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Proposed Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-416
VAC Chapter title(s)	Sexual Assault Survivor Treatment and Transfer Regulation
Action title	Promulgation of New Regulation to Implement Chapter 725 of the 2020 Acts of Assembly
Date this document prepared	August 8, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

Chapter 725 (2020 Acts of Assembly) creates Article 8 of Chapter 5 of Title 32.1 of the Code of Virginia, which requires the Board to promulgate regulations to effectuate the act, specifically the standards for review and approval of sexual assault survivor transfer plans, pediatric sexual assault survivor transfer plans, sexual assault survivor treatment plans, and pediatric sexual assault survivor treatment plans. As the requirement to have such plans extends to hospitals, clinics, and physician's offices, there is no already existing regulatory chapter that would best fit this mandate, so the Virginia Board of Health intends to promulgate a new regulatory chapter for these standards.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

"Board" means the Virginia Board of Health.

"EMTALA" means the Emergency Medical Treatment and Labor Act (42 USC § 1395dd et seq.).

"PERK" means physical evidence recovery kit.

"PSAS" means pediatric sexual assault survivor.

"SAFE" means sexual assault forensic examiner.

"SAS" means a sexual assault survivor.

"STI" means sexually transmitted infection.

"VDH" means the Virginia Department of Health.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in the ORM procedures, "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Chapter 725 (2020 Acts of Assembly) creates Article 8 of Chapter 5 of Title 32.1 of the Code of Virginia, which requires the Board to promulgate regulations to effectuate the act. Specifically, subsection A of § 32.1-162.15:4 of the Code of Virginia requires the Board to adopt regulations to establish standards for review and approval of SAS treatment plans. Section 32.1-162.15:5 of the Code of Virginia requires the Board to adopt regulations to establish standards for review and approval of SAS transfer plans and PSAS transfer plans. Subsection B of § 32.1-162.15:6 of the Code of Virginia requires the Board to adopt regulations to establish standards for the review and approval of PSAS treatment plans; subsection C of that same statute requires the Board to adopt regulations to establish standards for review and approval of PSAS transfer plans.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Subsection A of § 32.1-162.15:4 of the Code of Virginia requires the Board to adopt regulations to establish standards for review and approval of SAS treatment plans. Section 32.1-162.15:5 of the Code of Virginia requires the Board to adopt regulations to establish standards for review and approval of SAS transfer plans and PSAS transfer plans. Subsection B of § 32.1-162.15:6 of the Code of Virginia requires the Board to adopt regulations to establish standards for the review and approval of PSAS treatment plans; subsection C of that same statute requires the Board to adopt regulations to establish standards for review and approval of PSAS transfer plans. More generally, pursuant to § 32.1-12 of the Code of Virginia, the Board

has the authority to make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provisions of Title 32.1 of the Code of Virginia and other laws of the Commonwealth administered by it, the State Health Commissioner, or the Department of Health.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.

The rationale or justification for the regulatory change is that Chapter 725 (2020 Acts of Assembly) requires the Board to promulgate regulations for the treatment and transfer of survivors of sexual assault (adult and pediatric). The regulatory change is essential to protect the health, safety, and welfare of citizens because it sets minimum standards for treatment services and transfer services specific to survivors of sexual assault and appropriate handling of evidence collected. The goals of the regulatory change and the problems it is intended to solve is to ensure that there are more robust, planned health care services for survivors of sexual assault throughout the Commonwealth and that there is clarity for patients about where to go to receive treatment services.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

Part I General Information

12VAC5-416-10. Definitions

Adds definitions for administrator, anonymous physical evidence recovery kit or anonymous PERK, applicant, approved pediatric transfer facility, approved pediatric treatment facility, approved plan, assent, board, clinic, commissioner, DCLS, department, directed plan of correction, emergency contraception, EMTALA, follow-up health care, forensic medical examination, health care professional, hospital, inspector, legal representative, OLC, pediatric health care facility, physician's office, physical evidence recovery kit or PERK, plan of correction, proposed plan, PSAS, PSAS transfer plan, PSAS transfer services, PSAS treatment plan, PSAS treatment services, rape crisis center, regulant, SAS, sexual assault forensic examiner or SAFE, SAS transfer plan, SAS transfer services, SAS treatment plan, SAS treatment services, STI, transfer hospital, transportation services, and treatment hospital.

