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SALUS POPULI SUPREMA LEX ESTO

"The welfare of the people shall be the supreme law."

JOHN R. ASHCROFT
SECRETARY OF STATE

MISSOURI REGISTER

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MISSOURI REGISTER

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Documents will be accepted for filing on all regular workdays from 8:00 a.m. until 5:00 p.m. We encourage early filings to facilitate the timely publication of the *Missouri Register*. Orders of Rulemaking appearing in the *Missouri Register* will be published in the *Code of State Regulations* and become effective as listed in the chart above. Advance notice of large volume filings will facilitate their timely publication. We reserve the right to change the schedule due to special circumstances. Please check the latest publication to verify that no changes have been made in this schedule. To review the entire year's schedule, please see the website at sos.mo.gov/adrules/pubsched.

HOW TO CITE RULES AND RSMO

RULES

The rules are codified in the *Code of State Regulations* in this system–

Title	CSR	Division	Chapter	Rule
3	*Code of*	10-	4	.115
Department	*State*	Agency	General area	Specific area
	Regulations	division	regulated	regulated

and should be cited in this manner: 3 CSR 10-4.115.

Each department of state government is assigned a title. Each agency or division in the department is assigned a division number. The agency then groups its rules into general subject matter areas called chapters and specific areas called rules. Within a rule, the first breakdown is called a section and is designated as (1). Subsection is (A) with further breakdown into paragraphs 1., subparagraphs A., parts (I), subparts (a), items I. and subitems a.

The rule is properly cited by using the full citation; for example, 3 CSR 10-4.115, NOT Rule 10-4.115.

Citations of RSMo are to the *Missouri Revised Statutes* as of the date indicated.

Code and *Register* on the Internet

The *Code of State Regulations* and *Missouri Register* are available on the Internet.

The *Code* address is sos.mo.gov/adrules/csr/csr

The *Register* address is sos.mo.gov/adrules/moreg/moreg

These websites contain rulemakings and regulations as they appear in the *Code* and *Registers*.

Rules appearing under this heading are filed under the authority granted by section 536.025, RSMo. An emergency rule may be adopted by an agency if the agency finds that an immediate danger to the public health, safety, or welfare, or a compelling governmental interest requires emergency action; follows procedures best calculated to assure fairness to all interested persons and parties under the circumstances; follows procedures which comply with the protections extended by the *Missouri* and the *United States Constitutions*; limits the scope of such rule to the circumstances creating an emergency and requiring emergency procedure, and at the time of or prior to the adoption of such rule files with the secretary of state the text of the rule together with the specific facts, reasons, and findings which support its conclusion that there is an immediate danger to the public health, safety, or welfare which can be met only through the adoption of such rule and its reasons for concluding that the procedure employed is fair to all interested persons and parties under the circumstances.

Rules filed as emergency rules may be effective not less than ten (10) business days after filing or at such later date as may be specified in the rule and may be terminated at any time by the state agency by filing an order with the secretary of state fixing the date of such termination, which order shall be published by the secretary of state in the *Missouri Register* as soon as practicable.

All emergency rules must state the period during which they are in effect, and in no case can they be in effect more than one hundred eighty (180) calendar days or thirty (30) legislative days, whichever period is longer. Emergency rules are not renewable, although an agency may at any time adopt an identical rule under the normal rulemaking procedures.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 20—Division of Community and Public Health
Chapter 20—Communicable Diseases

EMERGENCY AMENDMENT

19 CSR 20-20.020 Reporting Infectious, Contagious, Communicable, or Dangerous Diseases. The department is amending section (2).

PURPOSE: This amendment adds monkeypox virus (orthopoxvirus/non-variola orthopoxvirus) to the list of diseases or findings that must be reported within one (1) day.

PURPOSE: This rule designates the diseases which are infectious, contagious, communicable or dangerous and must be reported to the local health authority or the Department of Health and Senior Services. It also establishes when they must be reported.

EMERGENCY STATEMENT: The Department of Health and Senior Services ("DHSS") determined that this emergency amendment is necessary to protect the public health, safety, and welfare of Missouri residents and visitors.

This emergency amendment is necessary to ensure that Monkeypox (Orthopoxvirus, non-variola Orthopoxvirus) is reported to the local health authority or DHSS within one day of detection. The Center for Disease Control and Prevention (CDC) is closely monitoring an outbreak of disease caused by the Monkeypox virus. There are currently over 8,900 cases linked to Monkeypox in the United States, and more than 30,000 worldwide. There have been ten (10) deaths linked to the current Monkeypox virus outbreak.

Reporting of the Monkeypox virus has not been required in the past, but due to its severity and the rapid increase in the number of cases, it is imperative for the local health authority or DHSS to be notified within one day of detection in order to take appropriate measures. Finally, since 19 CSR 20-20.040 assigns duties, responsibilities, and actions to the DHSS director as well as local health authorities that are explicitly triggered by the detection of a condition listed in 19 CSR 20-20.020, Monkeypox (Orthopoxvirus, non-variola Orthopoxvirus) must be immediately added to 19 CSR 20-20.020.

This rule designates the diseases which are infectious, contagious, communicable or dangerous and must be reported to the local health authority or the Department of Health and Senior Services. It also establishes when they must be reported. DHSS needs this emergency amendment to ensure that the presence of Monkeypox virus (Orthopoxvirus/non-variola Orthopoxvirus) is reported to the local health authority or the Department within one day of detection.

*DHSS finds that there is an immediate danger to the public health, safety or welfare, which requires this emergency action. A proposed amendment, which covers the same material, is published in this issue of the **Missouri Register**. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended in the **Missouri** and **United States Constitutions**. DHSS believes this emergency amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed August 15, 2022, becomes effective August 29, 2022, and expires February 24, 2023.*

(2) Reportable within one (1) day, diseases or findings shall be reported to the local health authority or to the Department of Health and Senior Services within one (1) calendar day of first knowledge or suspicion by telephone, facsimile, or other rapid communication. Reportable within one (1) day, diseases or findings are—

(A) Diseases, findings, or agents that occur naturally, or from accidental exposure, or as a result of an undetected bioterrorism event:

Animal (mammal) bite, wound, humans
Brucellosis
Chikungunya
Cholera
Dengue virus infection
Diphtheria
Glanders (Burkholderia mallei)
Haemophilus influenzae, invasive disease
Hantavirus pulmonary syndrome
Hemolytic uremic syndrome (HUS), postdiarrheal
Hepatitis A
Influenza-associated mortality
Influenza-associated public and/or private school closures
Lead (blood) level greater than or equal to forty-five micrograms per deciliter ($\geq$45 μg/dl) in any person
Legionellosis
Measles (rubeola)
Melioidosis (Burkholderia pseudomallei)
Meningococcal disease, invasive
Monkeypox virus (Orthopoxvirus/non-variola Orthopoxvirus)
Novel Influenza A virus infections, human
Outbreaks (including nosocomial) or epidemics of any illness, disease, or condition that may be of public health concern, including any illness in a food handler that is potentially transmissible through food
Pertussis
Poliovirus infection, nonparalytic
Q fever (acute and chronic)

