Title 16—RETIREMENT SYSTEMS Division 20—Missouri Local Government Employees' Retirement System (LAGERS) Chapter 2—Administrative Rules

ORDER OF RULEMAKING

By the authority vested in the Missouri Local Government Employees' Retirement System (LAGERS) under section 70.605.21, RSMo 2016, the Retirement System amends a rule as follows:

16 CSR 20-2.040 Refunds is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on June 17, 2019 (44 MoReg 1682). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 16—RETIREMENT SYSTEMS Division 20—Missouri Local Government Employees' Retirement System (LAGERS) Chapter 2—Administrative Rules

ORDER OF RULEMAKING

By the authority vested in the Missouri Local Government Employees' Retirement System (LAGERS) under sections 70.605.21 and 70.645, RSMo 2016, the Retirement System amends a rule as follows:

16 CSR 20-2.045 Application for Retirement is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on June 17, 2019 (44 MoReg 1682-1683). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 16—RETIREMENT SYSTEMS Division 20—Missouri Local Government Employees' Retirement System (LAGERS) Chapter 2—Administrative Rules

ORDER OF RULEMAKING

By the authority vested in the Missouri Local Government Employees' Retirement System (LAGERS) under section 70.605.21, RSMo 2016, the Retirement System amends a rule as follows:

16 CSR 20-2.056 Lump-Sum Cash Payout of Retirement Allowance is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on June 17, 2019 (44 MoReg 1683). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 16—RETIREMENT SYSTEMS Division 20—Missouri Local Government Employees' Retirement System (LAGERS) Chapter 2—Administrative Rules

ORDER OF RULEMAKING

By the authority vested in the Missouri Local Government Employees' Retirement System (LAGERS) under sections 70.605.21 and 70.735, RSMo 2016, the Retirement System amends a rule as follows:

16 CSR 20-2.070 Collection of Delinquent Payments is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on June 17, 2019 (44 MoReg 1683-1684). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 16—RETIREMENT SYSTEMS Division 20—Missouri Local Government Employees' Retirement System (LAGERS) Chapter 2—Administrative Rules

ORDER OF RULEMAKING

By the authority vested in the Missouri Local Government Employees' Retirement System (LAGERS) under sections 70.605.21, RSMo 2016, the Retirement System amends a rule as follows:

16 CSR 20-2.105 Redetermination of Allowances During Deflation and Consumer Pricing Indices To Be Considered is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on June 17, 2019 (44 MoReg 1684). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.001 Anesthesiologist Assistants in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44

MoReg 1277). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 192.006, 197.154, and 338.165, RSMo 2016, and sections 197.080 and 197.293, RSMo Supp. 2019, the department amends a rule as follows:

19 CSR 30-20.011 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1277-1280). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received seven (7) comments on the proposed amendment.

COMMENT #1: The Missouri Hospital Association (MHA) commented that the definition of "Premises" in section (21) seemed very broad as compared to 197.052, RSMo. MHA also commented that it was unclear if a building owned by the hospital but leased to another entity would need to be included as a part of the premises and, if so, under what standards it would be surveyed. MHA thus proposed modifications based on its comments, including defining premises as those areas defined by the hospital as such, removing the requirement of meeting construction standards, and specifying that the buildings and areas listed as hospital premises would be surveyed to the function of the areas.

RESPONSE AND EXPLANATION OF CHANGE: The department does not agree that the definition for "Premises" in section (21) should be defined as what a hospital identifies as its premises, and the department did not believe that a statement that the premises would be surveyed according to their function should be included in the definition or was sufficiently specific. Nevertheless, the department believes that the lack of clarity discerned by MHA results from the inclusion of existing requirements for hospitals in the definition of "Premises," such as the statutory definition of hospital and the construction requirements, which seems duplicative. Rather than restating these requirements to form a definition of premises, the department believes that such a definition is unnecessary. Therefore, the department will remove the definition of "Premises" and will renumber later sections as necessary.

COMMENT #2: The Missouri Board of Pharmacy in the Division of Professional Registration (BOP) commented that the definition of "Intern Pharmacist" in section (13) should be modified to include that the individual is currently licensed as an intern pharmacist under Chapter 338, RSMo. BOP expressed that this change would be consistent with the proposed definitions for "Pharmacist" in section (18) and "Pharmacy technician" in section (19).

RESPONSE AND EXPLANATION FOR THE CHANGE: The department agrees and will adopt this recommended change except for the addition of "currently," which if added could suggest that the

individual must be licensed on the effective date of this rule.

COMMENT #3: The Missouri Pharmacy Association (MPA) commented that the department lacks the authority to define in the rule the terms "Compounding," "Intern pharmacists," and "Pharmacy technicians" for the same reasons that MPA commented the department does not have the authority to promulgate 19 CSR 30-20.100, which the department incorporates here. With respect to proposed 19 CSR 30-20.100, MPA commented, among other things, that the rule does not reasonably flow from any applicable statute, that the department does not have the statutory authority to promulgate regulations setting forth the qualifications or scope of practice of licensed pharmacists or registered pharmacy technicians-regardless of the fact that those persons work in hospital pharmacies—and that this function was limited to BOP, citing sections 338.010 and 338.013, RSMo. MPA indicated and that allowing the department to have authority to define the qualifications and scope of practice of pharmacy technicians working in hospital pharmacies would create inconsistencies in requirements and enforcement, as well as confusion amongst licensees or registrants regarding their scope of practice. Citing Chapter 197, RSMo, MPA notes that "[n]ot a single section governing hospitals mentions pharmacies, pharmacists, pharmacy technicians, or pharmaceutical services." Citing Chapter 192, RSMo, MPA similarly notes that "none of the statutes discuss the regulation of pharmacies, pharmacists, pharmacy technicians, or pharmaceutical services." MPA commented that these chapters do not permit the department to expand the scope of practice of a pharmacy technician within a hospital beyond what is permitted in a retail or other type of licensed pharmacy. And asserting that CMS's State Operations Manual does not permit a "pharmacy technician to provide pharmaceutical services when a pharmacist is off-site," MPA also maintains that nothing in federal Medicare and Medicaid regulations supports the rule and contends that the rule is inconsistent with 42 CFR 482.25, thereby violating section 197.080.2(2), RSMo.