12VAC5-416-20. Plans required.

Requires hospitals to develop and submit for approval a SAS transfer plan or SAS treatment plan and prohibits providing SAS transfer or treatment services without an approved plan. Requires pediatric health care facilities to develop and submit for approval a PSAS transfer plan or PSAS treatment plan and prohibits PSAS transfer or treatment services without an approved plan.

12VCA5-416-30. Request for plan approval.

Creates the process by which hospitals and pediatric health care facilities submit proposed plans for VDH's review, including the timeline for submission and approval and the process to correct unacceptable plans.

12VAC5-416-40. Review and renewal of plan approval.

Requires hospitals and pediatric health care facilities to triennially review approved plans for any needed changes and creates the process by which hospitals and pediatric health care facilities submit revised plans for VDH's review, including the timeline for submission and approval and the process to correct unacceptable plans.

12VAC5-416-50. Change notification.

Requires hospitals and pediatric health care facilities to give advance notice to VDH before switching from transfer to treatment or vice versa and requires submission of the new plan with that advance notice.

12VAC5-416-60. Complaints.

Requires VDH to investigate complaints arising from alleged noncompliance, including criteria for determining whether on-site investigation is needed and for records to be provided upon request. Requires VDH to notify the hospital or pediatric health care facility—and the complainant, if known—of the outcome and requires the hospital or pediatric health care facility to submit a plan of correction for violations cited.

12VAC5-416-70. Inspections.

Permits VDH to combine hospital inspections and requires VDH to provide a written inspection report to the hospital. Permits hospitals to redact patient names and addresses and requires hospitals to provide requested records to VDH.

12VAC5-416-80. Plan of correction; directed plan of correction.

Creates the process for plans of correction and creates minimum standards for plans of corrections. Describes the criteria for when a directed plan of correction may be required.

12VAC5-416-90. Allowable variances.

Creates a variance process by which a hospital or pediatric health care facility with an approved plan may request modification of regulatory requirements.

12VAC5-416-100. Violations of this chapter.

Describes the enforcement options available to the State Health Commissioner if a hospital or pediatric health care facility violated the regulatory chapter or enabling statutes.

Part II SAS Treatment Plan12VAC5-416-110. Minimum standards for SAS treatment plan.

Requires hospitals providing SAS treatment services to meet the minimum standards established for SAS treatment plans.

12VAC5-416-120. Staffing and education.

Requires hospitals to have a sexual assault forensic examiner available in person during hours of operation and that emergency department staff receive annual training.

12VAC5-416-130. Informed consent.

Requires hospitals to obtain informed consent and document informed consent.

12VAC5-416-140. Documentation.

Requires hospitals to document findings of the forensic medical examination.

12VAC5-416-150. Medical history.

Requires hospitals to document specific information about the alleged sexual assault and minimum information for medical history.

12VAC5-416-160. Physical examination, laboratory testing, and evidence collection.

Describes standards for conducting a physical examination of a SAS and requires all necessary laboratory testing be conducted.

12VAC5-416-170. Chain of custody.

Requires hospitals to maintain chain of custody, specifies the minimum information to label on specimens, requires hospitals to document specific information when transferring evidence, and permits hospitals to store evidence in a secure location.

12VAC5-416-180. Prophylaxis and contraception.

Requires hospitals to provide specific oral and written information about STIs and emergency contraception, requires provision of or arrangements for prophylaxis for STIs unless medically contraindicated or consent is refused, requires provision or arrangements for emergency contraception unless medically contraindicated or consent is refused or the hospital is operated under the auspices of a religious institution objecting to emergency contraception on religious grounds.

12VAC5-416-190. Anonymous PERK.

