provisions of this subsection shall only apply to Medicaid dual eligible individuals.**

4. The department shall promulgate rules outlining standards for documenting proof of household income.

208.798. The provisions of sections 208.780 to 208.798 shall terminate on August 28, [2017] 2022.

334.506. 1. As used in this section, "approved health care provider" means a person holding a current and active license as a physician and surgeon under this chapter, a chiropractor under chapter 331, a dentist under chapter 332, a podiatrist under chapter 330, a physician assistant under this chapter, an advanced practice registered nurse under chapter 335, or any licensed and registered physician, chiropractor, dentist, or podiatrist practicing in another jurisdiction whose license is in good standing.

2. A physical therapist shall not initiate treatment for a new injury or illness without a prescription from an approved health care provider.

3. A physical therapist may provide educational resources and training, develop fitness or wellness programs for asymptomatic persons, or provide screening or consultative services within the scope of physical therapy practice without the prescription and direction of an approved health care provider.

4. A physical therapist may examine and treat without the prescription and direction of an approved health care provider any person with a recurring self-limited injury within one year of diagnosis by an approved health care provider or a chronic illness that has been previously diagnosed by an approved health care provider. The physical therapist shall:

   (1) Contact the patient's current approved health care provider within seven days of initiating physical therapy services under this subsection;

   (2) Not change an existing physical therapy referral available to the physical therapist without approval of the patient's current approved health care provider;

   (3) Refer to an approved health care provider any patient whose medical condition at the time of examination or treatment is determined to be beyond the scope of practice of physical therapy;

   (4) Refer to an approved health care provider any patient whose condition for which physical therapy services are rendered under this subsection has not been documented to be progressing toward documented treatment goals after six visits or fourteen days, whichever first occurs;
(5) Notify the patient's current approved health care provider prior to the continuation of treatment if treatment rendered under this subsection is to continue beyond thirty days. The physical therapist shall provide such notification for each successive period of thirty days.

5. The provision of physical therapy services of evaluation and screening pursuant to this section shall be limited to a physical therapist, and any authority for evaluation and screening granted within this section may not be delegated. Upon each reinitiation of physical therapy services, a physical therapist shall provide a full physical therapy evaluation prior to the reinitiation of physical therapy treatment. Physical therapy treatment provided pursuant to the provisions of subsection 4 of this section may be delegated by physical therapists to physical therapist assistants only if the patient's current approved health care provider has been so informed as part of the physical therapist's seven-day notification upon reinitiation of physical therapy services as required in subsection 4 of this section. Nothing in this subsection shall be construed as to limit the ability of physical therapists or physical therapist assistants to provide physical therapy services in accordance with the provisions of this chapter, and upon the referral of an approved health care provider. Nothing in this subsection shall prohibit an approved health care provider from acting within the scope of their practice as defined by the applicable chapters of RSMo.

6. No person licensed to practice, or applicant for licensure, as a physical therapist or physical therapist assistant shall make a medical diagnosis.

7. A physical therapist shall only delegate physical therapy treatment to a physical therapist assistant or to a person in an entry level of a professional education program approved by the Commission on Accreditation of Physical Therapy Education (CAPTE) who satisfies supervised clinical education requirements related to the person's physical therapist or physical therapist assistant education. The entry-level person shall be under the supervision of a physical therapist.

338.700. As used in sections 338.700 to 338.710, the following terms shall mean:

1. "Board", the Missouri board of pharmacy;

2. "Department", the Missouri department of health and senior services;

3. "Program", the RX cares for Missouri program.

338.710. 1. There is hereby created in the Missouri board of
pharmacy the "RX Cares for Missouri Program". The goal of the program shall be to promote medication safety and to prevent prescription drug abuse, misuse, and diversion in Missouri.

2. The board, in consultation with the department, shall be authorized to expend, allocate, or award funds appropriated to the board to private or public entities to develop or provide programs or education to promote medication safety or to suppress or prevent prescription drug abuse, misuse, and diversion in the state of Missouri. In no case shall the authorization include, nor the funds be expended for, any state prescription drug monitoring program including, but not limited to, such as are defined in 38 CFR 1.515. Funds disbursed to a state agency under this section may enhance, but shall not supplant, funds otherwise appropriated to such state agency.

3. The board shall be the administrative agency responsible for implementing the program in consultation with the department. The board and the department may enter into interagency agreements between themselves to allow the department to assist in the management or operation of the program. The board may award funds directly to the department to implement, manage, develop, or provide programs or education pursuant to the program.

4. After a full year of program operation, the board shall prepare and submit an evaluation report to the governor and the general assembly describing the operation of the program and the funds allocated. Unless otherwise authorized by the general assembly, the program shall expire on August 28, 2019.
AN ACT

To repeal sections 190.241, 191.332, 197.040, 197.050, 197.070, 197.071, 197.080, 197.100, 332.081, 334.036, and 345.051, RSMo, and to enact in lieu thereof sixteen new sections relating to health care, with an effective date for certain sections.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 190.241, 191.332, 197.040, 197.050, 197.070, 197.071, 197.080, 197.100, 332.081, 334.036, and 345.051, RSMo, are repealed and sixteen new sections enacted in lieu thereof, to be known as sections 190.241, 190.242, 191.332, 192.380, 192.500, 194.600, 197.005, 197.040, 197.050, 197.070, 197.071, 197.080, 197.100, 332.081, 334.036, and 345.051, to read as follows:

190.241. 1. The department shall designate a hospital as an adult, pediatric or adult and pediatric trauma center when a hospital, upon proper application submitted by the hospital and site review, has been found by the department to meet the applicable level of trauma center criteria for designation in accordance with rules adopted by the department as prescribed by section 190.185. Such rules shall include designation as a trauma center without site review if such hospital is verified by a national verifying or designating body at the level which corresponds to a level approved in rule.

2. Except as provided for in subsection [4] 5 of this section, the department shall designate a hospital as a STEMI or stroke center when such hospital, upon proper application and site review, has been found by the department to meet the applicable level of stroke center criteria for designation in accordance with rules adopted by the department as prescribed by section 190.185. Such rules shall include designation as a stroke center without site review if such hospital is certified by a national certifying or designating body at the level which corresponds to a level approved in rule.