that the rule was not promulgated in conjunction with BOP. RESPONSE: For the reasons stated by the department in the Order of Rulemaking for 19 CSR 30-20.100 which the department incorporates here, the department does not agree with MPA's assertions regarding the department's authority over hospital pharmacies. Among other reasons set forth in the Order of Rulemaking for 19 CSR 30-20.100, the department notes with respect to the definitions of the terms "Compounding," "Intern pharmacists," and "Pharmacy technicians" that the department has the "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." § 197.100.1 RSMo (emphasis added). Pharmacies in hospitals, and pharmacy services and activities in hospitals provided by pharmacists and pharmacy technicians, contribute directly or indirectly to patient care of any kind. This authority and responsibility is reiterated in section 338.165.2 RSMo. And this authority and responsibility is notwithstanding "[a]ny provision of chapter 198 and chapter 338 to the contrary ." § 197.100.1,

Citing section 338.165.3, RSMo, MPA additionally commented

Regarding this responsibility for inspection and licensure of all parts and services of hospitals contributing to patient care, section 192.006, RSMo, permits the department to adopt rules "necessary to carry out the duties assigned to it." Some of those duties are the duties to "adopt . . . 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." § 197.080.1, RSMo. The department does not find Chapter 192, RSMo's, and Chapter 197, RSMo's, failures to expressly mention pharmacies or other pharmacy-related terms (like compounding or pharmacy technician) significant given

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the comprehensive breadth of authority granted the department over hospital licensure. As such, Chapters 192 and 197, RSMo, unequivocally grant the department the authority to promulgate rules thoroughly setting forth standards governing all services and activities in hospitals that touch on patient care, and the department believes that the definitions for the terms "Compounding," "Intern pharmacists," and "Pharmacy technicians" reasonably flow from the applicable statutes. The department finds that the rule does not contravene BOP's authority or that the department is performing a function of BOP (positions which BOP itself did not take), even if the department is defining terms (for the hospital context) also defined by BOP for its contexts. And the department does not agree that the rule violates federal law or any of CMS's guidance in the State Operations Manual.

To the extent that the department was required to promulgate these definitions "in conjunction with" BOP under section 338.165.3, RSMo, the department has done so. In developing definitions, the department specifically sought BOP's input which BOP provided, and BOP has expressed no opposition to the department's definitions other than the suggested change noted above, which the department (as noted) agrees with. Therefore, this statutory requirement has been met, and the definitions will not be removed.

COMMENT #4: Morgan Simpson commented that the definition for "Licensed practitioner" in section (14) be modified by adding "by Missouri statutes" after "qualified" and "or services" after "profession."

RESPONSE: The department believes that the proposals may have some merit but also may have unintended negative effects and thus does not adopt them. Adding "by Missouri statutes" as proposed could introduce an ambiguity to the definition that would be considered limiting. Adding "services" as proposed could include individuals who must be licensed to perform a service in a health care setting but do not actually practice health care. Therefore, the department appreciates the comments but does not adopt them.

COMMENT #5: Staff from the department commented that—if section (2) of proposed 19 CSR 30-20.100 is not promulgated—the definitions for "Electronic Supervision" in section (9) and "Real-Time" in section (22) should be removed because they do not define terms used in any other section of a rule being promulgated.

RESPONSE AND EXPLANATION OF CHANGE: The department agrees that the rule should be changed as proposed and will renumber sections as necessary after removing these definitions, starting with the definition of "Hospital" as being section (9) in the promulgated rule.

COMMENT #6: Staff from the department commented that the rule should include a definition of "immediate and serious threat to the patients' health and safety" to meet the requirements of section 197.293, RSMo, and that this definition should reflect, to the extent practicable, the definition of "immediate jeopardy" used in the context of the Medicare survey, certification, and enforcement procedures for consistency.

RESPONSE AND EXPLANATION OF CHANGE: The department agrees that the rule should be changed as proposed and will renumber sections as a result of adding this definition.

COMMENT #7: Staff from the department commented that 338.165, RSMo, should be added to the statutory authority for the rule.

RESPONSE AND EXPLANATION OF CHANGE: The department agrees that the Authority section should be changed as proposed.

19 CSR 30-20.011 Definitions Relating to Hospitals

- (9) Hospital-
 - (A) A facility that provides inpatient care for medical or surgical

patients, or both, and may include pediatric, obstetrical and newborn, psychiatric, or rehabilitation patients; and