Requires hospitals to make minimum disclosures to SASs about PERKs if the SAS chooses not to report to law enforcement and requires hospitals to ensure PERKs are forwarded to DCLS.

12VAC5-416-200. Medical advocacy services.

Requires hospitals to have an memorandum of understanding (MOU) with at least one rape crisis center, to triennially review the MOU, to have policies and procedures for mandatory reporting, and to provide oral and written information about medical advocacy services.

12VAC5-416-210. Discharge and follow-up health care.

Requires hospitals to provide oral and written discharge instructions and contact information and hours of operation for local advocacy programs. Describes what may be included in follow-up health care.

12VAC5-416-220. Reporting requirements.

Requires hospitals to annually report the total number of SASs to whom a forensic medical examination was provided and the total number of PERKS offered and completed.

Part III PSAS Treatment Plan12VAC5-416-230. Minimum standards for PSAS treatment plan.

Requires pediatric health care facilities providing PSAS treatment services to meet the minimum standards established for PSAS treatment plans.

12VAC5-416-240. Pediatric staffing.

Requires pediatric health care facilities to have a sexual assault forensic examiner available in person during hours of operation.

12VAC5-416-250. Informed assent and consent for treatment.

Requires pediatric health care facilities to exercise all reasonable and necessary efforts to obtain informed assent from the PSAS, subject to certain age and capacity limits. Requires pediatric health care facilities to obtain informed consent and document informed assent and consent.

12VAC5-416-260. Documentation.

Requires pediatric health care facilities to document findings of the forensic medical examination.

12VAC5-416-270. Medical history.

Requires pediatric health care facilities to document specific information about the alleged sexual assault and minimum information for medical history.

12VAC5-416-280. Physical examination, laboratory testing, and evidence collection.

Describes standards for conducting a physical examination of a PSAS and requires all necessary laboratory testing be conducted.

12VAC5-416-290. Chain of custody.

Requires pediatric health care facilities to maintain chain of custody, specifies the minimum information to label on specimens, requires pediatric health care facilities to document specific information when transferring evidence, and permits pediatric health care facilities to store evidence in a secure location.

12VAC5-416-300. Prophylaxis and contraception.

Requires pediatric health care facilities to provide specific oral and written information about STIs and emergency contraception, requires provision of or arrangements for prophylaxis for STIs unless medically contraindicated or consent is refused, requires provision or arrangements for emergency contraception unless medically contraindicated or consent is refused or the pediatric health care facility is operated under the auspices of a religious institution objecting to emergency contraception on religious grounds.

12VAC5-416-310. Anonymous PERK.

Requires pediatric health care facilities to make minimum disclosures to PSASs about PERKs if the PSAS chooses not to report to law enforcement and requires hospitals to ensure PERKs are forward to DCLS.

12VAC5-416-320. Medical advocacy services.

Requires pediatric health care facilities to have a memorandum of understanding (MOU) with at least one rape crisis center, to triennially review the MOU, to have policies and procedures for mandatory reporting, and to provide oral and written information about medical advocacy services.

12VAC5-416-330. Discharge and follow-up health care.

Requires pediatric health care facilities to provide oral and written discharge instructions and contact information and hours of operation for local advocacy programs. Describes what may be included in follow-up health care.

12VAC5-416-340. Approved pediatric treatment facilities with limited capacity.

Requires pediatric health care facilities with limited capacity to make certain adjustments to their treatment plans and requires pediatric health care facilities that are not open 24/7 to share that information publicly, including with signage.

PART IV SAS Transfer Plan

12VAC5-416-350. Minimum requirements for SAS transfer plan.

Requires hospitals providing SAS transfer services to meet the minimum standards established for SAS transfer plans.

12VAC5-416-360. Screening.

Requires hospitals to provide appropriate screening and have mandatory reporting procedures.

12VAC5-416-370. Acute injuries.

Requires hospitals to screen, treat, and stabilize acute injuries before transfer.

12VAC5-416-380. Transfer coordination.