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.
department to meet the applicable level of STEMI or stroke center criteria for designation in accordance with rules adopted by the department as prescribed by section 190.185. In developing STEMI center and stroke center designation criteria, the department shall use, as it deems practicable, appropriate peer-reviewed or evidence-based research on such topics including, but not limited to, the most recent guidelines of the American College of Cardiology and American Heart Association for STEMI centers, or the Joint Commission's Primary Stroke Center Certification program criteria for stroke centers, or Primary and Comprehensive Stroke Center Recommendations as published by the American Stroke Association. **Such rules shall include designation as a STEMI center without site review if such hospital is certified by a national body.**

3. The department of health and senior services shall, not less than once every five years, conduct an on-site review of every trauma, STEMI, and stroke center through appropriate department personnel or a qualified contractor, with the exception of stroke centers designated pursuant to subsection [4] 5 of this section; however, this provision is not intended to limit the department’s ability to conduct a complaint investigation pursuant to subdivision (3) of subsection 2 of section 197.080 of any trauma, STEMI, or stroke center. On-site reviews shall be coordinated for the different types of centers to the extent practicable with hospital licensure inspections conducted under chapter 197. No person shall be a qualified contractor for purposes of this subsection who has a substantial conflict of interest in the operation of any trauma, STEMI, or stroke center under review. The department may deny, place on probation, suspend or revoke such designation in any case in which it has reasonable cause to believe that there has been a substantial failure to comply with the provisions of this chapter or any rules or regulations promulgated pursuant to this chapter. If the department of health and senior services has reasonable cause to believe that a hospital is not in compliance with such provisions or regulations, it may conduct additional announced or unannounced site reviews of the hospital to verify compliance. If a trauma, STEMI, or stroke center fails two consecutive on-site reviews because of substantial noncompliance with standards prescribed by sections 190.001 to 190.245 or rules adopted by the department pursuant to sections 190.001 to 190.245, its center designation shall be revoked.

4. **Instead of applying for STEMI center designation under subsection 2 of this section, a hospital may apply for STEMI center designation under this subsection.** Upon receipt of an application from
a hospital on a form prescribed by the department, the department shall designate such hospital:

(1) A level I STEMI center if such hospital has been certified as a Joint Commission comprehensive cardiac center or another department-approved nationally-recognized organization that provides comparable STEMI center accreditation; or

(2) A level II STEMI center if such hospital has been accredited as a Mission: Lifeline STEMI receiving center by the American Heart Association accreditation process or another department-approved nationally-recognized organization that provides STEMI receiving center accreditation.

5. Instead of applying for stroke center designation pursuant to the provisions of subsection 2 of this section, a hospital may apply for stroke center designation pursuant to this subsection. Upon receipt of an application from a hospital on a form prescribed by the department, the department shall designate such hospital:

(1) A level I stroke center if such hospital has been certified as a comprehensive stroke center by the Joint Commission or any other certifying organization designated by the department when such certification is in accordance with the American Heart Association/American Stroke Association guidelines;

(2) A level II stroke center if such hospital has been certified as a primary stroke center by the Joint Commission or any other certifying organization designated by the department when such certification is in accordance with the American Heart Association/American Stroke Association guidelines; or

(3) A level III stroke center if such hospital has been certified as an acute stroke-ready hospital by the Joint Commission or any other certifying organization designated by the department when such certification is in accordance with the American Heart Association/American Stroke Association guidelines.

Except as provided by subsection [5] 6 of this section, the department shall not require compliance with any additional standards for establishing or renewing stroke designations. The designation shall continue if such hospital remains certified. The department may remove a hospital’s designation as a stroke center if the hospital requests removal of the designation or the department determines that the certificate recognizing the hospital as a stroke center has been suspended or revoked. Any decision made by the department to withdraw its designation of
a stroke center pursuant to this subsection that is based on the revocation or
suspension of a certification by a certifying organization shall not be subject to
judicial review. The department shall report to the certifying organization any
complaint it receives related to the stroke center certification of a stroke center
designated pursuant to this subsection. The department shall also advise the
complainant which organization certified the stroke center and provide the
necessary contact information should the complainant wish to pursue a complaint
with the certifying organization.

[5.] 6. Any hospital receiving designation as a stroke center pursuant to
subsection 45 of this section shall:

(1) Annually and within thirty days of any changes submit to the
department proof of stroke certification and the names and contact information
of the medical director and the program manager of the stroke center;

(2) Submit to the department a copy of the certifying organization's final
stroke certification survey results within thirty days of receiving such results;

(3) Submit every four years an application on a form prescribed by the
department for stroke center review and designation;

(4) Participate in the emergency medical services regional system of
stroke care in its respective emergency medical services region as defined in rules
promulgated by the department;

(5) Participate in local and regional emergency medical services systems
by reviewing and sharing outcome data and providing training and clinical
educational resources.

Any hospital receiving designation as a level III stroke center pursuant to
subsection 45 of this section shall have a formal agreement with a level I or
level II stroke center for physician consultative services for evaluation of stroke
patients for thrombolytic therapy and the care of the patient post-thrombolytic
therapy.

[6.] 7. Hospitals designated as a STEMI or stroke center by the
department, including those designated pursuant to subsection 45 of this
section, shall submit data to meet the data submission requirements specified by
rules promulgated by the department. Such submission of data may be done by
the following methods:

(1) Entering hospital data directly into a state registry by direct data
entry;

(2) Downloading hospital data from a nationally recognized registry or
data bank and importing the data files into a state registry; or
(3) Authorizing a nationally recognized registry or data bank to disclose or grant access to the department facility-specific data held by the registry or data bank.

A hospital submitting data pursuant to subdivision (2) or (3) of this subsection shall not be required to collect and submit any additional STEMI or stroke center data elements.

[7.] 8. When collecting and analyzing data pursuant to the provisions of this section, the department shall comply with the following requirements:

(1) Names of any health care professionals, as defined in section 376.1350, shall not be subject to disclosure;

(2) The data shall not be disclosed in a manner that permits the identification of an individual patient or encounter;

(3) The data shall be used for the evaluation and improvement of hospital and emergency medical services' trauma, stroke, and STEMI care;

(4) The data collection system shall be capable of accepting file transfers of data entered into any national recognized trauma, stroke, or STEMI registry or data bank to fulfill trauma, stroke, or STEMI certification reporting requirements; and

(5) STEMI and stroke center data elements shall conform to nationally recognized performance measures, such as the American Heart Association's Get With the Guidelines, and include published detailed measure specifications, data coding instructions, and patient population inclusion and exclusion criteria to ensure data reliability and validity; and

(6) Generate from the trauma, stroke, and STEMI registries quarterly regional and state outcome data reports for trauma, stroke, and STEMI designated centers, the state advisory council on EMS, and regional EMS committees to review for performance improvement and patient safety.