- (B) A facility that is devoted primarily for the diagnosis, treatment, or care for not less than twenty-four (24) consecutive hours in any week of three (3) or more nonrelated individuals suffering from illness, disease, injury, deformity, or other abnormal physical conditions, or devoted primarily to provide for not less than twenty-four (24) consecutive hours in any week medical or nursing care for three (3) or more nonrelated individuals and includes;
 - (C) Building(s)—
- 1. Constructed to hospital standards as outlined in 19 CSR 30-20.030; and
- 2. Identified on the hospital's license application as part of the facility; and
- (D) The term "hospital" does not include convalescent, nursing, shelter, or boarding homes as defined in Chapter 198, RSMo.
- (10) Immediate and serious threat—A situation in which a hospital's non-compliance with one (1) or more requirements established under the Hospital Licensing Law or section 197.005, RSMo has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient. Unless the language or context clearly indicates otherwise, this definition is intended to have the same meaning, to the extent practicable, as the definition of immediate jeopardy in 42 CFR section 488.1 (2018). The *Code of Federal Regulations* is published by the U.S. Government and is available by calling toll-free (866) 512-1800 or going to https://bookstore.gpo.gov/. The address is: U.S. Government Publishing Office, U.S. Superintendent of Documents, Washington, DC 20402-0001. This rule does not incorporate later amendments or additions to 42 CFR section 488.1 (2018).
- (21) Registered professional nurse—An individual who is licensed under Chapter 335, RSMo, to practice as a registered professional nurse in the State of Missouri.
- (22) Repackage—To remove any drug from the original manufacturer's container and place the drug in a dispensing container for other than immediate dispensing to a patient.
- (23) Resident—A person who by reason of aging, illness, disease, or physical or mental infirmity requires care and services furnished by a long-term care unit and who resides within the unit for care and treatment.
- (24) Respiratory Care Practitioner—An individual who is licensed under Chapter 334, RSMo, to practice respiratory care in the State of Missouri.
- (25) Root cause analysis—A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.
- (26) Unit—A functional division or facility of the hospital.
- (27) Unlicensed Assistive Personnel (UAP)—unlicensed health care personnel who provide direct patient care twenty-five percent (25%) or more of the time, under the delegation and supervision of a registered professional nurse. Individuals who provide a specific job function such as, but not limited to, phlebotomist, radiology technician, or patient transporter are not included in this definition.
- AUTHORITY: sections 192.006, 197.154, and 338.165, RSMo 2016, and sections 197.080 and 197.293, RSMo Supp. 2019. This rule was previously filed as 13 CSR 50-20.011. Original rule filed June 2, 1982, effective Nov. 11, 1982. For intervening history, please consult the Code of State Regulations. Amended: Filed March 20, 2019.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 192.006, 197.065, and 197.297, RSMo 2016, and section 197.080, RSMo Supp. 2019, the department amends a rule as follows:

19 CSR 30-20.015 is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1280-1288). Those sections with changes are reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received three (3) comments on the proposed amendment, one (1) proposing a change to the text of the proposed amendment and two (2) proposing changes to the text of the application for licensure.

COMMENT #1: The Missouri Hospital Association (MHA) provided a comment applicable to the Application for licensure, specifically the section entitled Co-location status be revised to read: "Is there another provider or department licensed entity, or a satellite location or another provider or department licensed entity that occupies space in a building identified by the hospital as being a part of the licensed premises?" MHA believes this was necessary because of draft guidance on co-location issued by the Centers for Medicare and Medicaid Services.

RESPONSE AND EXPLANATION OF CHANGE: The department has updated the text of the license application on page 2 under Colocation Status, but the department does not agree with all of the revision suggestions within this comment. The words "same campus as buildings used by the hospitals" will be replaced with "hospital's licensed premises." The department believes that co-location for the application should not be determined solely by a hospital's identification of a building as being part of a licensed premises.

COMMENT #2: MHA also commented that (4) should specifically reference an initial application and should end with the statement that the criteria in section (4) is for initial application for a single hospital licensure and that the annual renewal for a single licensed hospitals will follow the annual licensure process. In addition, MHA commented that (5) should reference the annual renewal license and application.

RESPONSE AND EXPLANATION OF CHANGE: The department agrees with the recommended clarification for (4). The department did not agree with the recommendation for (5). The first sentence of this section refers to the license issued by the department, not the renewal application. Also, the addition of "renewal" with respect to the annual application did not seem necessary.

COMMENT #3: Staff from the department provided a comment recommending the correction of a typographical error on page 2 of the application, so that the word "building" would be "buildings." RESPONSE AND EXPLANATION OF CHANGE: The department agrees with the recommendation. Therefore the application will be updated to reflect the recommendation.

19 CSR 30-20.015 Administration of the Hospital Licensing Program

(4) An operator of two (2) or more licensed hospitals may submit an

initial application to the Department of Health and Senior Services to operate the hospitals as a single licensed hospital. The two (2) or more licensed hospitals may be separated by a distance which can be traveled in no more than one (1) hour by customary ground transportation in normal weather conditions. The operator shall designate a permanent hospital base from which the one- (1-) hour travel distance is determined. If the application is approved, the hospitals may be named on the licensure application and a single license issued. Before the Department of Health and Senior Services approves the application, the applicant shall submit an operational proposal to the director of the Department of Health and Senior Services for approval. At a minimum the proposal shall include:

- (A) Approval from the Certificate of Need program if a Certificate of Need is required under sections 197.300–197.367, RSMo;
- (B) Assurance that the applicant presented the initial proposal at a public hearing within the community where the currently licensed hospital(s) is located. The proposal shall provide evidence that the entire community was adequately notified at least two (2) weeks in advance, of the public hearings. The written record of the hearings, including the community response to the proposal, shall be submitted to the Department of Health and Senior Services as a part of the applicant's proposal. The Department of Health and Senior Services shall be given two (2) weeks advance notice of the public hearings. The Department of Health and Senior Services may consider the information presented as part of the determination process; and
- (C) Assurance that the initial applicant is in compliance with Chapter 197, RSMo, and the regulations promulgated thereunder. The above criteria is for initial application for single hospital licensure. The annual renewal for the single licensed hospitals will follow the annual licensure process.