Rabies (animal)
Rubella, including congenital syndrome
Shiga toxin-producing Escherichia coli (STEC)
Shiga toxin positive, unknown organism
Shigellosis
Staphylococcal enterotoxin B
Syphilis, including congenital syphilis
T-2 mycotoxin
Tetanus
Tuberculosis disease
Tularemia (all cases other than suspected intentional release)
Typhoid fever (Salmonella typhi)
Vancomycin-intermediate Staphylococcus aureus (VISA), and Vancomycin-resistant Staphylococcus aureus (VRSA)
Venezuelan equine encephalitis virus neuroinvasive disease
Venezuelan equine encephalitis virus nonneuroinvasive disease
Viral hemorrhagic fevers other than suspected intentional (e.g., Viral hemorrhagic fever diseases: Ebola, Marburg, Lassa, Lujo, new world Arenavirus (Guanarito, Machupo, Junin, and Sabia viruses), or Crimean-Congo)
Yellow fever
Zika;

AUTHORITY: sections 192.006, 192.020, 210.040, and 210.050, RSMo 2016. This rule was previously filed as 13 CSR 50-101.020. Original rule filed July 15, 1948, effective Sept. 13, 1948. For intervening history, please consult the ***Code of State Regulations****. Emergency amendment filed Aug. 15, 2022, effective Aug. 29, 2022, expires Feb. 24, 2023. A proposed amendment covering this same material is published in this issue of the* ***Missouri Register****.*

PUBLIC COST: This emergency amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the time the emergency is effective.

PRIVATE COST: This emergency amendment will not cost private entities more than five hundred dollars ($500) in the time the emergency is effective.

Under this heading will appear the text of proposed rules and changes. The notice of proposed rulemaking is required to contain an explanation of any new rule or any change in an existing rule and the reasons therefor. This is set out in the Purpose section with each rule. Also required is a citation to the legal authority to make rules. This appears following the text of the rule, after the word "Authority."

Entirely new rules are printed without any special symbology under the heading of proposed rule. If an existing rule is to be amended or rescinded, it will have a heading of proposed amendment or proposed rescission. Rules which are proposed to be amended will have new matter printed in boldface type and matter to be deleted placed in brackets.

An important function of the *Missouri Register* is to solicit and encourage public participation in the rulemaking process. The law provides that for every proposed rule, amendment, or rescission there must be a notice that anyone may comment on the proposed action. This comment may take different forms.

If an agency is required by statute to hold a public hearing before making any new rules, then a Notice of Public Hearing will appear following the text of the rule. Hearing dates must be at least thirty (30) days after publication of the notice in the *Missouri Register.* If no hearing is planned or required, the agency must give a Notice to Submit Comments. This allows anyone to file statements in support of or in opposition to the proposed action with the agency within a specified time, no less than thirty (30) days after publication of the notice in the *Missouri Register*.

An agency may hold a public hearing on a rule even though not required by law to hold one. If an agency allows comments to be received following the hearing date, the close of comments date will be used as the beginning day in the ninety- (90-) day-count necessary for the filing of the order of rulemaking.

If an agency decides to hold a public hearing after planning not to, it must withdraw the earlier notice and file a new notice of proposed rulemaking and schedule a hearing for a date not less than thirty (30) days from the date of publication of the new notice.

Proposed Amendment Text Reminder:
Boldface text indicates new matter.
[Bracketed text indicates matter being deleted.]

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 20—Division of Community and Public Health
Chapter 20—Communicable Diseases

PROPOSED AMENDMENT

19 CSR 20-20.020 Reporting Infectious, Contagious, Communicable, or Dangerous Diseases. The department is amending section (2).

PURPOSE: This amendment adds monkeypox virus (orthopoxvirus/non-variola orthopoxvirus) to the list of diseases or findings that must be reported within one (1) day.

(2) Reportable within one (1) day, diseases or findings shall be reported to the local health authority or to the Department of Health and Senior Services within one (1) calendar day of first knowledge or suspicion by telephone, facsimile, or other rapid communication. Reportable within one (1) day, diseases or findings are—

(A) Diseases, findings, or agents that occur naturally, or from accidental exposure, or as a result of an undetected bioterrorism event:

Animal (mammal) bite, wound, humans
Brucellosis
Chikungunya
Cholera
Dengue virus infection
Diphtheria
Glanders (Burkholderia mallei)
Haemophilus influenzae, invasive disease
Hantavirus pulmonary syndrome
Hemolytic uremic syndrome (HUS), postdiarrheal
Hepatitis A
Influenza-associated mortality
Influenza-associated public and/or private school closures
Lead (blood) level greater than or equal to forty-five micrograms per deciliter ($\geq$45 μg/dl) in any person
Legionellosis
Measles (rubeola)
Melioidosis (Burkholderia pseudomallei)
Meningococcal disease, invasive
Monkeypox virus (Orthopoxvirus/non-variola Orthopoxvirus)
Novel Influenza A virus infections, human
Outbreaks (including nosocomial) or epidemics of any illness, disease, or condition that may be of public health concern, including any illness in a food handler that is potentially transmissible through food
Pertussis
Poliovirus infection, nonparalytic
Q fever (acute and chronic)
Rabies (animal)
Rubella, including congenital syndrome
Shiga toxin-producing Escherichia coli (STEC)
Shiga toxin positive, unknown organism
Shigellosis
Staphylococcal enterotoxin B
Syphilis, including congenital syphilis
T-2 mycotoxin
Tetanus
Tuberculosis disease
Tularemia (all cases other than suspected intentional release)
Typhoid fever (Salmonella typhi)
Vancomycin-intermediate Staphylococcus aureus (VISA), and Vancomycin-resistant Staphylococcus aureus (VRSA)
Venezuelan equine encephalitis virus neuroinvasive disease
Venezuelan equine encephalitis virus nonneuroinvasive disease
Viral hemorrhagic fevers other than suspected intentional (e.g., Viral hemorrhagic fever diseases: Ebola, Marburg, Lassa, Lujo, new world Arenavirus (Guanarito, Machupo, Junin, and Sabia viruses), or Crimean-Congo)
Yellow fever
Zika;

AUTHORITY: sections 192.006, 192.020, 210.040, and 210.050, RSMo 2016. This rule was previously filed as 13 CSR 50-101.020. Original rule filed July 15, 1948, effective Sept. 13, 1948. For intervening history, please consult the ***Code of State Regulations****. Emergency amendment filed Aug. 15, 2022, effective Aug. 29, 2022, expires Feb. 24, 2023. Amended: Filed Aug. 15, 2022.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will cost private entities approximately one thousand four hundred forty-two dollars ($1,442) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Lori Brenneke, Division Director, Department of Health and Senior Services, Division of Community and Public Health, PO Box 570, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

FISCAL NOTE
PRIVATE COST

I. Department Title: Title 19 – Department of Health and Senior Services
Division Title: Division 20 – Division of Community and Public Health
Chapter Title: Chapter 20 – Communicable Diseases

Rule Number and Title:	19 CSR 20-20.020 Reporting Infectious, Contagious, Communicable, or Dangerous Diseases
Type of Rulemaking:	Amendment

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
482	Hospitals and Laboratories	$1,442

III. WORKSHEET

The proposed rule would have an estimated aggregate annual cost of $1,442 over the next five years across all laboratories or other entities (e.g. hospitals) that perform Monkeypox tests. This is derived from a projection that the baseline number of positive cases in a year will be 150 with the estimation that each positive test reported took five minutes of staff time and that each lab tech is paid $23.07 an hour.