[8.] 9. The board of registration for the healing arts shall have sole authority to establish education requirements for physicians who practice in an emergency department of a facility designated as a trauma, STEMI, or stroke center by the department under this section. The department shall deem such education requirements promulgated by the board of registration for the healing arts sufficient to meet the standards for designations under this section.

[9.] 10. The department of health and senior services may establish appropriate fees to offset the costs of trauma, STEMI, and stroke center reviews.

[10.] 11. No hospital shall hold itself out to the public as a STEMI center, stroke center, adult trauma center, pediatric trauma center, or an adult
and pediatric trauma center unless it is designated as such by the department of health and senior services.

[11.] 12. Any person aggrieved by an action of the department of health and senior services affecting the trauma, STEMI, or stroke center designation pursuant to this chapter, including the revocation, the suspension, or the granting of, refusal to grant, or failure to renew a designation, may seek a determination thereon by the administrative hearing commission under chapter 621. It shall not be a condition to such determination that the person aggrieved seek a reconsideration, a rehearing, or exhaust any other procedure within the department.

190.242. 1. In order to ensure that hospitals can be free from excessive regulation that increases health care costs without increasing patient safety, any rules and regulations promulgated by the department of health and senior services under sections 190.185, 190.241, or 192.006; chapter 197; or any other provision of Missouri law shall not require hospitals, as a condition of designation under section 190.241, to obtain emergency medical services data under section 190.241, unless such data may be obtained from the state database for emergency medical services. The provisions of this subsection shall not be construed to limit in any way the requirements of any person or entity to submit emergency medical services data to any person or entity.

2. A hospital shall not be required to comply with an interpretation of a specific provision in any regulation concerning trauma, STEMI, or stroke centers if such hospital can demonstrate that the specific provision in the regulation has been interpreted differently for a similarly-situated hospital. The department may require compliance if the specific provision in the regulation has been subsequently interpreted consistently for similarly-situated hospitals.

3. The department shall attend meetings with trauma, STEMI, and stroke centers for the benefit of improved communication, best-practice identification, and facilitation of improvements to the designation process.

4. As used in this section, the term "hospital" shall have the same meaning as in section 197.020.

191.332. 1. By January 1, 2002, the department of health and senior services shall, subject to appropriations, expand the newborn screening
requirements in section 191.331 to include potentially treatable or manageable
disorders, which may include but are not limited to cystic fibrosis, galactosemia,
biotinidase deficiency, congenital adrenal hyperplasia, maple syrup urine disease
(MSUD) and other amino acid disorders, glucose-6-phosphate dehydrogenase
deficiency (G-6-PD), MCAD and other fatty acid oxidation disorders,
methylmalonic acidemia, propionic acidemia, isovaleric acidemia and glutaric
acidemia Type I.

2. By January 1, 2017, the department of health and senior services shall,
subject to appropriations, expand the newborn screening requirements in section
191.331 to include severe combined immunodeficiency (SCID), also known as
bubble boy disease. The department may increase the fee authorized under
subsection 6 of section 191.331 to cover any additional costs of the expanded
newborn screening requirements under this subsection.

3. By January 1, 2019, the department of health and senior
services shall, subject to appropriations, expand the newborn screening
requirements in section 191.331 to include spinal muscular atrophy
(SMA) and Hunter syndrome (MPS II). The department may increase
the fee authorized under subsection 6 of section 191.331 to cover any
additional costs of the expanded newborn screening requirements
under this subsection. To help fund initial costs incurred by the state,
the department shall apply for available newborn screening grant
funding specific to screening for spinal muscular atrophy and Hunter
syndrome. The department shall have discretion in accepting the terms
of such grants.

4. The department of health and senior services may promulgate rules to
implement the provisions of this section. No rule or portion of a rule promulgated
pursuant to the authority of this section shall become effective unless it has been
promulgated pursuant to chapter 536.

192.380. 1. For purposes of this section, the following terms shall
mean:

(1) "Birthing facility", any hospital as defined under section
197.020 with more than one licensed obstetric bed or a neonatal
intensive care unit, a hospital operated by a state university, or a
birthing center licensed under sections 197.200 to 197.240;

(2) "Department", the department of health and senior services.

2. After holding multiple public hearings in diverse geographic
regions of the state and seeking broad public and stakeholder input,
the department shall establish criteria for levels of maternal care
designations and levels of neonatal care designations for birthing
facilities. The levels developed under this section shall be based upon:

(1) The most current published version of the "Levels of Neonatal
Care" developed by the American Academy of Pediatrics;

(2) The most current published version of the "Levels of Maternal
Care" developed by the American Congress of Obstetricians and
Gynecologists and the Society for Maternal-Fetal Medicine; and

(3) Necessary variance when considering the geographic and
varied needs of citizens of this state.

3. Nothing in this section shall be construed in any way to
modify or expand the licensure of any health care professional.

4. Nothing in this section shall be construed in any way to
require a patient be transferred to a different facility.

5. The department shall promulgate rules to implement the
provisions of this section no later than January 1, 2018. Such rules
shall be limited to those necessary for the establishment of levels of
neonatal care designations and levels of maternal care designations for
birthing facilities under subsection 2 of this section. Any rule or
portion of a rule, as that term is defined in section 536.010, that is
created under the authority delegated in this section shall become
effective only if it complies with and is subject to all of the provisions
of chapter 536 and, if applicable, section 536.028. This section and
chapter 536 are nonseverable, and if any of the powers vested with the
general assembly pursuant to chapter 536 to review, to delay the
effective date, or to disapprove and annul a rule are subsequently held
unconstitutional, then the grant of rulemaking authority and any rule
proposed or adopted after August 28, 2017, shall be invalid and void.

6. Beginning January 1, 2019, any hospital with a birthing
facility shall report to the department its appropriate level of maternal
care designation and neonatal care designation as determined by the
criteria outlined under subsection 2 of this section.

7. Beginning January 1, 2019, any hospital with a birthing
facility operated by a state university shall report to the department its
appropriate level of maternal care designation and neonatal care
designation as determined by the criteria outlined under subsection 2
of this section.
8. The department may partner with appropriate nationally-recognized professional organizations with demonstrated expertise in maternal and neonatal standards of care to administer the provisions of this section.

9. The criteria for levels of maternal and neonatal care developed under subsection 2 of this section shall not include pregnancy termination or counseling or referral for pregnancy termination.

192.500. 1. For purposes of this section, the following terms shall mean:

(1) "Cone beam computed tomography system", a medical imaging device using x-ray computed tomography to capture data using a cone-shaped x-ray beam;

(2) "Panoramic x-ray system", an imaging device that captures the entire mouth in a single, two-dimensional image including the teeth, upper and lower jaws, and surrounding structures and tissues.