OTHER				
1. New hospitals - attach Certificate of Need approvals if applicable. 2. Renovations or construction projects during this licensure period should be submitted in accordance with 19 CSR 30-20.030. 3. Provide a copy of all DHSS current, approved variances. a. If new variance(s) is requested, please submit in accordance with 19 CSR 30-20.015.				
Premises For all locations that will be identified as premises, as defined by 19 CSR 30-20.011, please provide a map or drawing of the premises to illustrate the location of each building. Attach a listing of all buildings with each listed by name, address and type of patient service offered.				
Co-location status Is there another provider or licensed entity, or a satellite location used by the hospital, or in one or more entire buildings located	-	- '	space in a building	
□YES □NO				
If answer is yes, then list the name and Medicare identification (i.e. 26xxxx) number of the co-located provider or licensed entity.				
NAME OF CO-LOCATION PROVIDER, LICENSED ENTITY OR SATELLITE LOCATION MEDICA		MEDICARE IDENTIFICAT	DICARE IDENTIFICATION NUMBER	
CERTIFICATION				
We the undersigned hereby certify that we have read the foregoing application and that the statements contained therein are true and correct				
to the best of our knowledge, and further assure the ability and intention of the				
Missouri statutes and regulations pertaining to hospital licensure.				
CHAIR OF THE GOVERNING BODY SIGNATURE	PRINT NAME		DATE	
CHIEF EXECUTIVE OFFICER SIGNATURE	PRINT NAME		DATE	
			7454	

MO 580-0007 (8-18)

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.030 Construction Standards for New Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1288). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 192.006 and 197.065, RSMo 2016, and sections 197.080 and 197.100, RSMo Supp. 2019, the department adopts a rule as follows:

19 CSR 30-20.030 Construction Standards for New Hospitals **is adopted**.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1288–1289). No changes have been made in the text of the proposed rule, so it is not reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received one (1) comment on the proposed rule to change the text of the proposed rule

COMMENT #1: The International Association of Healthcare Central Services Materiel Management (IAHCSMM) made a comment applicable to the Construction Standards for New Hospitals. Specifically, the comment applies subsection (4)(A), asserting that it is outdated and suggesting that the department change the text in accordance with ANSI/ST79:2017 which states:

"Steam sterilization cycles typically used in the healthcare facilities include the gravity-displacement cycle and two types of dynamic-air-removal cycles. One type of dynamic-air-removal cycle, the prevacuum cycle, removes air from the chamber and load by means of pressure and vacuum excursions. The other type, the steam-flush pressure-pulse (SFPP) cycle, removes air with a series of steam flushes and pressure pulses above atmospheric pressure."

RESPONSE: The department does not agree with the suggested change. The rule would require pressure sterilization, of which there are different types. Steam sterilization is only one (1) type of pressure sterilization. Under the rule as drafted, facilities may use any type of pressure sterilization they desire. If the department were to require steam sterilization only as suggested in the comment, this

would limit hospitals' discretion under the rule. For any specific sterilization processes that do not meet the minimum standard provided in the rule, the department will use the variance process outlined in 19 CSR 30-20.015 to consider requests to deviate from those requirements.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.040 Definitions Relating to Long-Term Care Units in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May I, 2019 (44 MoReg 1289). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 192.006 and 197.297, RSMo 2016, and section 197.080, RSMo Supp. 2019, the department amends a rule as follows:

19 CSR 30-20.050 Standards for the Operation of Long-Term Care Units **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1289–1292). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed amendment.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019,

the department rescinds a rule as follows:

19 CSR 30-20.060 Construction Standards for New Long-Term Care Units in Hospitals **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1293). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.080 Governing Body of Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1293). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.082 Chief Executive Officer in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1293). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior

Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.084 Patients' Rights in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1293). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.086 Medical Staff in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1294). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.088 Central Services is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1294). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior

Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.090 Food and Nutrition Services is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1294). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 192.006 and 197.154, RSMo 2016, and section 197.080, RSMo Supp. 2019, the department amends a rule as follows:

19 CSR 30-20.092 Diversion is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1294–1296). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed amendment.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.094 Medical Records is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1296). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior

Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.096 Nursing Services is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1296–1297). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.097 Safe Patient Handling and Movement in Hospitals **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1297). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.098 Pathology and Medical Laboratory Services is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1297). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior

Services under sections 192.006 and 197.154, RSMo 2016, and section 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.100 Pharmacy Services and Medication Management in Hospitals **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1297). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 192.006 and 338.165, RSMo 2016, and section 197.080, RSMo Supp. 2019, the department adopts a rule as follows:

19 CSR 30-20.100 is adopted.

A notice of proposed rulemaking containing the text of the proposed rule was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1297–1299). Those sections with changes are reprinted here. This proposed rule becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received twelve (12) comments on the proposed rule.

COMMENT #1: The Missouri Hospital Advisory Committee of the Missouri Board of Pharmacy in the Division of Professional Registration commented that it strongly supports the rule. The Hospital Advisory Committee commented that the rule would align Missouri rules with the standards of the Centers for Medicare and Medicaid Services (CMS). The Hospital Advisory Committee also commented that the rule would permit a pharmacy technician in a hospital to verify the final product prepared by another pharmacy technician (sometimes referred to as "tech-check-tech" and used hereafter), which would allow pharmacists more time to provide higher-level care, is supported by studies from many hospitals, and is supported by the American Society for Health-System Pharmacists. The Hospital Advisory Committee additionally commented that the rule would remove provisions resulting in discarding of medications when a patient goes home (provisions which have the effect increasing patient costs), and would permit remote verification of pharmacy technicians.

RESPONSE: The department agrees that the rule would expressly permit tech-check-tech and remote supervision and with the Hospital Advisory Committee's other comments. The department notes that the purpose of the Hospital Advisory Committee is to "review and make recommendations to the board [of pharmacy] on the merit of all rules and regulations to be jointly promulgated by the board and the department of health and senior services pursuant to the joint rulemaking authority granted by [section 338.165, RSMo]," § 338.165.11 RSMo, which include this rule.