[(750x5)/60] = 62.5 hours
62.5 x $23.07 = $1,442 (rounded up)

IV. ASSUMPTIONS

The proposed rule would require the submission of positive Monkeypox test results to the Missouri Department of Health and Senior Services (DHSS) or the local health authority. Each test submitted would require staff time for the laboratory or entity conducting the test. Although the time and cost for each individual test would be negligible, on the aggregate there would be a cost to Missouri businesses and organizations.

Each entity reporting test results to the department has the option of reporting via an electronic or manual paper submission method. The electronic method is estimated to take approximately five minutes per submission, while the manual paper method is estimated to take fifteen to twenty minutes per submission. As the electronic method is available to every entity and the proposed rule would allow for the least burdensome method of submission for every reported negative test, the department assumes for the purposes of this fiscal estimate that all submissions will be electronic.

At this time, looking to nations and U.S. states that experienced initial Monkeypox infections earlier than Missouri and that have continued to witness its spread; the department anticipates receiving a baseline of at least 150 new positive reports over the next year. A conservative estimate of cases would be 750 over five years. The real possibility exists actual cases will exceed that number, but the department has no past data to identify a more specific estimate. Please note this is not an official epidemiological estimate, forecast, or prediction by the department and is only for the purposes of this fiscal note.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 1—Controlled Substances

PROPOSED AMENDMENT

19 CSR 30-1.015 Registration and Fees. The Department of Health and Senior Services is amending section (3).

PURPOSE: This amendment changes the method for paying registration fees by requiring applicants to pay registration fees by credit card rather than in the form of personal, certified, or cashier's checks.

(3) Time and Method of Payment and Refunds. Registration and re-registration fees shall be paid at the time *[when]* the application for registration or re-registration is submitted for filing. This is a nonrefundable processing fee. Payment should be made in the form of *[a personal, certified, or cashier's check or money order made payable]* **an online credit card payment, payable** to the Department of Health and Senior Services. **Personal, certified, or cashier's checks, money orders, or other** *[P]***p**ayments made in the form of stamps, foreign currency, or third-party endorsed checks will not be accepted. Applications and fees **shall be** submitted electronically online **and applicants** shall use *[a credit card and use]* the online payment system provided on the department's website. **In the event the online application registration process becomes unavailable, applicants may contact the department for alternative options to apply for registration.**

*AUTHORITY: sections 195.030 and 195.195, RSMo [2000] **2016**. Original rule filed April 14,2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003.Amended: Filed April 29, 2011, effective Nov. 30, 2011. Amended: Filed Aug. 10, 2022.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will cost private entities forty-eight thousand ninety-nine dollars ($48,099) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Michael Boeger, Missouri Department of Health and Senior Services, Bureau of Narcotics and Dangerous Drugs, PO Box 570, Jefferson City, MO 65102 or via email at BNDD@health.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*

FISCAL NOTE
PRIVATE COST

I. Department Title: **Department of Health and Senior Services**
Division Title: **DIVISION 30—Division of Regulation and Licensure**
Chapter Title: **Chapter One—Controlled Substances**

Rule Number and Title:	19 CSR 30-1.015 Registrations and Fees
Type of Rulemaking:	Rule Amendment

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
32,066 people registered to conduct business with controlled substances	Hospitals, physicians, dentists, podiatrist, optometrists, veterinarians, mid-level practitioners, pharmacies, distributors, importers, exporters,	$48,099.00 annually

III. WORKSHEET

Currently, there are a total of 34,400 registrants. Out of this population, 32,066 registrants are in the private sector and the remainder are in the public sector. Out of the 32,066 registrants in the private sector that apply annually to get a state controlled substance registration, 95% apply online and click to pay with a credit card. The remaining 5% apply via a paper application. Public sector, government paid employees are exempt from paying registration fees.

Currently, registrants who pay for their registration via credit card pay on average a $1.50 credit card processing fee. Since this rule eliminates the option of paying the registration fees via personal, certified, or cashier's check, all registrants that are required to pay registration fees will incur the $1.50 credit card processing fee. Assuming 32,066 registrants will now have to pay the credit card processing fee of $1.50, the total cost to comply with this proposed rule is $48,099.00

IV. ASSUMPTIONS

The Department is working toward having everyone apply for their annual drug registrations online and then eliminate the paper application process unless there is an unforeseen emergency. Applicants will have to apply online electronically.

Medical providers in the industry already have computers and the ability to submit this data. They are already complying with laws regarding:

- Using electronic medical records;
- Mandatory computer submissions to bill and conduct business with Medicare and Medicaid;
- The federal DEA is implementing regulations that all applications must be online and electronic;
- Missouri Legislature enacted a law to require all controlled substance prescriptions to be electronically submitted

A paper application filled out by a registrant and mailed in to the department will take the registrants approximately 15 minutes of their time and then mailing costs. That registration process may take up to ten days.

At the department the application is handled by the mail room, then the fee receipt office for deposit, and then applications are hand entered into the database by staff. This process hits three separate department offices and is why it takes multiple days. The department pay to archive the applications.

Applying online takes 5 minutes and a new registration can be issued in one business day.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 1—Controlled Substances

PROPOSED AMENDMENT

19 CSR 30-1.017 Registration Process. The Department of Health and Senior Services is amending sections (1), (3), (5), (6), (7), and (8).

PURPOSE: This amendment requires applicants to apply for registrations through an electronic online system and eliminates the paper application process.

(1) Database and Survey Process.

(B) Applicants *[may]* **shall** apply *[with either a paper application or]* through the department's electronic online system.

(C) Simultaneously with completing an application for a controlled substances registration, practitioners may also complete an annual voluntary census to assist the department in determining practitioner shortages and underserved regions of the state. Required questions and fields for controlled substance registrations are marked with an asterisk (*) in the electronic online system *[and on paper applications]*.

(3) Requirements for All Applicants.

(A) Any person who is required to be registered and who is not so registered may apply **online** for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is processed and the registration is issued. All applications are for new registrations.

(B) Applications for registration shall be made on **online** forms designated by the Department of Health and Senior Services. Application *[forms may be requested from the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or may]* **for registration shall** be completed online and submitted electronically via the Missouri Department of Health and Senior Services' website at *[www.health.mo.gov]* **https://health.mo.gov/safety/bndd/** along with the required fee.

(C) *[A written]* **An** application *[in paper form]* shall contain the **electronic** signature of the applicant and shall be provided to the Department of Health and Senior Services with any required fee. This is a nonrefundable processing fee.

(5) Applications for Individual Practitioner Registrations. Applications by physicians, veterinarians, optometrists, podiatrists, and researchers for Missouri Controlled Substance Registrations shall include:

(M) The *[original]* **electronic** signature of the individual applicant*[, if the application is submitted on paper]*;

(6) Applications for Pharmacies and Businesses. Applications for retail pharmacies and ambulance services, ambulatory surgery centers, analytical laboratories, correctional centers, distributors, exporters, hospices, hospitals, importers, manufacturers, narcotic treatment programs, long-term care facility E-kits, teaching institutions, researchers, or other applicants not listed in sections (5)–(8), shall include:

(K) The application shall be submitted **online** with the required fee and fee information. If claiming an exemption from a fee, the applicant must identify the name of the government agency;

(N) The applicant shall **electronically** sign and date an application *[submitted on paper and may use the electronic process if applying online]*. An application may be signed by the owner, chief executive officer or administrator, corporate officer, medical director, or pharmacist in charge.