2. Cone beam computed tomography systems and panoramic x-ray systems that cannot produce radiation intensity greater than thirty milligrays shall not be required to be inspected more frequently than every three years.

3. Cone beam computed tomography systems that can produce radiation intensity of greater than thirty milligrays shall be inspected annually.

4. In addition to the requirements of subsections 2 and 3 of this section, all cone beam computed tomography systems and panoramic x-ray systems shall be inspected within thirty days of installation and whenever moved within an office.

5. Notwithstanding any law to the contrary, inspections of conventional x-ray equipment used exclusively on animals by a licensed veterinarian or veterinary facility under chapter 340 shall not be required to be inspected more frequently than every four years.

194.600. 1. As used in this section, the following terms mean:

(1) "Adult", an individual who is eighteen years of age or older;

(2) "Advance health care directive", a power of attorney for health care or a declaration signed or authorized by an adult, containing the person's direction concerning a health care decision;

(3) "Declaration", a record, including but not limited to a living
will or a do-not-resuscitate order, signed by an adult specifying the circumstances under which a life support system may be withheld or withdrawn;

(4) "Department", the department of health and senior services;
(5) "Health care decision", any decision regarding the health care of the person;
(6) "Intake point", any licensed health care provider or licensed attorney.

2. The department shall issue a request for proposal and contract with a third party for the establishment of a secure online central registry for individuals to be known as the "Advance Health Care Directives Registry" to store advance health care directives and to give authorized health care providers access to such directives.

3. An adult declarant may submit an advance health care directive or declaration and the revocations of such documents to the registry established under subsection 2 of this section.

4. Any document and any revocation of a document submitted for filing in the registry shall be submitted electronically at an intake point and signed electronically with a unique identifier, such as a social security number, a driver's license number, or another unique government-issued identifier. The electronic submission of the document shall be accompanied by a fee not to exceed ten dollars.

5. All data and information contained in the registry shall remain confidential and shall be exempt from the provisions of chapter 610.

6. The third party awarded a contract pursuant to subsection 2 of this section shall be solely responsible for all issues applicable to the registry, including, but not limited to, the development and operation of the registry; educating the general public, licensed health care providers, and legal professionals about the registry; responding to questions; providing technical assistance to users; and collection of user fees not to exceed ten dollars.

7. The department may promulgate rules to carry out the provisions of this section which may include, but not be limited to:
(1) A determination of who may access the registry, including physicians, other licensed health care providers, the declarant, and his or her legal representatives or designees; and
(2) A means for the contracting third party to annually remind registry users of which documents they have registered.

8. Any rule or portion of a rule, as that term is defined in section 536.010 that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2017, shall be invalid and void.

9. Failure to register a document with the registry maintained under this section shall not affect the document's validity. Failure to notify the registry of the revocation of a document previously filed with the registry shall not affect the validity of a revocation that meets the statutory requirements for such revocation to be valid.

197.005. 1. As used in this section, the term "Medicare conditions of participation" shall mean federal regulatory standards established under Title XVIII of the Social Security Act and defined in 42 CFR 482, as amended, for hospitals and 42 CFR 485, as amended, for hospitals designated as critical access hospitals under 42 U.S.C. Section 1395i-4.

2. To minimize the administrative cost of enforcing and complying with duplicative regulatory standards, on and after July 1, 2018, compliance with Medicare conditions of participation shall be deemed to constitute compliance with the standards for hospital licensure under sections 197.010 to 197.120 and regulations promulgated thereunder.

3. Nothing in this section shall preclude the department of health and senior services from promulgating regulations effective on or after July 1, 2018, to define separate regulatory standards that do not duplicate or contradict the Medicare conditions of participation, with specific state statutory authorization to create separate regulatory standards.

4. Regulations promulgated by the department of health and senior services to establish and enforce hospital licensure regulations under this chapter that duplicate or conflict with the Medicare
conditions of participation shall lapse and expire on and after July 1, 2018.

197.040. After ninety days from the date this law becomes effective, no person or governmental unit, acting severally or jointly with any other person or governmental unit, shall establish, conduct or maintain a hospital in this state without a license under this law and section 197.005 issued by the department of health and senior services.

197.050. Application for a license shall be made to the department of health and senior services upon forms provided by it and shall contain such information as the department of health and senior services requires, which may include affirmative evidence of ability to comply with such reasonable standards, rules and regulations as are lawfully prescribed hereunder in compliance with section 197.005. Until June 30, 1989, each application for a license, except applications from governmental units, shall be accompanied by an annual license fee of two hundred dollars plus two dollars per bed for the first one hundred beds and one dollar per bed for each additional bed. Beginning July 1, 1989, each application for a license, except applications from governmental units, shall be accompanied by an annual license fee of two hundred fifty dollars plus three dollars per bed for the first four hundred beds and two dollars per bed for each additional bed. All license fees shall be paid to the director of revenue and deposited in the state treasury to the credit of the general revenue fund.

197.070. The department of health and senior services may deny, suspend or revoke a license in any case in which it finds that there has been a substantial failure to comply with the requirements established under this law and section 197.005.

197.071. Any person aggrieved by an official action of the department of health and senior services affecting the licensed status of a person under the provisions of sections [197.010] 197.005 to 197.120, including the refusal to grant, the grant, the revocation, the suspension, or the failure to renew a license, may seek a determination thereon by the administrative hearing commission pursuant to the provisions of section 621.045, and it shall not be a condition to such determination that the person aggrieved seek a reconsideration, a rehearing, or exhaust any other procedure within the department of health and senior services.

197.080. 1. The department of health and senior services, with the advice of the state advisory council and pursuant to the provisions of this section, section 197.005, and chapter 536, shall adopt, amend, promulgate and enforce
such rules, regulations and standards with respect to all hospitals or different types of hospitals to be licensed hereunder as may be designed to further the accomplishment of the purposes of this law in promoting safe and adequate treatment of individuals in hospitals in the interest of public health, safety and welfare. No rule or portion of a rule promulgated under the authority of sections 197.010 to 197.280 shall become effective unless it has been promulgated pursuant to the provisions of section 536.024.