COMMENT #2: The Missouri Board of Pharmacy in the Division of Professional Registration (BOP) commented that proposed section (2) should not be promulgated. Section (2) is the section that express-

ly permits tech-check-tech and remote supervision of pharmacy technicians by a pharmacist and which the Hospital Advisory Committee of BOP (discussed above) strongly supports. BOP commented that BOP members expressed concerns with bifurcating technician regulation based on practice setting and the potential impact on pharmacy practice statewide. Noting that pharmacy technicians may fluctuate through a variety of practice sites during their careers, BOP commented that differing regulation based on practice setting may cause confusion for technicians and could endanger patient safety. Specifically with respect to tech-check-tech, BOP commented that, absent a strong and well-developed approach, patient safety may be placed at risk if tech-check-tech were allowed, and BOP suggested that the department conduct additional research and stakeholder dialogue regarding tech-check-tech before promulgating a rule expressly permitting it.

RESPONSE: The department appreciates BOP's comments but respectfully disagrees with them. The department does not believe that section (2) would cause confusion or risk patient safety, notwith-standing that different rules may apply in different settings. The department also believes that tech-check-tech has been adequately researched, and this research demonstrates its safety. The department's stakeholder dialogue, moreover, has reflected substantial support for the rule. Therefore, the changes suggested by BOP will not be implemented for the reasons provided by BOP.

COMMENT #3: The Missouri Pharmacy Association (MPA) commented that the department does not have the authority to propose regulations on the subject matter of pharmacy technicians, and, even if this were a subject matter over which the Department had authority, there is no statutory support for the policies set forth in the rule. Citing the non-passage of S.B. 1068, 99th Gen. Assembly, 2d sess. (2018) and the case of *Bresler v. Tietjen*, 424 S.W.2d 65, 70 (Mo. 1968), MPA commented that "[u]nsuccessful attempts to obtain passage of legislation on the same subject as a proposed rule creates serious doubt regarding the agency's authority, especially when the subject of the proposed rule does not reasonably follow from the statute granting rulemaking authority, as is the case here," and that the rule "is nothing more than an attempt to adopt by regulation a policy that the Missouri General Assembly did not itself pass."

MPA also commented that the rule includes various provisions regarding the qualifications and scope of practice of pharmacy technicians working in a hospital pharmacy—which MPA asserts are not contained in the version of the rule presently in effect—and that the (proposed) rule does not reasonably flow from any applicable statute. MPA also asserts that the department does not have the statutory authority to promulgate regulations setting forth the qualifications or scope of practice of licensed pharmacists or registered pharmacy technicians—regardless of the fact that those persons work in hospital pharmacies—and that this function was limited to BOP, citing sections 338.010 and 338.013, RSMo. MPA indicated and that allowing the department to have authority to define the qualifications and scope of practice of pharmacy technicians working in hospital pharmacies would create inconsistencies in requirements and enforcement, as well as confusion amongst licensees or registrants regarding their scope of practice. Citing Chapter 197, RSMo, MPA notes that "[n]ot a single section governing hospitals . . . mentions pharmacies, pharmacists, pharmacy technicians, or pharmaceutical services." Citing Chapter 192, RSMo, MPA similarly notes that "none of the statutes . . . discuss the regulation of pharmacies, pharmacists, pharmacy technicians, or pharmaceutical services." MPA commented that these chapters do not permit the department to expand the scope of practice of a pharmacy technician within a hospital beyond what is permitted in a retail or other type of licensed pharmacy. And asserting that CMS's State Operations Manual does not permit a "pharmacy technician to provide pharmaceutical services when a pharmacist is off-site," MPA also maintains that nothing in federal Medicare and Medicaid regulations supports the rule and contends that the rule is inconsistent with 42 CFR 482.25, thereby violating section 197.080.2(2), RSMo.

Citing section 338.165.3, RSMo, MPA additionally commented that the rule was not promulgated in conjunction with BOP.

RESPONSE AND EXPLANATION OF CHANGE: Despite citing sections 338.010 and 338.013, RSMo, the department notes that MPA does not expressly assert that the rule actually violates the authority in section 338.013.1 RSMo for pharmacy technicians to "assist a pharmacist in the practice of pharmacy" as defined in section 338.010.1, RSMo. In fact, MPA cites no BOP law prohibiting the activities and services that the rule would expressly allow. And, as stated in response to BOP's comment, the department does not believe that any inconsistencies between pharmacy technicians' permitted duties in a hospital pharmacy and duties in a retail pharmacy would cause confusion.

The department does not agree that the non-passage of S.B. 1068, 99th Gen. Assembly, 2d sess. (2018) creates any doubt as to the department's authority to promulgate the rule. To the contrary, the fact that the bill was not enacted supports the opposite conclusion—that a new statute was determined to be unnecessary because the department would be validly promulgating the rule (which was in development with stakeholder involvement at that time) under the authority of existing statutes. *Bresler* does not apply nor require a different conclusion.

To the extent that MPA asserts that the rule presently in effect does not include language governing the duties of pharmacy technicians, the department does not agree. The present rule prohibits the "assign[ment] [to support pharmacy personnel of] duties that by law must be performed by a pharmacist." 19 CSR 30-20.100(2). The department also does not agree that no statute supports the (proposed) rule or that the express permission it would grant for techcheck-tech and remote supervision (or the other activities and services it governs) in a hospital must come from BOP and not the department. The department has the "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." § 197.100.1 RSMo (emphasis added). Pharmacies in hospitals, and pharmacy services and activities in hospitals provided by pharmacy technicians, contribute directly or indirectly to patient care of any kind. This authority and responsibility is reiterated in section 338.165.2 RSMo. And this authority and responsibility is notwithstanding "[a]ny provision of chapter 198 and chapter 338 to the contrary " § 197.100.1, RSMo.