Requires hospitals to coordinate transfer with the receiving facility, ensure a qualified staff member is available to provide treatment, and to provide information about emergency contraception and the patient's medical record.

PART V PSAS Transfer Plan

12VAC5-416-390. Minimum requirements for PSAS transfer plan.

Requires pediatric health care facilities providing PSAS transfer services to meet the minimum standards established for PSAS transfer plans.

12VAC5-416-400. Screening.

Requires pediatric health care facilities to provide appropriate screening and have mandatory reporting procedures. Prohibits pediatric health care facilities from turning away a patient for screening on the basis they arrived close to—but not after—close of business.

12VAC5-416-410. Acute injuries.

Requires pediatric health care facilities to screen, treat, and stabilize acute injuries before transfer. Requires pediatric health care facilities to contact child protective services or local law enforcement if the patient is in danger.

12VAC5-416-420. Transfer coordination.

Requires pediatric health care facilities to coordinate transfer with the receiving facility, ensure a qualified staff member is available to provide treatment, and to provide the patient's medical record to the receiving facility.

12VAC5-416-430. Required transfer disclosures.

Requires pediatric health care facilities to discuss transfer with the PSAS's legal representative and to provide information about emergency contraception and the patient's medical record.

Documents Incorporated by Reference (12VAC5-416)

Lists documents incorporated by reference in 12VAC5-416-180 and 12VAC5-416-300.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

The primary advantages to the public in implementing the mandates of Chapter 725 (2020 Acts of Assembly) is increased transparency about what facilities can provide sexual assault treatment services and what facilities can provide transfer services and more consistent care across the Commonwealth for patients who are SASs or PSASs. The primary advantages to the agency or Commonwealth is new data about the availability of sexual assault treatment services and transfer service to drive policy making decisions. There are no primary disadvantages to the public, the agency, or the Commonwealth.

Requirements More Restrictive than Federal

Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

Hospitals that provide transfer services to SASs and PSASs are required to comply with EMTALA. The proposed regulation requires these hospitals to have procedures for mandatory reporting to adult and child protective services (12VAC5-416-360(B) and 12VAC5-416-400(C)), to communicate with the receiving hospital to ensure a SAFE is available to provide treatment services (12VAC5-416-380(B) and 12VAC5-416-420(B)), to provide information to patients about emergency contraception and a copy of their record (12VAC5-416-380(C) and 12VAC5-416-430(C)), to contact child protective services or local law enforcement as appropriate (12VAC5-416-410(C) and (D)), and to minimize undue burdens and loss of forensic evidence (12VAC-416-420(C)). These more restrictive requirements arise from the fact that the patient has experienced an alleged sexual assault. Alerting the appropriate protective services, and potentially law enforcement, when a crime is alleged to have taken place is often a state mandatory requirement for most if not all health care professionals. The preservation of evidence is also critical to the investigation or prosecution of any crime. The information about emergency contraception is mandated to be provided pursuant to Chapter 725 (2020 Acts of Assembly). Chapter 725 (2020 Acts of Assembly) also requires a SAFE to conduct forensic medical examinations, so ensuring the treating facility has a SAFE available to perform that function is necessary.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

Virginia Commonwealth University Health System Authority

Localities Particularly Affected

Chesapeake Hospital Authority

Other Entities Particularly Affected

General hospitals, special hospitals, and outpatient surgical hospitals licensed pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia; pediatric health care facilities as defined by § 32.1-162.15:2 of the Code of Virginia.

Economic Impact

Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits) anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.