2. The department shall review and revise regulations governing hospital licensure and enforcement to promote hospital and regulatory efficiencies [and]. The department shall eliminate all duplicative regulations and inspections by or on behalf of state agencies and the Centers for Medicare and Medicaid Services (CMS). The hospital licensure regulations adopted under this [section] chapter shall incorporate standards which shall include, but not be limited to, the following:

(1) Each citation or finding of a regulatory deficiency shall refer to the specific written regulation, any state associated written interpretive guidance developed by the department and any publicly available, professionally recognized standards of care that are the basis of the citation or finding;

(2) Subject to appropriations, the department shall ensure that its hospital licensure regulatory standards are consistent with and do not contradict the CMS Conditions of Participation (COP) and associated interpretive guidance. However, this shall not preclude the department from enforcing standards produced by the department which exceed the federal CMS' COP and associated interpretive guidance, so long as such standards produced by the department promote a higher degree of patient safety and do not contradict the federal CMS' COP and associated interpretive guidance;

(3) The department shall establish and publish guidelines for complaint investigation, including but not limited to:

(a) The department's process for reviewing and determining which complaints warrant an on-site investigation based on a preliminary review of available information from the complainant, other appropriate sources, and when not prohibited by CMS, the hospital. For purposes of providing hospitals with information necessary to improve processes and patient care, the number and nature of complaints filed and the recommended actions by the department and, as appropriate CMS, shall be disclosed upon request to hospitals so long as the otherwise confidential identity of the complainant or the patient for whom the complaint was filed is not disclosed;
(b) A departmental investigation of a complaint shall be focused on the specific regulatory standard and departmental written interpretive guidance and publicly available professionally recognized standard of care related to the complaint. During the course of any complaint investigation, the department shall cite any serious and immediate threat discovered that may potentially jeopardize the health and safety of patients;

c) A hospital shall be provided with a report of all complaints made against the hospital. Such report shall include the nature of the complaint, the date of the complaint, the department conclusions regarding the complaint, the number of investigators and days of investigation resulting from each complaint;

(4) Hospitals and hospital personnel shall have the opportunity to participate in annual continuing training sessions when such training is provided to state licensure surveyors with prior approval from the department director and CMS when appropriate. Hospitals and hospital personnel shall assume all costs associated with facilitating the training sessions and use of curriculum materials, including but not limited to the location for training, food, and printing costs;

(5) Time lines for the department to provide responses to hospitals regarding the status and outcome of pending investigations and regulatory actions and questions about interpretations of regulations shall be identical to, to the extent practicable, the time lines established for the federal hospital certification and enforcement system in the CMS State Operations Manual, as amended. These time lines shall be the guide for the department to follow. Every reasonable attempt shall be made to meet the time lines. However, failure to meet the established time lines shall in no way prevent the department from performing any necessary inspections to ensure the health and safety of patients.

3. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2013, shall be invalid and void.

197.100. 1. Any provision of chapter 198 and chapter 338 to the contrary notwithstanding, the department of health and senior services shall have sole authority, and responsibility for inspection and licensure of hospitals in this state
including, but not limited to, all parts, services, functions, support functions and activities which contribute directly or indirectly to patient care of any kind whatsoever. The department of health and senior services shall annually inspect each licensed hospital and shall make any other inspections and investigations as it deems necessary for good cause shown. The department of health and senior services shall accept reports of hospital inspections from or on behalf of governmental agencies, the joint commission, and the American Osteopathic Association Healthcare Facilities Accreditation Program, provided the accreditation inspection was conducted within one year of the date of license renewal. Prior to granting acceptance of any other accrediting organization reports in lieu of the required licensure survey, the accrediting organization's survey process must be deemed appropriate and found to be comparable to the department's licensure survey. It shall be the accrediting organization's responsibility to provide the department any and all information necessary to determine if the accrediting organization's survey process is comparable and fully meets the intent of the licensure regulations. The department of health and senior services shall attempt to schedule inspections and evaluations required by this section so as not to cause a hospital to be subject to more than one inspection in any twelve-month period from the department of health and senior services or any agency or accreditation organization the reports of which are accepted for licensure purposes pursuant to this section, except for good cause shown.

2. Other provisions of law to the contrary notwithstanding, the department of health and senior services shall be the only state agency to determine life safety and building codes for hospitals defined or licensed pursuant to the provisions of this chapter, including but not limited to sprinkler systems, smoke detection devices and other fire safety-related matters so long as any new standards shall apply only to new construction.

332.081. 1. Notwithstanding any other provision of law to the contrary, hospitals licensed under chapter 197 shall be authorized to employ any or all of the following oral health providers:

(1) A dentist licensed under this chapter for the purpose of treating on hospital premises those patients who present with a dental condition and such treatment is necessary to ameliorate the condition for which they presented such as severe pain or tooth abscesses;

(2) An oral and maxillofacial surgeon licensed under this chapter for the purpose of treating oral conditions that need to be ameliorated as part of treating the underlying cause of the patient's medical needs
including, but not limited to, head and neck cancer, HIV or AIDS, severe trauma resulting in admission to the hospital, organ transplant, diabetes, or seizure disorders. It shall be a condition of treatment that such patients are admitted to the hospital on either an in- or outpatient basis; and

(3) A maxillofacial prosthodontist licensed under this chapter for the purpose of treating and supporting patients of a head and neck cancer team or other complex care or surgical team for the fabrication of appliances following ablative surgery, surgery to correct birth anomalies, extensive radiation treatment of the head or neck, or trauma-related surgery.

2. No person or other entity shall practice dentistry in Missouri or provide dental services as defined in section 332.071 unless and until the board has issued to the person a certificate certifying that the person has been duly registered as a dentist in Missouri or to an entity that has been duly registered to provide dental services by licensed dentists and dental hygienists and unless and until the board has issued to the person a license, to be renewed each period, as provided in this chapter, to practice dentistry or as a dental hygienist, or has issued to the person or entity a permit, to be renewed each period, to provide dental services in Missouri. Nothing in this chapter shall be so construed as to make it unlawful for:

(1) A legally qualified physician or surgeon, who does not practice dentistry as a specialty, from extracting teeth;

(2) A dentist licensed in a state other than Missouri from making a clinical demonstration before a meeting of dentists in Missouri;

(3) Dental students in any accredited dental school to practice dentistry under the personal direction of instructors;

(4) Dental hygiene students in any accredited dental hygiene school to practice dental hygiene under the personal direction of instructors;

(5) A duly registered and licensed dental hygienist in Missouri to practice dental hygiene as defined in section 332.091;

(6) A dental assistant, certified dental assistant, or expanded functions dental assistant to be delegated duties as defined in section 332.093;

(7) A duly registered dentist or dental hygienist to teach in an accredited dental or dental hygiene school;

(8) A duly qualified anesthesiologist or nurse anesthetist to administer an anesthetic in connection with dental services or dental surgery; or
(9) A person to practice dentistry in or for:
(a) The United States Armed Forces;
(b) The United States Public Health Service;
(c) Migrant, community, or health care for the homeless health centers provided in Section 330 of the Public Health Service Act (42 U.S.C. 254(b));
(d) Federally qualified health centers as defined in Section 1905(l) (42 U.S.C. 1396d(l)) of the Social Security Act;
(e) Governmental entities, including county health departments; or
(f) The United States Veterans Bureau; or
(10) A dentist licensed in a state other than Missouri to evaluate a patient or render an oral, written, or otherwise documented dental opinion when providing testimony or records for the purpose of a civil or criminal action before any judicial or administrative proceeding of this state or other forum in this state.