(7) Applications for Dentists. Applications for dentists with the degrees of D.D.S. or D.M.D. shall include:

(Q) The applicant shall sign and date an application submitted *[on paper and may use the electronic process if applying online]* **electronically**.

(8) Applications for Mid-Level Practitioners. Applications for mid-level practitioners as defined by 21 CFR 1300.01(b)(28) such as advanced practice nurses and physician assistants shall include:

(Q) The applicant shall sign and date an application submitted *[on paper and may use the electronic process if applying online]* **electronically**.

*AUTHORITY: section 195.195, RSMo [2000] **2016**. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011. Amended: Filed Aug. 10, 2022.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will cost private entities forty-eight thousand ninety-nine dollars ($48,099) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Michael Boeger, Missouri Department of Health and Senior Services, Bureau of Narcotics and Dangerous Drugs, PO Box 570, Jefferson City, MO 65102 or via email at BNDD@health.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: DIVISION 30—Division of Regulation and Licensure
Chapter Title: Chapter One—Controlled Substances

Rule Number and Title:	19 CSR 30-1.017 Registration Process
Type of Rulemaking:	Rule Amendment

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
32,066 people registered to conduct business with controlled substances	Hospitals, physicians, dentists, podiatrist, optometrists, veterinarians, mid-level practitioners, pharmacies, distributors, importers, exporters,	$48,099.00 annually

III. WORKSHEET

There are 32,066 registrants in the private sector that apply annually to get state controlled substances registration. Right now, about 95% apply online and click t pay with a credit card. The remaining 5% send in a paper application through the mail.

Registrants already have the ability to apply online since they would already have computer hardware and software technology in their medical practice.

As this rule eliminates the ability to apply or renew a registration by the paper process (i.e. mailing in a paper application) and requires an applicant to apply online, the applicant will have to pay registration fees with a credit card. Currently, registrants who pay for their registration via credit card pay on average a $1.50 credit card processing fee. Assuming 32,066 registrants will now have to pay the average credit card processing fee of $1.50, the total cost to comply with this proposed rule is $48,099.00

IV. ASSUMPTIONS

The department is working toward having everyone apply for their annual drug registrations online and then eliminate the paper application process unless there is an unforeseen emergency. Applicants will have to apply online electronically.

Medical providers in the industry already have computers and the ability to submit this data. They are already complying with laws regarding:

- Using electronic medical records;
- Mandatory computer submissions to bill and conduct business with Medicare and Medicaid;
- The federal DEA is implementing a regulations that all applications must be online and electronic;
- Missouri Legislature enacted a law to require all controlled substance prescriptions to be electronically submitted

A paper application filled out by a registrant and mailed in to the department will take the registrants approximately 15 minutes of their time and then mailing costs. That registration process may take up to ten days.

At the department the application is handled by the mail room, then the fee receipt office for deposit, and then applications are hand entered into the database by staff. This process hits three separate department offices and is why it takes multiple days. The department pay to archive the applications.

Applying online takes 5 minutes and a new registration can be issued in one business day.

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 500—Property and Casualty
Chapter 4—Rating Laws

PROPOSED AMENDMENT

20 CSR 500-4.300 Rate Variations (Consent Rate) Prerequisites. The director is amending this rule by adding a new section (3).

PURPOSE: The purpose of this amendment is to add standards for the use of the consent to rate provisions of section 379.318, RSMo, to aircraft insurance.

(3) Standards for the Use of Consent to Rate Applicable to Aircraft Insurance.

(A) This section applies to policies of insurance against liability, other than employers' liability, arising out of the ownership, maintenance, or use of aircraft.

(B) No insurance company or reciprocal interinsurance exchange using rates subject to section 379.318, RSMo, shall effect a policy of insurance or a renewal at a rate varying from the rate properly filed for its use on that specific risk unless the company documents the need to deviate from the filed rate based on the unique nature of the individual risk.

(C) All insurance companies subject to this section shall—

1. Collect and maintain documentation that demonstrates the unique characteristics of the risk and how the final premium was determined;

2. File and maintain the documentation in the company's policy file; and

3. Make the documentation available to the director upon request.

*AUTHORITY: sections 374.045, 375.031, 375.136, 379.318(2), and 379.470(6), RSMo 2016, and section 379.321[(3)]**.3**, RSMo Supp. [2018] **2021**. This rule was previously filed as 4 CSR 190-16.080. Original rule filed Dec. 20, 1974, effective Dec. 30, 1974. Amended: Filed April 23, 1999, effective Nov. 30, 1999. Amended: Filed July 12, 2002, effective Jan. 30, 2003. Amended: Filed Dec. 13, 2018, effective July 30, 2019. Amended: Filed Aug. 15, 2022.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

*NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Department of Commerce and Insurance, 301 West High Street, Jefferson City, MO 65101. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for 9:30 am, October 19, 2022, in Room 530, Truman State Office Building, 301 West High Street, Jefferson City, MO 65101.*

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 2150—State Board of Registration for the Healing Arts
Chapter 5—General Rules

PROPOSED RULE

20 CSR 2150-5.024 HIV Post-Exposure Prophylaxis

PURPOSE: This rule establishes requirements for authorized pharmacists dispensing HIV post-exposure prophylaxis as authorized by section 338.730, RSMo.

(1) Definitions.

(A) Authorized pharmacist—A Missouri-licensed pharmacist who has completed a training course or certificate program in HIV antiretroviral prophylaxis that includes training in CDC guidelines for HIV PEP

(B) Authorizing physician—A physician identified in a written protocol as authorizing a pharmacist to dispense HIV PEP and who will be collaborating with an authorized pharmacist in HIV PEP dispensing.

(C) CDC guidelines—The current human immunodeficiency virus (HIV) guidelines published by the federal Centers for Disease Control and Prevention (CDC) for non-occupational and occupational HIV exposure.

(D) Medical staff committee—The medical staff committee of a hospital or hospital system as defined by section 338.165, RSMo, that includes a Missouri-licensed physician, or the medical staff committee or similar body of a Missouri-licensed long-term care facility that includes a Missouri-licensed physician and is responsible for formulating policies regarding pharmacy services and medication management for the long-term care facility.

(E) Pharmacy resident—A graduate of a pharmacy school/college accredited by the Accreditation Council for Pharmacy Education (ACPE) who is a licensed pharmacist enrolled in a residency training program accredited by the American Society of Health-System Pharmacists, a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists, or a residency program operated by or in conjunction with an ACPE-accredited school or college of pharmacy.

(F) Physician—An individual who is actively engaged in the practice of medicine in the state of Missouri and holds a current Missouri physician and surgeon license pursuant to Chapter 334, RSMo, which is not encumbered in any way, such as by designation as probated, restricted, limited, temporary, inactive, or retired;

(G) Post-exposure prophylaxis (PEP)—Any medication approved by the Food and Drug Administration (FDA) that meets the same clinical eligibility recommendations provided in CDC guidelines.