Impact on State Agencies

<i>For your agency:</i> projected costs, savings, fees, or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources.	There are no projected savings, fees, or revenues resulting from the regulatory change. VDH projects a one-time cost of \$283,696 in Year 1, a one-time cost of \$692,391 in Year 2, and an on-going cost of \$582,391. These amounts will support the hiring of three FTEs to review and approve initial plans and revised plans, conduct statewide travel for complaints, and the development of the mandated training for staff in hospital emergency departments who provide care to SASs and PSASs VDH could not absorb the costs identified above with existing resources, so VDH received an appropriation of \$283,696 for SFY2023 and an appropriation of \$567,391 for SFY2024, both from the general fund, to hire the necessary FTEs. VDH did not receive appropriations to cover the cost of
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	developing the mandated training, and is planning on asking for an appropriation from the general fund to cover this cost in the upcoming 2023 General Assembly session.
<i>For other state agencies:</i> projected costs, savings, fees, or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	In 2019, the hospital operated by Virginia Commonwealth University Health System Authority had a forensic nursing program that treated SASs; VDH is unsure if this also includes PSASs. Virginia Commonwealth University Health System Authority will likely incur some costs resulting from this regulatory change. The projected costs for transferring or treating patients include the development of policies and procedures that meet the minimums described in this regulatory action. The hospital that Virginia Commonwealth University Health System Authority operates has an emergency department, so it already has policies and procedures about transfers, as that is part of the requirements under EMTALA; it also already at least provides treatment for SASs. For its existing policies and procedures, VDH is estimating it would cost \$1,250 one time to amend their policies to conform to the regulatory minimums. It may be the case that no amendments are needed if the policies and procedures meet or exceed the proposed regulatory minimums, in which case no cost is expected to be incurred. There may be some recordkeeping and administrative costs because Chapter 725 (2020 Acts of Assembly) mandates that hospitals that treat SASs file annual reports with VDH. VDH estimates these costs are not likely to exceed \$2,500 per year. Virginia Commonwealth University Health System Authority likely will not have savings or fees. It may have some revenue resulting from providing care to SASs, though this is difficult to project due to the complexity of health care financing involving a multitude of reimbursement rates from Medicaid and third party insurance carriers, as well as any charity care conditions it has on its certificates of public need.
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	The benefits the regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for SASs and PSASs. It also creates minimum standards for those services so that care for this patient population is more consistent throughout the Commonwealth.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees, or revenues resulting from the regulatory change.	In 2019, the hospital operated by Chesapeake Hospital Authority did not have a forensic nursing program, so VDH assumes it may not have been treating SASs and PSASs, beyond what is required for stabilization by EMTALA. Chesapeake Hospital Authority will likely incur some costs resulting from this regulatory change. The projected costs for transferring or treating patients include the development of policies and procedures that meet the minimums described in this regulatory action. The hospital that Chesapeake Hospital Authority operates has an emergency department, so it already has policies and procedures about transfers, as that is part of the requirements under EMTALA. For its existing policies and procedures if it opts to transfer SASs and/or PSASs, VDH is estimating it would cost \$1,250 one time to amend their policies to conform to the regulatory minimums. It may be the case that no amendments are needed, if the policies and procedures exceed the regulatory minimums, in which case no cost is expected to be incurred. If Chesapeake Hospital Authority decides that its hospital should instead treat SASs and/or PSASs, VDH is estimating it would cost \$5,000 to develop these policies and procedures. Chesapeake Hospital Authority likely will not have savings or fees. It may have some revenue resulting from providing care (even it is just stabilizing care under EMTALA) to SASs and PSASs, though this is difficult to project due to the complexity of health care financing involving a multitude of reimbursement rates from Medicaid and third party insurance carriers, as well as any charity care conditions it has on its certificates of public need.
Benefits the regulatory change is designed to produce.	The benefits the regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for SASs and PSASs. It also creates minimum standards for those services so that care for this patient population is more consistent throughout the Commonwealth.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	The entities likely to be affected by the regulatory change are hospitals and pediatric health care facilities, as defined by Code of Virginia § 32.1-162.15:2.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated, and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	There are currently 170 hospitals licensed pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia; this includes the hospitals operated by the Virginia Commonwealth University Health System Authority and Chesapeake Hospital Authority that were already discussed above. Currently, there is no accurate count of how many pediatric health care facilities there are in the Commonwealth. Based on data collected by the Healthcare Workforce Data Center in the Department of Health Professions, there are 21,257 employed physicians in the Commonwealth and there are 6,017 that are board certified in either pediatrics or family medicine. VDH does not have data about the patient populations served or where these patients are seen by the 21,257 employed physicians, as physicians do not need to be board certified in pediatrics or family medicine to potentially treat PSAs outside of a hospital setting. VDH estimates that it is likely that most pediatric health care facilities that are not hospitals would be considered small businesses.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	VDH anticipates that roughly one-sixth of inpatient hospitals will choose to treat patients and the remaining inpatient hospitals will transfer patients, based on data collected by the Joint Commission on Health Care in 2019. VDH anticipates that most outpatient surgical hospitals and pediatric health care facilities will opt to transfer patients rather than treat them. a) The projected costs for transferring or treating patients would include the development of policies and procedures that meet the minimums described in this regulatory action. The inpatient hospitals that have emergency departments should already have policies and procedures about transfers, as that is part of the requirements under the federal Emergency Medical Treatment and Labor Act (EMTALA). To the extent that a hospital or pediatric health care facility does not have any existing policies or procedures about transfer or treatment of SAs and/or PSAs, VDH is estimating it would cost \$5,000 one-time to