Regarding this responsibility for inspection and licensure of all parts and services of hospitals contributing to patient care, section 192.006, RSMo, permits the department to adopt rules "necessary to carry out the duties assigned to it." Some of those duties are the duties to "adopt . . . 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." § 197.080.1, RSMo. The department does not find Chapter 192, RSMo's, and Chapter 197, RSMo's, failures to expressly mention pharmacies or other pharmacy-related terms (like pharmacy technician) significant given the comprehensive breadth of authority granted the department over hospital licensure.

As such, Chapters 192 and 197, RSMo, unequivocally grant the department the authority to promulgate rules thoroughly setting forth standards governing all services and activities in hospitals that touch on patient care, and the department believes that the rule reasonably flows from the applicable statutes. The department finds that the rule does not contravene BOP's authority or that the department is performing a function of BOP (positions which BOP itself did not take). And the department does not agree that the rule violates federal law, specifically 42 C.F.R. § 482.25, or any of CMS's guidance in the State Operations Manual. That manual contemplates that pharmaceutical services involving dispensing drugs will be conducted by *or*

under the supervision of a pharmacist, and hospitals are given considerable discretion there in determining measures to ensure a pharmacist's effective oversight and supervision of pharmaceutical services in a hospital.

Although the department believes that the activities, services, and requirements expressly permitted by section (2) of the rule (techcheck-tech and remote supervision) would promote the safe and adequate treatment of individuals in hospitals, are well-supported by published research, and would enhance hospital efficiencies, the department notes that BOP disagreed that this section of the rule should be promulgated (as noted above). Therefore, if the department were to promulgate the rule with section (2), it would not be "in conjunction with" BOP as required by section 338.165.3, RSMo. Nevertheless, BOP did not express disagreement with any other section of the rule, and in fact the department repeatedly sought and received BOP's comments on the rule during its development. Therefore, the department believes that—if the rule were promulgated without section (2)—it would be promulgated "in conjunction with" BOP as required by section 338.165.3, RSMo. The department will thus remove section (2) and will promulgate the rule with the sections renumbered reflecting section (2)'s removal.

COMMENT #4: The Missouri Hospital Association (MHA) commented that it strongly supports the rule. MHA commented that regulatory burden was reduced by the absence of duplicative or contradictory federal or state standards, that the hospital environment is (unlike other pharmacy environments) designed to have multiple checks regarding medications before administration, that pharmacy technicians are an important part of the process of medication management, that appropriate education and training for pharmacy technicians were supported, that pharmacists would be able to utilize their education and training to offer effective solutions for medication management and assist in the management of complex patients, and that permitting the dispensing of hospital medications to the discharging patient would reduce patient burden and support positive outcomes.

RESPONSE: The department agrees with these comments, except that section (2) must be removed for the reasons provided in response to MPA's comment.

COMMENT #5: Saint Luke's Health System commented that it strongly supports the rule. Saint Luke's Health System provided the same reasons in support of the rule as MHA.

RESPONSE: The department agrees with these comments, except that section (2) must be removed for the reasons provided in response to MPA's comment.

COMMENT #6: Lake Regional Health System commented that it strongly supports the rule. Lake Regional Health System provided the same reasons in support of the rule as MHA.

RESPONSE: The department agrees with these comments, except that section (2) must be removed for the reasons provided in response to MPA's comment.

COMMENT #7: Mercy commented that it strongly supports the rule. Mercy provided the same reasons in support of the rule as MHA. RESPONSE: The department agrees with these comments, except that section (2) must be removed for the reasons provided in response to MPA's comment.

COMMENT #8: BJC HealthCare commented that it strongly supports the rule. In addition to reasons provided by MHA and other commenters, BJC HealthCare commented that its fifteen-member hospitals provide a variety of pharmacy services to patients and communities, they were excited the department was proposing to take important steps toward finding workable solutions that allow for expanded pharmacy technician roles, and that, once approved, the rule would be an important positive step for hospital pharmacy practice in Missouri.

BJC HealthCare also commented that allowing appropriately trained pharmacy technicians in licensed hospitals to check the work of other technicians would be in alignment with many other states across the country and that existing evidence supported technicians in this role, performing as accurately as pharmacists related to final product verification. BJC HealthCare commented that the rule could positively impact overall health care costs by allowing technicians to perform some of the activities currently relegated to pharmacists. With respect to the dispensing of medications to discharging patients, BJC HealthCare commented that this would positively result in decreased pharmaceutical waste, assist with continuity of care while the patient would be transitioning to home, and decrease overall expenses for both the patient and the health care system.

RESPONSE: The department agrees with these comments, except that section (2) must be removed for the reasons provided in response to MPA's comment.

COMMENT #9: Stephanie Lumley-Hemme, RPh, MBA commented that she strongly supports the rule. She provided the same reasons as BJC HealthCare above.

RESPONSE: The department agrees with these comments, except that section (2) must be removed for the reasons provided in response to MPA's comment.

COMMENT #10: Ryan Birk, PharmD commented that he strongly supports the rule. In addition to reasons provided by MHA and other commenters, Dr. Birk cited studies supporting tech-check-tech and that the practice is supported by the American Society for Health-System Pharmacists. Dr. Birk also commented favorably on the provisions regarding dispensing of medications to discharging patients and commented that the rule would permit remote verification of pharmacy technician's work.

RESPONSE: The department agrees with these comments, except that section (2) must be removed for the reasons provided in response to MPA's comment.

COMMENT #11: Nancy Konieczny, RPh commented that she strongly supports the rule. She provided the same reasons as Dr. Birk above.