(H) Protocol—For purposes of section 338.730, RSMo, and this rule, a protocol is defined as—

1. A written protocol approved by a Missouri-licensed physician that meets the minimum standards in section (2) of this rule and agreed to by the authorized pharmacist who would be dispensing HIV PEP;

2. A written protocol approved by the medical staff committee of a hospital or hospital system as defined by section 338.165, RSMo, that includes a Missouri-licensed physician;

3. A written protocol approved by the medical staff committee of a Missouri-licensed long-term care facility that includes a Missouri-licensed physician; or

4. A standing order issued by the Director of the Missouri Department of Health and Senior Services (DHSS) if a physician, or by a physician approved and designated by DHSS.

(2) Authorized pharmacists may enter a written protocol to prescribe and dispense HIV PEP, as provided by section 338.730, RSMo. HIV PEP protocols must be within the skill, education, training, and competence of both the authorizing physician and authorized pharmacist.

(A) HIV PEP protocols must adhere to CDC guidelines and include specific directions for the authorized pharmacist to follow. Except as otherwise provided by DHSS for a DHSS protocol, HIV PEP protocols must, at a minimum, include the following:

1. Directions/guidelines for patient assessment and counseling;

2. Authorized drug therapies to be dispensed, including the specified dosage regimen and dosage forms;

3. Authorized route(s) of administration;

4. Specific requirements for referring patients to a healthcare provider for additional evaluation/treatment;

5. Any patient counseling requirements designated by the authorizing physician; and

6. Any documentation or recordkeeping required by the authorizing physician.

(B) Protocols may include provisions that allow an authorized pharmacist to create a prescription in the physician's name for HIV PEP medication. The prescription must comply with all applicable state and federal law. The prescription may be dispensed by a licensed pharmacy and must be maintained in the prescription records of the dispensing pharmacy as provided by the Missouri State Board of Pharmacy's rules.

(C) Protocols may allow the authorized pharmacist to order or perform testing as authorized by the protocol physician or medical staff committee. If the protocol includes conducting physical assessments or ordering and evaluating laboratory or other tests, the protocol must identify required assessments, authorized tests to be ordered, the criteria for ordering the assessments and tests, interpretation of assessments/tests, and what action the authorized pharmacist is authorized to take based on assessment/test results.

(D) Except as otherwise authorized for a DHSS statewide standing order, protocols must be signed and dated by the authorizing physician and the authorized pharmacist. If the protocol includes multiple physicians or authorized pharmacists, a separate protocol is not required for each physician or authorized pharmacist if all authorizing physicians and authorized pharmacists have signed and dated a statement agreeing to be governed by the terms of the written protocol. Unless otherwise required by DHSS, a HIV PEP statewide standing order is exempt from the signature/dating requirements of this subsection. When utilizing the HIV PEP statewide standing order issued by DHSS, the pharmacist or the designee of the pharmacist shall periodically review the HIV PEP statewide standing order and ensure it is current and active.

(E) Pharmacy residents. In lieu of an individual protocol, a pharmacy resident may dispense HIV PEP as part of their residency training under the HIV PEP protocol of an authorized pharmacist, if authorized by the governing protocol.

(F) Protocols must be physically or electronically maintained by both the authorizing physician and authorized pharmacist and available to the Board of Pharmacy and the Board of Registration for the Healing Arts for a minimum of eight (8) years after termination of the protocol.

(G) DHSS protocols shall be governed by and comply with all DHSS requirements and provisions.

(3) Compliance and Supervision.

(A) Authorized pharmacists must ensure patient care activities are safely and properly performed in accordance with the governing protocol, recognized standards of practice, and current CDC guidelines. Additionally, authorized pharmacists must comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board of Pharmacy governing prescribing and recordkeeping.

(B) The authorizing physician shall be responsible for overseeing compliance with protocol requirements, section 338.730, RSMo, and current CDC guidelines, but may designate such responsibilities to a pharmacist if a medication therapy services protocol is in place that includes dispensing HIV PEP. Except as otherwise provided by a DHSS protocol, the authorizing physician or a designee of the authorizing physician who is a Missouri-licensed healthcare provider must be available to—

1. Provide follow-up appointments for care of patients who received PEP pursuant to a HIV PEP protocol, or maintain a list of physician, surgeons, clinics, or other Missouri-licensed healthcare providers who the authorizing physician or the designee of the authorizing physician confirmed are willing and able to accept referrals of patients within a reasonable time of the authorized pharmacist initiating HIV PEP and deliver care; and

2. Respond to calls/inquiries from the authorized pharmacist regarding HIV PEP dispensing, treatment, or patient assessment.

(4) Authorized pharmacists prescribing/dispensing HIV PEP pursuant to a DHSS standing order must comply with all DHSS requirements. Authorized pharmacists must comply with the following requirements when prescribing/dispensing HIV PEP based on all other protocols:

(A) Unless otherwise provided by CDC guidelines or restricted by the governing protocol, an authorized pharmacist may dispense a twenty-eight- (28-) day course of HIV PEP therapy, if all of the following conditions are met:

1. The patient is thirteen (13) years of age or older;

2. The patient is HIV negative, as documented by a negative HIV test result obtained within the previous twenty-four (24) hours from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the authorized pharmacist shall order an HIV test. If the test results are not transmitted directly to the authorized pharmacist, the pharmacist shall verify the test results to the authorized pharmacist's satisfaction. If the patient tests positive for HIV infection, the authorized pharmacist must immediately notify the patient and refer the patient to the patient's primary care provider if known, and provide a list of providers and clinics in the patient's region for confirmatory testing and follow-up care. If an HIV test is not reasonably available for twenty-four (24) hours or longer, the authorized pharmacist may use clinical discretion to dispense HIV PEP upon verification that other criteria for dispensing has been met and HIV PEP is otherwise indicated;

3. The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms;

4. The patient is not taking any contraindicated medications per guidelines and package insert information;

5. The single high-risk event of non-occupational exposure to HIV occurred within seventy-two (72) hours of the pharmacist-patient encounter; and

6. An authorized pharmacist may not dispense HIV PEP to an individual patient by protocol more than twice every three hundred sixty-five (365) days. The authorized pharmacist must notify the patient of the three hundred sixty-five- (365-) day limit and advise the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for PEP if the patient exceeds the three hundred sixty-five- (365-) day dispensing limit;

(B) Authorized pharmacists must counsel patients on the safe and appropriate use of HIV PEP to maximize therapeutic outcomes. Counseling may include, but is not limited to, education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of childbearing capacity. The authorized pharmacist should stress the importance of ongoing monitoring and follow-up care with a primary care provider, and recommend routine primary care and health maintenance. Authorized pharmacists must also notify patients that confirmation HIV testing is recommended at three (3) and six (6) months or the interval(s) recommended by the CDC;

(C) Because of the importance of follow-up care and the potential difficulty of obtaining an appointment on short notice, authorized pharmacists must provide patients prescribed or dispensed HIV PEP a list of, and addresses and contact information for, nearby federally qualified health centers, local county health departments, hospitals, emergency departments, or other governmental providers/agencies that may provide follow-up care or HIV testing, treatment, or counseling for the patient; and

(D) The authorized pharmacist must notify the patient's primary care provider when the pharmacist prescribes/dispenses HIV PEP to the patient. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the authorized pharmacist must provide the patient a list of physicians and surgeons, clinics, or other healthcare service providers who the authorizing physician or the designee of the authorizing physician confirmed are willing and able to accept new or uninsured patients and deliver care in a timely fashion. The required list must be developed in consultation with or approved by the authorizing physician, and must be updated by December 31 of each calendar year and as needed to ensure patients have access to follow-up care and success with obtaining appointments. If the patient does not have a primary care provider, the authorized pharmacist must also recommend that the patient use a patient healthcare navigator or community healthcare case worker as defined by the CDC to access healthcare services. An authorized pharmacist must document authorization from the patient prior to facilitating referrals, coordinating follow-up care, or making appointments with a provider on the patient's behalf.