	develop. For those that do have existing policies, VDH is estimating it would cost \$1,250 one-time to amend their policies to conform to the regulatory minimums. It may be the case that no amendments are needed, if the policies and procedures exceed the regulatory minimums, in which case no cost is expected to be incurred. There will be some recordkeeping and administrative costs for hospitals that are treating SASs because Chapter 725 (2020 Acts of Assembly) mandates that those hospitals file annual reports with VDH. VDH estimates these costs are not likely to exceed \$2,500 per year. b) There are no projected costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change. c) The projected costs for equipment or services for hospitals and non-hospital pediatric health care facilities that choose to transfer patients should be zero. Hospitals and non-hospital pediatric health care facilities that choose to treat patients are not anticipated to have any costs related to equipment, but would have ensure it has at least one sexual assault forensic examiner available. If this person is not already a part of the staff, that person would have to be hired or put on contract. e) The mandates of Chapter 725 (2020 Acts of Assembly) go into effect on July 1, 2023. Hospitals and pediatric health care facilities have known these mandates were coming since the passage of Chapter 725 (2020 Acts of Assembly). Additionally, VDH built in some regulatory flexibility in that hospitals and pediatric health care facilities that were already treating or transferring SASs and PSASs prior to July 1, 2023 can continue to do so while VDH reviews their initial plan submission, to avoid disruption to care in the their communities.
Benefits the regulatory change is designed to produce.	The benefits the regulatory change is designed to produce is increased knowledge of and awareness of what hospitals and pediatric health care facilities can provide treatment services or transfer services for SASs and PSASs. It also creates minimum standards for those services so that care for this patient population is more consistent throughout the Commonwealth.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

No alternative was considered because the legislation required the Board to adopt regulations governing the treatment and transfer of SASs and PSASs, and the least burdensome method to accomplish the purpose of this action is to promulgate the regulation.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

In developing the proposed regulations, the Board considered that pediatric health care facilities likely consist primarily of small businesses. Providing a small business exemption would result in the overwhelming number of pediatric health care facilities being exempt from the requirements, just as establishing performance standards or less stringent requirements specific to small business would have the effect of lowered standards and requirements for a large majority of those to whom this regulatory chapter applies. Chapter 725 (2020 Acts of Assembly) does not give the Board the discretion to exempt small businesses from the requirements.