RESPONSE: The department agrees with these comments, except that section (2) must be removed for the reasons provided in response to MPA's comment.

COMMENT #12: Staff from the department commented that 338.165, RSMo, should be added to the statutory authority for the rule.

RESPONSE: The department agrees that the Authority section should be changed as proposed.

19 CSR 30-20.100 Pharmacy Services and Medication Management

- (2) An intern pharmacist licensed by the Board of Pharmacy may also perform any activity authorized for pharmacy technicians pursuant to this rule.
- (3) Persons involved in compounding, repackaging, dispensing, administration, and controlled substance disposal shall be identified and the records shall be retrievable. Retention time for records of bulk compounding, repackaging, administration, and all controlled substance transactions shall be a minimum of two (2) years. Retention time for records of dispensing and extemporaneous compounding, including sterile medications, shall be a minimum of six (6) months.
- (4) All variances, discrepancies, inconsistencies, or non-compliance involving controlled substances—including inventory, audits, security, record keeping, administration, and disposal—shall be reported to

the director of pharmacy services for review and investigation.

- (5) Patient medications may be received from an authorized provider. The medications shall—
- (A) Be delivered directly to the pharmacy and not to a patient care area unless the pharmacist is not available;
- (B) When a pharmacist is present, be identified, determined suitable for use and documented by the pharmacist. When a pharmacist is not present, be identified and documented by an authorized practitioner. Unused doses of medication shall be identified by the pharmacist when the pharmacist is present; and
- (C) The pharmacy may compound, repackage, or re-label medications received from an outside provider, including prescriptions dispensed by a pharmacy, as necessary for proper distribution and administration. Records of compounding, repackaging, or relabeling of prescriptions dispensed by a pharmacy shall allow identification of the original prescription.
- (6) Sample medications, if allowed, shall be received and distributed only by the pharmacy.
- (7) Medications may be provided to patients for use outside the hospital, by persons other than the pharmacist.
- (A) When the patient is a registered patient of the emergency department or is being discharged from the hospital—
- 1. Medications shall be provided according to the hospital's policies and procedures, including:
 - A. Circumstances when medications may be provided;
 - B. Practitioners authorized to order;
 - C. Specific medications;
 - D. Limited quantities;
 - E. Prepackaging and labeling by the pharmacist;
 - F. Final labeling to facilitate correct administration;
 - G. Delivery;
 - H. Counseling; and
 - I. A transaction record.
- 2. Medications shall be labeled with the date, patient's name, prescriber's name, name and address of the hospital, exact medication name and strength, instructions for use, and other pertinent information;
- 3. Medications may be provided only when prescription services from a pharmacy are not reasonably available. Reasonably available includes a pharmacist on duty in the hospital or a community pharmacy that is reasonably accessible to the patient;
- 4. The medication provided shall be limited to urgently needed treatment:
- 5. The quantity of medication provided shall be limited to the amount necessary until pharmacy services are available;
- 6. The provisions of paragraph (A)3. and paragraph (A)5. of this subsection shall not apply when the patient is being treated for an acute condition and it is believed that the immediate health and welfare of the patient and/or the community are in jeopardy. The quantity limit may be extended to provide single-course therapy; and
- 7. Final labeling, delivery and counseling shall be performed by a pharmacist, the prescriber or a registered nurse, except that final labeling and delivery may be performed by an automated dispensing system.
- (B) Automated dispensing systems may be used in accordance with all requirements of this section—
- 1. When the automated dispensing system is controlled by the prescriber it may be used only during times when no pharmacy services are reasonably available, except as allowed in paragraph (A)6 of this section; and
- 2. When the automated dispensing system is controlled by a pharmacy according to regulations of the Missouri Board of Pharmacy, including, but not limited to 20 CSR 2220-2.900.
- (C) Medications in multidose containers that were administered to or used for the patient during the patient's hospital stay may be sent

with the patient at discharge when so ordered by an authorized practitioner.

- 1. Examples of multidose medication containers include, but are not limited to, inhalers, ointments, creams, medications requiring the original container for dispensing, insulin pens, eye drops, ear drops, and infusions that are currently connected to the patient's infusion device.
- 2. Written instructions for use shall be provided by a pharmacist, prescriber, or registered nurse at the time of discharge.
- 3. Controlled substances shall not be sent with the patient, except that controlled substance infusions or continuous delivery systems currently connected to the patient may be sent as follows:
- A. The medication is necessary for administration during transport of the patient; and
- B. The quantity of controlled substance sent is documented in the patient's medical record by the person sending the medication.
- (8) The director of pharmacy services or his/her pharmacist designee shall be an active member of the pharmacy and therapeutics committee or its equivalent, which shall advise the medical staff on all medication matters.
- (9) Medications shall be ordered only by practitioners who have independent statutory authority to prescribe or who are authorized to order medications by their professional licensing agency as provided by state law. Authority to order medications may be granted to a non-physician licensed practitioner in accordance with state law
- (10) Medications in the possession of the patient at time of admission shall be given to the patient's representative unless there is an identified need to retain them.
- (A) Medications that are not given to the patient's representative and that are not to be administered shall be documented, sealed, and stored in a locked area accessible only to individuals authorized to access medications.
- (B) Controlled substances shall be security sealed and stored in a locked area accessible only to individuals authorized to administer controlled substances or to authorized pharmacy personnel.