(5) Mandatory Referrals/Reporting. Authorized pharmacists must make the following referrals when prescribing/dispensing HIV PEP by protocol:

(A) An authorized pharmacist shall not prescribe or dispense HIV PEP and must immediately refer the patient to an emergency department or a primary care provider for urgent treatment if the patient is under thirteen (13) years old or is taking any contraindicated medications per guidelines and package insert information;

(B) If a patient tests positive for HIV infection, a sexually transmitted disease, or hepatitis B or C, the authorized pharmacist must refer or direct the patient to a primary care provider and provide the patient a list of providers or clinics in the patient's region for confirmatory testing and follow-up care;

(C) If the patient returns to the authorized pharmacist for follow-up care and shows signs or symptoms of acute renal injury, acute HIV infection, acute drug toxicities, or serious side effects after taking HIV PEP, the authorized pharmacist shall immediately refer the patient to an emergency department for urgent evaluation and treatment; and

(D) Authorized pharmacists shall report actual or suspected child abuse or neglect to the Missouri Department of Social Services, Children's Division, as required by Missouri law, including but not limited to sections 210.115 and 210.130, RSMo. If the case involves a known sexual assault victim, the authorized pharmacist shall refer the patient to an emergency department, and recommend that the patient contact law enforcement and be examined and co-managed by professionals trained in assessing and counseling individuals who have been sexually assaulted.

(6) Patient Medical Records. Authorized pharmacists shall maintain a patient medical record for each patient that documents the care provided for the patient pursuant to a HIV PEP protocol.

(A) At a minimum, the required patient medical record must include:

1. The patient's name, birthdate, address, and telephone number;
2. The date(s) the patient was seen;
3. The name or identity of the authorized pharmacist;
4. The patient's primary care provider, if provided;
5. Documentation of patient screening;
6. All information required by the governing protocol or requested by the authorizing physician;
7. Any other pertinent medical or medication information/history;
8. The name and dosage of medication dispensed or prescribed under the authorizing physician's name; and
9. Any healthcare provider referrals.

(B) Patient medical records must be individually retrievable and must be securely and confidentially maintained in compliance with applicable state and federal law. At a minimum, patient medical records must be maintained for seven (7) years from the date created. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from a board or a board's authorized designee. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

(C) Patient records for pharmacy services provided by an authorized pharmacist pursuant to an HIV PEP protocol must be produced to the authorizing physician or medical staff committee on request.

(7) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation by the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, or their authorized representatives, as requested by the respective board or the board's designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

AUTHORITY: section 334.125, RSMo 2016, and section 338.730, RSMo Supp. 2021. Original rule filed Aug. 10, 2022.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Missouri State Board of Registration for the Healing Arts, PO Box 4, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 751-3166, or via email at healingarts@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220—State Board of Pharmacy
Chapter 6—Pharmaceutical Care Standards

PROPOSED RULE

20 CSR 2220-6.025 HIV Post-Exposure Prophylaxis

PURPOSE: This rule establishes requirements for authorized pharmacists dispensing HIV post-exposure prophylaxis as authorized by section 338.730, RSMo.

(1) Definitions.

(A) Authorized pharmacist—A Missouri-licensed pharmacist who has completed a training course or certificate program in HIV antiretroviral prophylaxis that includes training in CDC guidelines for HIV PEP.

(B) Authorizing physician—A physician identified in a written protocol as authorizing a pharmacist to dispense HIV PEP and who will be collaborating with an authorized pharmacist in HIV PEP dispensing.

(C) CDC guidelines—The current human immunodeficiency virus (HIV) guidelines published by the federal Centers for Disease Control and Prevention (CDC) for non-occupational and occupational HIV exposure.

(D) Medical staff committee—The medical staff committee of a hospital or hospital system as defined by section 338.165, RSMo, that includes a Missouri-licensed physician, or the medical staff committee or similar body of a Missouri-licensed long-term care facility that includes a Missouri-licensed physician and is responsible for formulating policies regarding pharmacy services and medication management for the long-term care facility.

(E) Pharmacy resident—A graduate of a pharmacy school/college accredited by the Accreditation Council for Pharmacy Education (ACPE) who is a licensed pharmacist enrolled in a residency training program accredited by the American Society of Health-System Pharmacists, a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists, or a residency program operated by or in conjunction with an ACPE-accredited school or college of pharmacy.

(F) Physician—An individual who is actively engaged in the practice of medicine in the state of Missouri and holds a current Missouri physician and surgeon license pursuant to Chapter 334, RSMo, which is not encumbered in any way, such as by designation as probated, restricted, limited, temporary, inactive, or retired;

(G) Post-exposure prophylaxis (PEP)—Any medication approved by the Food and Drug Administration (FDA) that meets the same clinical eligibility recommendations provided in CDC guidelines.

(H) Protocol—For purposes of section 338.730, RSMo, and this rule, a protocol is defined as—

1. A written protocol approved by a Missouri-licensed physician that meets the minimum standards in section (2) of this rule and agreed to by the authorized pharmacist who would be dispensing HIV PEP;

2. A written protocol approved by the medical staff committee of a hospital or hospital system as defined by section 338.165, RSMo, that includes a Missouri-licensed physician;

3. A written protocol approved by the medical staff committee of a Missouri-licensed long-term care facility that includes a Missouri-licensed physician; or

4. A standing order issued by the Director of the Missouri Department of Health and Senior Services (DHSS) if a physician, or by a physician approved and designated by DHSS.

(2) Authorized pharmacists may enter a written protocol to prescribe and dispense HIV PEP, as provided by section 338.730, RSMo. HIV PEP protocols must be within the skill, education, training, and competence of both the authorizing physician and authorized pharmacist.

(A) HIV PEP protocols must adhere to CDC guidelines and include specific directions for the authorized pharmacist to follow. Except as otherwise provided by DHSS for a DHSS protocol, HIV PEP protocols must, at a minimum, include the following:

1. Directions/guidelines for patient assessment and counseling;

2. Authorized drug therapies to be dispensed including the specified dosage regimen and dosage forms;

3. Authorized route(s) of administration;

4. Specific requirements for referring patients to a healthcare provider for additional evaluation/treatment;

5. Any patient counseling requirements designated by the authorizing physician; and

6. Any documentation or recordkeeping required by the authorizing physician.

(B) Protocols may include provisions that allow an authorized pharmacist to create a prescription in the physician's name for HIV PEP medication. The prescription must comply with all applicable state and federal law. The prescription may be dispensed by a licensed pharmacy and must be maintained in the prescription records of the dispensing pharmacy as provided by the Missouri State Board of Pharmacy's rules.