[2.] 3. No corporation shall practice dentistry as defined in section 332.071 unless that corporation is organized under the provisions of chapter 355 or 356 provided that a corporation organized under the provisions of chapter 355 and qualifying as an organization under 26 U.S.C. Section 501(c)(3) may only employ dentists and dental hygienists licensed in this state to render dental services to Medicaid recipients, low-income individuals who have available income below two hundred percent of the federal poverty level, and all participants in the SCHIP program, unless such limitation is contrary to or inconsistent with federal or state law or regulation. This subsection shall not apply to:
(1) A hospital licensed under chapter 197 that provides care and treatment only to children under the age of eighteen at which a person regulated under this chapter provides dental care within the scope of his or her license or registration;
(2) A federally qualified health center as defined in Section 1905(l) of the Social Security Act (42 U.S.C. 1396d(l)), or a migrant, community, or health care for the homeless health center provided for in Section 330 of the Public Health Services Act (42 U.S.C. 254(b)) at which a person regulated under this chapter provides dental care within the scope of his or her license or registration;
(3) A city or county health department organized under chapter 192 or chapter 205 at which a person regulated under this chapter provides dental care within the scope of his or her license or registration;
(4) A social welfare board organized under section 205.770, a city health department operating under a city charter, or a city-county health department at
which a person regulated under this chapter provides dental care within the
scope of his or her license or registration;
(5) Any entity that has received a permit from the dental board and does
not receive compensation from the patient or from any third party on the patient's
behalf at which a person regulated under this chapter provides dental care within
the scope of his or her license or registration;
(6) Any hospital nonprofit corporation exempt from taxation under Section
501(c)(3) of the Internal Revenue Code, as amended, that engages in its
operations and provides dental services at facilities owned by a city, county, or
other political subdivision of the state at which a person regulated under this
chapter provides dental care within the scope of his or her license or registration.
If any of the entities exempted from the requirements of this subsection are
unable to provide services to a patient due to the lack of a qualified provider and
a referral to another entity is made, the exemption shall extend to the person or
entity that subsequently provides services to the patient.
[3.] 4. No unincorporated organization shall practice dentistry as defined
in section 332.071 unless such organization is exempt from federal taxation under
Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, and provides
dental treatment without compensation from the patient or any third party on
their behalf as a part of a broader program of social services including food
distribution. Nothing in this chapter shall prohibit organizations under this
subsection from employing any person regulated by this chapter.
[4.] 5. A dentist shall not enter into a contract that allows a person who
is not a dentist to influence or interfere with the exercise of the dentist's
independent professional judgment.
[5.] 6. A not-for-profit corporation organized under the provisions of
chapter 355 and qualifying as an organization under 26 U.S.C. Section 501(c)(3),
an unincorporated organization operating pursuant to subsection [3] 4 of this
section, or any other person should not direct or interfere or attempt to direct or
interfere with a licensed dentist's professional judgment and competent practice
of dentistry. Nothing in this subsection shall be so construed as to make it
unlawful for not-for-profit organizations to enforce employment contracts,
corporate policy and procedure manuals, or quality improvement or assurance
requirements.
[6.] 7. All entities defined in subsection [2] 3 of this section and those
exempted under subsection [3] 4 of this section shall apply for a permit to employ
dentists and dental hygienists licensed in this state to render dental services, and
the entity shall apply for the permit in writing on forms provided by the Missouri dental board. The board shall not charge a fee of any kind for the issuance or renewal of such permit. The provisions of this subsection shall not apply to a federally qualified health center as defined in Section 1905(l) of the Social Security Act (42 U.S.C. 1396d(l)).

[7.] 8. Any entity that obtains a permit to render dental services in this state is subject to discipline pursuant to section 332.321. If the board concludes that the person or entity has committed an act or is engaging in a course of conduct that would be grounds for disciplinary action, the board may file a complaint before the administrative hearing commission. The board may refuse to issue or renew the permit of any entity for one or any combination of causes stated in subsection 2 of section 332.321. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621.

[8.] 9. A federally qualified health center as defined in Section 1905(l) of the Social Security Act (42 U.S.C. 1396d(l)) shall register with the board. The information provided to the board as part of the registration shall include the name of the health center, the nonprofit status of the health center, sites where dental services will be provided, and the names of all persons employed by, or contracting with, the health center who are required to hold a license pursuant to this chapter. The registration shall be renewed every twenty-four months. The board shall not charge a fee of any kind for the issuance or renewal of the registration. The registration of the health center shall not be subject to discipline pursuant to section 332.321. Nothing in this subsection shall prohibit disciplinary action against a licensee of this chapter who is employed by, or contracts with, such health center for the actions of the licensee in connection with such employment or contract. All licensed persons employed by, or contracting with, the health center shall certify in writing to the board at the time of issuance and renewal of the registration that the facility of the health center meets the same operating standards regarding cleanliness, sanitation, and professionalism as would the facility of a dentist licensed by this chapter. The board shall promulgate rules regarding such standards.

[9.] 10. The board may promulgate rules and regulations to ensure not-for-profit corporations are rendering care to the patient populations as set forth herein, including requirements for covered not-for-profit corporations to report patient census data to the board. The provisions of this subsection shall not
apply to a federally qualified health center as defined in Section 1905(l) of the Social Security Act (42 U.S.C. 1396d(l)).

[10.] 11. All not-for-profit corporations organized or operated pursuant to the provisions of chapter 355 and qualifying as an organization under 26 U.S.C. Section 501(c)(3), or the requirements relating to migrant, community, or health care for the homeless health centers provided in Section 330 of the Public Health Service Act (42 U.S.C. 254(b)) and federally qualified health centers as defined in Section 1905(l) (42 U.S.C. 1396d(l)) of the Social Security Act, that employ persons who practice dentistry or dental hygiene in this state shall do so in accordance with the relevant laws of this state except to the extent that such laws are contrary to, or inconsistent with, federal statute or regulation.