AUTHORITY: sections 192.006 and 338.165, RSMo 2016, and section 197.080, RSMo Supp. 2019. This rule previously filed as 19 CSR 30-20.021(3)(G). Original rule filed June 27, 2007, effective Feb. 29, 2008. Rescinded and readopted: Filed March 20, 2019.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.102 Radiology Services in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1299). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.104 Social Services is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1299). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.106 Inpatient Care Units in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1299). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows

19 CSR 30-20.108 Fire Safety, General Safety and Operating Features **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1300). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.110 Orientation and Continuing Education is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1300). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.112 Quality Assessment and Performance Improvement Program **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1300). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.116 Infection Prevention and Control is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1300-1301). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.118 Outpatient Services in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1301). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.120 Anesthesia Services in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1301). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.124 Medical Services is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1301). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.126 Obstetrical and Newborn Services in Hospitals **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1301–1302). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.128 Pediatric Services in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1302). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.130 Post-Anesthesia Recovery Services in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg

1302). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.132 Psychiatric Services in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1302). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.134 Rehabilitation Services in Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1302–1303). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.136 Respiratory Care Services is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1303). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.138 Specialized Inpatient Care Services is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1303). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.140 Surgical Services is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1303). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 20—Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-20.142 Variance Requests is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1303–1304). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 24—Psychiatric Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-24.010 General Design and Construction Standards for Psychiatric Hospitals is rescinded.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1304). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 24—Psychiatric Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-24.020 Administration Standards for Psychiatric Hospitals **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1304). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 30—Division of Regulation and Licensure Chapter 24—Psychiatric Hospitals

ORDER OF RULEMAKING

By the authority vested in the Department of Health and Senior

Services under sections 197.005 and 197.080, RSMo Supp. 2019, the department rescinds a rule as follows:

19 CSR 30-24.030 Preparation of Plans and Specifications for Psychiatric Hospitals **is rescinded**.

A notice of proposed rulemaking containing the proposed rescission was published in the *Missouri Register* on May 1, 2019 (44 MoReg 1304). No changes have been made in the proposed rescission, so it is not reprinted here. This proposed rescission becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The department received no comments on the proposed rescission.

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE

Division 100—Insurer Conduct Chapter 1—Improper or Unfair Claims Settlement Practices

ORDER OF RULEMAKING

By the authority vested in the Director of the Department of Commerce and Insurance under section 374.045, RSMo 2016, the director amends a rule as follows:

20 CSR 100-1.030 Failure to Acknowledge Pertinent Communication **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on June 17, 2019 (44 MoReg 1684-1685). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE Division 100—Insurer Conduct Chapter 4—General

ORDER OF RULEMAKING

By the authority vested in the Director of the Department of Commerce and Insurance under section 374.045, RSMo 2016, the director amends a rule as follows:

20 CSR 100-4.100 Response to Inquiries by the Consumer Affairs Division **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on June 17, 2019 (44 MoReg 1685). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: No comments were received.

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE Division 100—Insurer Conduct Chapter 8—Market Conduct Examination

ORDER OF RULEMAKING

By the authority vested in the Director of the Department of

Commerce and Insurance under section 374.045, RSMo 2016, the director amends a rule as follows:

20 CSR 100-8.016 Examination Procedures is amended.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on June 17, 2019 (44 MoReg 1685-1686). No changes have been made in the text of the proposed amendment, so it is not reprinted here. This proposed amendment becomes effective thirty (30) days after publication in the *Code of State Regulations*.

SUMMARY OF COMMENTS: The public comment period ended July 18, 2019 and a public hearing on the proposed amendment was held July 18, 2019. Timely written comments were received from the Missouri Insurance Coalition. At the hearing, no comments were received.

COMMENT: Brandon Koch, on behalf of Missouri Insurance Coalition, commented that the current regulation states that market conduct surveillance personnel shall prepare a work plan and proposed budget and provide that information to the insurer prior to the commencement of an on-site market conduct examination. The rule further provides that market conduct examinations shall, to the extent feasible, utilize desk examinations and data requests prior to commencing on-site examination activity. The proposed amendment to this rule would appear to delete these requirements by repealing the first two subsections of the rule (sections (1) and (2)). The proposed amendment also adds a new provision (section (3)) which allows an insurer to request a review of the examination costs or data requests if significantly increased from the original work plan. The request is to be reviewed by the market conduct regulation division director or chief examiner who will be required to provide a response within twenty (20) days. The proposed changes to 20 CSR 100-8.016 are somewhat confusing. On one hand - the regulation appears to be removing the requirements to provide a work plan or budget and to use desk-examinations and data calls. On the other hand - the regulation is providing a remedy for an insurer to request a review of examination costs and the amount of data requested. While the deleted language contained in sections (1) and (2) may be contained elsewhere (perhaps the requirements are set forth in the NAIC Market Regulation Handbook or implied as a requirement in 20 CSR 100-8.015), we would prefer that sections (1) and (2) remain in the current regulation.

RESPONSE: In late 2017, Director Chlora Lindley-Myers convened a working group including department staff and ten members of the insurance industry to review Division 100, Chapters 7 and 8 in their entirety to address many concerns the industry had raised regarding the market conduct process. Through several meetings, all of the rules contained in Chapters 7 and 8 were discussed at great length and representatives from both the department and the insurance industry collaborated closely to arrive at the proposed rules filed with the secretary of state's office. The comment indicates the members of the Missouri Insurance Coalition are questioning some of the revised provisions regarding the examination budget. In the conversations of the working group, the members expressed concern over the lack of transparency into the factors underlying the examination. To address these issues, the department streamlined the overall timeline to front load additional information to be delivered contemporaneously with the warrant. The comment disregards the provision contained in 20 CSR 100-8.015, which will be in effect on July 30, 2019, that requires the notice of examination to include a "budget and work plan for the examination." This notice of examination will be provided contemporaneously with the examination warrant. The provisions noted by the commenter regarding the obligation of the Chief Examiner and Division Director to provide updated budget information upon request is an additional requirement upon the department. It does not replace or supercede any current requirements. No