(C) Protocols may allow the authorized pharmacist to order or perform testing as authorized by the protocol physician or medical staff committee. If the protocol includes conducting physical assessments or ordering and evaluating laboratory or other tests, the protocol must identify required assessments, authorized tests to be ordered, the criteria for ordering the assessments and tests, interpretation of assessments/tests, and what action the authorized pharmacist is authorized to take based on assessment/test results.

(D) Except as otherwise authorized for a DHSS statewide standing order, protocols must be signed and dated by the authorizing physician and the authorized pharmacist. If the protocol includes multiple physicians or authorized pharmacists, a separate protocol is not required for each physician or authorized pharmacist if all authorizing physicians and authorized pharmacists have signed and dated a statement agreeing to be governed by the terms of the written protocol. Unless otherwise required by DHSS, a HIV PEP statewide standing order is exempt from the signature/dating requirements of this subsection. When utilizing the HIV PEP statewide standing order issued by DHSS, the pharmacist or the designee of the pharmacist shall periodically review the HIV PEP statewide standing order and ensure it is current and active.

(E) Pharmacy residents. In lieu of an individual protocol, a pharmacy resident may dispense HIV PEP as part of their residency training under the HIV PEP protocol of an authorized pharmacist, if authorized by the governing protocol.

(F) Protocols must be physically or electronically maintained by both the authorizing physician and authorized pharmacist and available to the Board of Pharmacy and the Board of Registration for the Healing Arts for a minimum of eight (8) years after termination of the protocol.

(G) DHSS protocols shall be governed by and comply with all DHSS requirements and provisions.

(3) Compliance and Supervision.

(A) Authorized pharmacists must ensure patient care activities are safely and properly performed in accordance with the governing protocol, recognized standards of practice, and current CDC guidelines. Additionally, authorized pharmacists must comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board of Pharmacy governing prescribing and recordkeeping.

(B) The authorizing physician shall be responsible for overseeing compliance with protocol requirements, section 338.730, RSMo, and current CDC guidelines, but may designate such responsibilities to a pharmacist if a medication therapy services protocol is in place that includes dispensing HIV PEP. Except as otherwise provided by a DHSS protocol, the authorizing physician or a designee of the authorizing physician who is a Missouri-licensed healthcare provider must be available to—

1. Provide follow-up appointments for care of patients who received PEP pursuant to a HIV PEP protocol, or maintain a list of physician, surgeons, clinics, or other Missouri-licensed healthcare providers who the authorizing physician or the designee of the authorizing physician confirmed are willing and able to accept referrals of patients within a reasonable time of the authorized pharmacist initiating HIV PEP and deliver care; and

2. Respond to calls/inquiries from the authorized pharmacist regarding HIV PEP dispensing, treatment, or patient assessment.

(4) Authorized pharmacists prescribing/dispensing HIV PEP pursuant to a DHSS standing order must comply with all DHSS requirements. Authorized pharmacists must comply with the following requirements when prescribing/dispensing HIV PEP based on all other protocols:

(A) Unless otherwise provided by CDC guidelines or restricted by the governing protocol, an authorized pharmacist may dispense a twenty-eight- (28-) day course of HIV PEP therapy, if all of the following conditions are met:

1. The patient is thirteen (13) years of age or older;

2. The patient is HIV negative, as documented by a negative HIV test result obtained within the previous twenty-four (24) hours from an HIV antigen/antibody test or antibody-only test or from a

rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the authorized pharmacist shall order an HIV test. If the test results are not transmitted directly to the authorized pharmacist, the pharmacist shall verify the test results to the authorized pharmacist's satisfaction. If the patient tests positive for HIV infection, the authorized pharmacist must immediately notify the patient and refer the patient to the patient's primary care provider if known, and provide a list of providers and clinics in the patient's region for confirmatory testing and follow-up care. If an HIV test is not reasonably available for twenty-four (24) hours or longer, the authorized pharmacist may use clinical discretion to dispense HIV PEP upon verification that other criteria for dispensing has been met and HIV PEP is otherwise indicated;

3. The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms;

4. The patient is not taking any contraindicated medications per guidelines and package insert information;

5. The single high-risk event of non-occupational exposure to HIV occurred within seventy-two (72) hours of the pharmacist-patient encounter; and

6. An authorized pharmacist may not dispense HIV PEP to an individual patient by protocol more than twice every three hundred sixty-five (365) days. The authorized pharmacist must notify the patient of the three hundred sixty-five- (365-) day limit and advise the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for PEP if the patient exceeds the three hundred sixty-five- (365-) day dispensing limit;

(B) Authorized pharmacists must counsel patients on the safe and appropriate use of HIV PEP to maximize therapeutic outcomes. Counseling may include, but is not limited to, education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of childbearing capacity. The authorized pharmacist should stress the importance of ongoing monitoring and follow-up care with a primary care provider, and recommend routine primary care and health maintenance. Authorized pharmacists must also notify patients that confirmation HIV testing is recommended at three (3) and six (6) months or the interval(s) recommended by the CDC;

(C) Because of the importance of follow-up care and the potential difficulty of obtaining an appointment on short notice, authorized pharmacists must provide patients prescribed or dispensed HIV PEP a list of, and addresses and contact information for, nearby federally qualified health centers, local county health departments, hospitals, emergency departments, or other governmental providers/agencies that may provide follow-up care or HIV testing, treatment, or counseling for the patient; and

(D) The authorized pharmacist must notify the patient's primary care provider when the pharmacist prescribes/dispenses HIV PEP to the patient. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the authorized pharmacist must provide the patient a list of physicians and surgeons, clinics, or other healthcare service providers who the authorizing physician or the designee of the authorizing physician confirmed are willing and able to accept new or uninsured patients and deliver care in a timely fashion. The required list must be developed in consultation with or approved by the authorizing physician, and must be updated by December 31 of each calendar year and as needed to ensure patients have access to follow-up care and success with obtaining appointments. If the patient does not have a primary care provider, the authorized pharmacist must also recommend that the patient use a patient healthcare navigator or community healthcare case worker as defined by the CDC to access healthcare services. An authorized pharmacist must document authorization from the patient prior to facilitating referrals, coordinating follow-up care, or making appointments with a provider on the patient's behalf.

(5) Mandatory Referrals/Reporting. Authorized pharmacists must make the following referrals when prescribing/dispensing HIV PEP by protocol:

(A) An authorized pharmacist shall not prescribe or dispense HIV PEP and must immediately refer the patient to an emergency department or a primary care provider for urgent treatment if the patient is under thirteen (13) years old or is taking any contraindicated medications per guidelines and package insert information;

(B) If a patient tests positive for HIV infection, a sexually transmitted disease, or hepatitis B or C, the authorized pharmacist must refer or direct the patient to a primary care provider and provide the patient a list of providers or clinics in the patient's region for confirmatory testing and follow-up care;

(C) If the patient returns to the authorized pharmacist for follow-up care and shows signs or symptoms of acute renal injury, acute HIV infection, acute drug toxicities, or serious side effects after taking HIV PEP, the authorized pharmacist shall immediately refer the patient to an emergency department for urgent evaluation and treatment; and

(D) Authorized pharmacists shall report actual or suspected child abuse or neglect to the Missouri Department of Social Services, Children's Division, as required by Missouri law, including but not limited to sections 210.115 and 210.130, RSMo. If the case involves a known sexual assault victim, the authorized pharmacist shall refer the patient to an emergency department, and recommend that the patient contact law enforcement and be examined and co-managed by professionals trained in assessing and counseling individuals who have been sexually assaulted.