334.036. 1. For purposes of this section, the following terms shall mean:

(1) "Assistant physician", any medical school graduate who:

(a) Is a resident and citizen of the United States or is a legal resident alien;

(b) Has successfully completed Step 1 and Step 2 of the United States Medical Licensing Examination or the equivalent of such steps of any other board-approved medical licensing examination within the two-year period immediately preceding application for licensure as an assistant physician, but in no event more than three years after graduation from a medical college or osteopathic medical college;

(c) Has not completed an approved postgraduate residency and has successfully completed Step 2 of the United States Medical Licensing Examination or the equivalent of such step of any other board-approved medical licensing examination within the immediately preceding two-year period unless when such two-year anniversary occurred he or she was serving as a resident physician in an accredited residency in the United States and continued to do so within thirty days prior to application for licensure as an assistant physician; and

(d) Has proficiency in the English language.

Any medical school graduate who could have applied for licensure and complied with the provisions of this subdivision at any time between August 28, 2014, and August 28, 2017, may apply for licensure and shall be deemed in compliance with the provisions of this subdivision;

(2) "Assistant physician collaborative practice arrangement", an agreement between a physician and an assistant physician that meets the requirements of this section and section 334.037;

(3) "Medical school graduate", any person who has graduated from a
medical college or osteopathic medical college described in section 334.031.

2. (1) An assistant physician collaborative practice arrangement shall limit the assistant physician to providing only primary care services and only in medically underserved rural or urban areas of this state or in any pilot project areas established in which assistant physicians may practice.

(2) For a physician-assistant physician team working in a rural health clinic under the federal Rural Health Clinic Services Act, P.L. 95-210, as amended:

(a) An assistant physician shall be considered a physician assistant for purposes of regulations of the Centers for Medicare and Medicaid Services (CMS); and

(b) No supervision requirements in addition to the minimum federal law shall be required.

3. (1) For purposes of this section, the licensure of assistant physicians shall take place within processes established by rules of the state board of registration for the healing arts. The board of healing arts is authorized to establish rules under chapter 536 establishing licensure and renewal procedures, supervision, collaborative practice arrangements, fees, and addressing such other matters as are necessary to protect the public and discipline the profession. An application for licensure may be denied or the licensure of an assistant physician may be suspended or revoked by the board in the same manner and for violation of the standards as set forth by section 334.100, or such other standards of conduct set by the board by rule.

(2) Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly under chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2014, shall be invalid and void.

4. An assistant physician shall clearly identify himself or herself as an assistant physician and shall be permitted to use the terms "doctor", "Dr.", or "doc". No assistant physician shall practice or attempt to practice without an assistant physician collaborative practice arrangement, except as otherwise provided in this section and in an emergency situation.
5. The collaborating physician is responsible at all times for the oversight of the activities of and accepts responsibility for primary care services rendered by the assistant physician.

6. The provisions of section 334.037 shall apply to all assistant physician collaborative practice arrangements. To be eligible to practice as an assistant physician, a licensed assistant physician shall enter into an assistant physician collaborative practice arrangement within six months of his or her initial licensure and shall not have more than a six-month time period between collaborative practice arrangements during his or her licensure period. Any renewal of licensure under this section shall include verification of actual practice under a collaborative practice arrangement in accordance with this subsection during the immediately preceding licensure period.

345.051. 1. Every person licensed or registered pursuant to the provisions of sections 345.010 to 345.080 shall renew the license or registration on or before the renewal date. Such renewal date shall be determined by the board, but shall be no less than three years. The application shall be made on a form furnished by the board. The application shall include, but not be limited to, disclosure of the applicant's full name and the applicant's office and residence addresses and the date and number of the applicant's license or registration, all final disciplinary actions taken against the applicant by any speech-language-hearing association or society, state, territory or federal agency or country and information concerning the applicant's current physical and mental fitness to practice.

2. A blank form for application for license or registration renewal shall be mailed to each person licensed or registered in this state at the person's last known office or residence address. The failure to mail the form of application or the failure to receive it does not, however, relieve any person of the duty to renew the license or registration and pay the fee required by sections 345.010 to 345.080 for failure to renew the license or registration.

3. An applicant for renewal of a license or registration under this section shall:

   (1) Submit an amount established by the board; and
   (2) Meet any other requirements the board establishes as conditions for license or registration renewal, including the demonstration of continued competence to practice the profession for which the license or registration is issued. A requirement of continued competence may include, but is not limited to, up to thirty hours triennially of continuing education, examination,
self-evaluation, peer review, performance appraisal or practical simulation.

4. If a license or registration is suspended pursuant to section 345.065, the license or registration expires on the expiration date as established by the board for all licenses and registrations issued pursuant to sections 345.010 to 345.080. Such license or registration may be renewed but does not entitle the licensee to engage in the licensed or registered activity or in any other conduct or activity which violates the order of judgment by which the license or registration was suspended until such license or registration has been reinstated.

5. If a license or registration is revoked on disciplinary grounds pursuant to section 345.065, the license or registration expires on the expiration date as established by the board for all licenses and registrations issued pursuant to sections 345.010 to 345.080. Such license or registration may not be renewed. If a license or registration is reinstated after its expiration, the licensee, as a condition of reinstatement, shall pay a reinstatement fee that is equal to the renewal fee in effect on the last regular renewal date immediately preceding the date of reinstatement plus any late fee established by the board.

Section B. The enactment of section 197.005 and the repeal and reenactment of sections 197.040, 197.050, 197.070, 197.071, 197.080, and 197.100 of this act shall become effective on July 1, 2018.
338.013. 1. Any person desiring to assist a pharmacist in the practice of pharmacy as defined in this chapter shall apply to the board of pharmacy for registration as a pharmacy technician. Such applicant shall be, at a minimum, legal working age and shall forward to the board the appropriate fee and written application on a form provided by the board. Such registration shall be the sole authorization permitted to allow persons to assist licensed pharmacists in the practice of pharmacy as defined in this chapter.

1. Definitions.

(1) Pharmacy Technician Trainee- A pharmacy support staff registrant who is in training for a pharmacy technician or an advanced pharmacy technician registration or a registered pharmacy technician who is in training for an advanced pharmacy technician registration.

(2) Pharmacy Support Staff- An individual with physical access to a pharmacy, or who has the authority or ability to order legend medication for pharmacy use, but does not assist or support a pharmacist in the practice of pharmacy. Pharmacy Support Staff shall not include individuals with incidental access to the pharmacy while under the direct supervision of a board licensee or registrant, as defined by the Board by rule.