(6) Patient Medical Records. Authorized pharmacists shall maintain a patient medical record for each patient that documents the care provided for the patient pursuant to a HIV PEP protocol.

(A) At a minimum, the required patient medical record must include:

1. The patient's name, birthdate, address, and telephone number;

2. The date(s) the patient was seen;

3. The name or identity of the authorized pharmacist;

4. The patient's primary care provider, if provided;

5. Documentation of patient screening;

6. All information required by the governing protocol or requested by the authorizing physician;

7. Any other pertinent medical or medication information/history;

8. The name and dosage of medication dispensed or prescribed under the authorizing physician's name; and

9. Any healthcare provider referrals.

(B) Patient medical records must be individually retrievable and must be securely and confidentially maintained in compliance with applicable state and federal law. At a minimum, patient medical records must be maintained for seven (7) years from the date created. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from a board or a board's authorized designee. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

(C) Patient records for pharmacy services provided by an authorized pharmacist pursuant to an HIV PEP protocol must be produced to the authorizing physician or medical staff committee on request.

(7) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation by the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, or their authorized representatives, as requested by the respective board or the board's designee. Records not maintained at a pharmacy shall be produced within three (3) business days after

a request from the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

AUTHORITY: sections 338.140, 338.210, and 338.730, RSMo Supp. 2021. Original rule filed Aug. 10, 2022.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

This section will contain the final text of the rules proposed by agencies. The order of rulemaking is required to contain a citation to the legal authority upon which the order of rulemaking is based; reference to the date and page or pages where the notice of proposed rulemaking was published in the *Missouri Register*; an explanation of any change between the text of the rule as contained in the notice of proposed rulemaking and the text of the rule as finally adopted, together with the reason for any such change; and the full text of any section or subsection of the rule as adopted which has been changed from that contained in the notice of proposed rulemaking. The effective date of the rule shall be not less than thirty (30) days after the date of publication of the revision to the *Code of State Regulations*.

The agency is also required to make a brief summary of the general nature and extent of comments submitted in support of or opposition to the proposed rule and a concise summary of the testimony presented at the hearing, if any, held in connection with the rulemaking, together with a concise summary of the agency's findings with respect to the merits of any such testimony or comments which are opposed in whole or in part to the proposed rule. The ninety- (90-) day period during which an agency shall file its Order of Rulemaking for publication in the *Missouri Register* begins either: 1) after the hearing on the Proposed Rulemaking is held; or 2) at the end of the time for submission of comments to the agency. During this period, the agency shall file with the secretary of state the order of rulemaking, either putting the proposed rule into effect, with or without further changes, or withdrawing the proposed rule.

Title 7—MISSOURI DEPARTMENT OF TRANSPORTATION
Division 10—Missouri Highways and Transportation Commission
Chapter 1—Organization; General Provisions

ORDER OF RULEMAKING

By the authority vested in the Missouri Highways and Transportation Commission under section 536.023, RSMo 2016, the commission amends a rule as follows:

7 CSR 10-1.010 Description, Organization, and Information **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on April 15, 2022 (47 MoReg 551-554). 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 7—MISSOURI DEPARTMENT OF TRANSPORTATION
Division 10—Missouri Highways and Transportation Commission
Chapter 11—Procurement of Supplies

ORDER OF RULEMAKING

By the authority vested in the Missouri Highways and Transportation Commission under sections 226.020, 226.130, 227.030, and 227.210, RSMo 2016, the commission amends a rule as follows:

7 CSR 10-11.020 Procedures for Solicitation, Receipt of Bids, and Award and Administration of Contracts **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on April 15, 2022 (47 MoReg 554-555). 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 2145—Missouri Board of Geologist Registration
Chapter 1—General Rules

ORDER OF RULEMAKING

By the authority vested in the Missouri Board of Geologist Registration under section 256.462, RSMo Supp. 2021, the board amends a rule as follows:

20 CSR 2145-1.040 Fees **is amended**.

A notice of proposed rulemaking containing the text of the proposed amendment was published in the *Missouri Register* on June 1, 2022 (47 MoReg 784-785). 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.

This section may contain notice of hearings, correction notices, public information notices, rule action notices, statements of actual costs, and other items required to be published in the *Missouri Register* by law.

Title 10—DEPARTMENT OF NATURAL RESOURCES
Division 25—Hazardous Waste Management Commission
Chapter 7—Rules Applicable to Owners/Operators of Hazardous Waste Facilities

IN ADDITION

Permit Modifications List Available Online

The Missouri Department of Natural Resources invites the public to review the list of completed hazardous waste permit modifications for the 2021 calendar year. The permit modification list for calendar year 2021, as well as lists from previous years, is available online at Completed Hazardous Waste Permit Modifications Calendar Year 2021| Missouri Department of Natural Resources, https://dnr.mo.gov/document-search/completed-hazardous-waste-permit-modifications-calendar-year-2021.

Businesses actively treating, storing (for longer than allowed by the hazardous waste generator regulations), or disposing hazardous waste in Missouri are required to obtain a hazardous waste permit. These permits contain operating and closure requirements, as well as necessary post-closure, corrective action, and financial assurance requirements. The department or facility can make changes to the currently effective permit, allowing the facility to change or improve its operations, or respond to new or changed regulatory requirements. Additional information and examples of significant permit modifications in Missouri are highlighted in the EPA publication, *Permit Modifications Report: Safeguarding the Environment in the Face of Changing Business Needs*, available online at epa.gov/hwpermitting/permit-modifications-report-safeguarding-environment-facechanging-business-needs.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 60—Missouri Health Facilities Review Committee
Chapter 50—Certificate of Need Program

NOTIFICATION OF REVIEW: APPLICATION REVIEW SCHEDULE

The Missouri Health Facilities Review Committee has initiated review of the CON applications listed below. A decision is tentatively scheduled for November 7, 2022. These applications are available for public inspection at the address shown below.

Date Filed
Project Number: Project Name
City (County)
Cost, Description

8/25/2022
#5962 HS: Liberty Hospital
Liberty (Clay County)
$2,045,750, Replace robotic surgery unit

8/26/2022
#5970 DS: St. Louis Altenheim
St. Louis (St. Louis City)
$2,124,000, Add 23 ALF beds and 25 SNF beds

#5967 HS: Mercy Hospital St. Louis
St. Louis (St. Louis County)
$4,105,124, Acquire 2 additional MRI units

#5971 RS: Topwood Home, LLC
Manchester (St. Louis County)
$13,850,000, Establish 75-bed ALF

Any person wishing to request a public hearing for the purpose of commenting on these applications must submit a written request to this effect, which must be received by September 28, 2022. All written requests and comments should be sent to—

Chairman
Missouri Health Facilities Review Committee
c/o Certificate of Need Program
3418 Knipp Drive, Suite F
PO Box 570
Jefferson City, MO 65102
For additional information, contact Alison Dorge at alison.dorge@health.mo.gov.