(3) Pharmacy Technician: An individual who assists or supports a pharmacist in the practice of pharmacy as defined by Chapter 338, RSMo.

(4) Advanced Pharmacy Technician- A pharmacy technician who assists or supports a pharmacist in the practice of pharmacy and who performs advanced technician functions as authorized by the Board by rule, including, but not limited to:

   (a) Sterile Compounding, including, but not limited to, sterilely compounded chemotherapy or other hazardous preparations;

   (b) Handling and preparation of nuclear medications; or

   (c) Remote pharmacy technician activity.
2. All pharmacy support staff, pharmacy technicians and advanced pharmacy technicians must be registered with the board. To be eligible for registration, applicants shall file an application on a form provided by the board with the appropriate fee, complete a criminal background check and comply with the following:

   (1) Pharmacy Support Staff applicants must be of legal working age;
   
   (2) Pharmacy Technician applicants must be at least sixteen (16) years old and have completed an employer based training program, as provided by the Board by rule. The training program may be tailored to the applicable pharmacy practice as deemed appropriate by the permitholder or the pharmacist-in-charge. At a minimum, the employer-based training program must include training in the following:

   (a) Pharmacy terminology;
   
   (b) Pharmacy calculations;
   
   (c) Dispensing systems;
   
   (d) Labeling requirements;
   
   (e) Applicable state and federal pharmacy and drug laws and regulations;
   
   (f) Record keeping and documentation;
   
   (g) Proper handling and storage of medications, and;
   
   (h) Pharmacy policies and procedures.

   (3) Advanced Pharmacy Technician applicants must be at least sixteen (16) years old and must complete an employer based training program as designated by the Board by rule and hold an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies or, for applicants that will be assisting in the practice of nuclear pharmacy, have completed a nuclear pharmacy technician certificate program approved by the Board or from a provider accredited by the Accreditation Council for Pharmacy Education or its successor.

3. Pharmacy Technician Trainees. The pharmacy shall maintain a list of all pharmacy technician trainees and the training start date. Once designated, the trainee may engage in pharmacy technician or advanced pharmacy technician functions, as authorized by the rules of the Board and the pharmacist-in-charge. A registrant may not be designated as a pharmacy technician trainee for more than one (1) year, provided
the pharmacist-in-charge may grant a six (6) month extension for good cause. If training is not completed within the required one (1) year or eighteen (18) months, the registrant may not be re-designated as a trainee for a minimum of six (6) months.

24. The board may refuse to issue a certificate of registration as a pharmacy technician registration authorized by this section to an applicant that has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055. Alternately, the board may issue such person a registration, but may authorize the person to work as a pharmacy technician provided that person adheres to certain terms and conditions imposed by the board. The board shall place on the employment disqualification list the name of an applicant who the board has refused to issue a certificate of registration as a pharmacy technician, or the name of a person who the board has issued a certificate of registration as a pharmacy technician but has authorized to work under certain terms and conditions. The board shall notify the applicant of the applicant's right to file a complaint with the administrative hearing commission as provided by chapter 621.

35. If an applicant has submitted the required fee and an application for registration to the board of pharmacy, the applicant for registration as a pharmacy technician may assist a licensed pharmacist in the practice of pharmacy as defined in this chapter may begin performing activities authorized for the registration class once the completed application has been submitted to the board. The applicant shall keep a copy of the submitted application on the premises where the applicant is employed. If the board refuses to issue a certificate of registration as a pharmacy technician to an applicant, the applicant shall immediately cease assisting a licensed pharmacist in the practice of pharmacy performing the applicable technician activities.

46. A certificate or other proof of registration issued by the board shall be conspicuously displayed in the pharmacy or place of business where the registrant is employed available in the pharmacy as provided by the Board by rule.
57. Every pharmacy technician registrant who desires to continue to be registered as provided in this section shall, within thirty days before the registration expiration date, file an application for the renewal, accompanied by the fee prescribed by the board. The registration shall lapse and become null and void thirty days after the expiration date. To renew, registered a advanced pharmacy technician must submit proof that he/she holds a current and active certification identified in section (2)(C).

68. The board shall maintain an employment disqualification list. No person whose name appears on the employment disqualification list shall work as a pharmacy technician registrant, except as otherwise authorized by the board. The board may authorize a person whose name appears on the employment disqualification list to work or continue to work as a pharmacy technician registrant provided the person adheres to certain terms and conditions imposed by the board.

79. The board may place on the employment disqualification list the name of a pharmacy technician registrant who has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055.

810. After an investigation and a determination has been made to place a person’s name on the employment disqualification list, the board shall notify such person in writing mailed to the person's last known address:

(1) That an allegation has been made against the person, the substance of the allegation and that an investigation has been conducted which tends to substantiate the allegation;

(2) That such person's name has been added in the employment disqualification list of the board;

(3) The consequences to the person of being listed and the length of time the person’s name will be on the list; and

(4) The person's right to file a complaint with the administrative hearing commission as provided in chapter 621.
911. The length of time a person’s name shall remain on the disqualification list shall be determined by the board.

1012. No hospital or licensed pharmacy shall knowingly employ any person whose name appears on the employee disqualification list, except that a hospital or licensed pharmacy may employ a person whose name appears on the employment disqualification list but the board has authorized to work under certain terms and conditions. Any hospital or licensed pharmacy shall report to the board any final disciplinary action taken against a pharmacy technician registrant or the voluntary resignation of a pharmacy technician registrant against whom any complaints or reports have been made which might have led to final disciplinary action that can be a cause of action for discipline by the board as provided for in subsection 2 of section 338.055. Compliance with the foregoing sentence may be interposed as an affirmative defense by the employer. Any hospital or licensed pharmacy which reports to the board in good faith shall not be liable for civil damages.

13. Any person who holds a current and active pharmacy technician registration on or before May 31, 2019, may apply to the Board for a pharmacy support staff, pharmacy technician or advanced pharmacy technician registration without fee. To be eligible for advanced pharmacy technician registration under this subsection, the application must be accompanied by a statement from a Missouri licensed pharmacist attesting that the applicant has practiced as a pharmacy technician for a minimum of 2,080 hours and that such practice included, in whole or in part, the performance of advanced technician duties, as designated by the Board by rule. If an advanced pharmacy technician registration issued pursuant to this subsection is allowed to lapse, the former registrant shall be treated in the same manner as a new applicant and must comply with all advanced pharmacy technician registration requirements upon reapplication.