Additionally, as these standards and requirements are aimed at ensuring both adequate care to SASs and PSASs as well as evidence for potential criminal prosecution, the Board cannot lower these standards without potentially endangering patients or jeopardizing the administration of justice. Further, Chapter 725 (2020 Acts of Assembly) also prescribes the content of transfer and treatment plans, the requirement that hospitals and pediatric health care facilities submit them for approval, VDH's timeline for reviewing and approving submitted plans, and the reporting requirements for hospitals. Consequently, there are no other alternative regulatory methods to minimizing the adverse impact on small businesses that the Board could utilize without being inconsistent with the principles of justice and the public health, safety, and welfare in accomplishing the objectives of the legislative mandates.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in EO 19 and the ORM procedures, e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

No periodic review/small business impact review was announced during the NOIRA stage and thus, no results are being reported. There is a continued need for the regulation, as no legislation has passed that repeals the mandate for this regulation. VDH has received no complaints or comments concerning the regulation. The regulation is appropriately detailed to describe both the processes applicable to hospitals and pediatric health care facilities and the minimum standards for treatment and transfer, without crossing into scope of practice issues or criminal law enforcement. VDH is not aware of any overlap, duplication, or conflict involving this regulation and federal or state law or regulation. This is a new regulatory chapter, and the technology, economic conditions, or other factors in the area affected by the regulation have not demonstrably changed since the passage of Chapter 725 (2020 Acts of Assembly). VDH cannot lessen the standards to minimize the economic impact of regulation on small businesses because it would likely frustrate the administration of justice and the health, safety, and welfare of SASs and PSASs to lower standards for adequate medical care to and for the collection, documentation, and preservation of evidence.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency's response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

No comment was received.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

The Board is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency's regulatory flexibility analysis stated in that section of this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>.

Comments may also be submitted by mail, email or fax to **Rebekah E. Allen, Senior Policy Analyst, Virginia Department of Health, Office of Licensure and Certification, 9960 Mayland Drive, Suite 401, Henrico, VA 23233**; email: regulatorycomment@vdh.virginia.gov; fax: (804) 527-4502. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

Table 2: Promulgating New VAC Chapter(s) without Repeal and Replace

New chapter-section number	New requirements to be added to VAC	Other regulations and laws that apply	Change, intent, rationale, and likely impact of new requirements
416-10	Part I General Information <u>12VAC5-416-10. Definitions.</u> <u>The following words and terms when used in this regulation shall have the following meanings unless the context clearly indicates otherwise:</u> <u>"Administrator" means the person appointed by the governing body as having responsibility for the overall management of a hospital or pediatric health care facility. Job titles may include chief executive officer, director, executive director, office manager, or business manager.</u> <u>"Anonymous physical evidence recovery kit" or "anonymous PERK" has the same meaning as in § 19.2-11.5 of the Code of Virginia.</u> <u>"Applicant" means a hospital or pediatric health care facility that does not have an approved plan.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to provide definitions for terms used in the regulation. RATIONALE: The rationale for these new requirements is that these terms could have multiple meanings unless defined and that the lack of definitions could lead to confusions among applicants and regulators. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulators.

	<u>"Approved pediatric transfer facility" means a pediatric health care facility for which a PSAS transfer plan has been approved pursuant to this chapter</u> <u>"Approved _____ pediatric treatment facility" means a pediatric health care facility for which a PSAS treatment plan has been approved pursuant to this chapter.</u> <u>"Approved plan" means a SAS treatment plan, PSAS treatment plan, SAS transfer plan, or PSAS transfer plan that has been approved pursuant to this chapter.</u> <u>"Assent" means the expressed willingness of an individual to participate in an activity.</u> <u>"Board" means the State Board of Health.</u> <u>"Clinic" means an outpatient establishment, facility, or department of a hospital where patients are given medical diagnosis, treatment, or advice, including of a specialist nature. This includes a clinic operated by a local health department, but does not include a clinic directly maintained or operated by the federal government.</u> <u>"Commissioner" means the State Health Commissioner.</u> <u>"DCLS" means the Division of Consolidated Laboratory Services of the Virginia Department of General Services.</u> <u>"Department" means the Department of Health.</u> <u>"Directed plan of correction" means a plan prescribed by the department that details specific corrective actions for cited violations in inspection findings that shall be taken by the regulant to achieve specific outcomes within specific timeframes.</u>		
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	<u>"Emergency contraception" means medication approved by the U.S. Food and Drug Administration that can significantly reduce the risk of pregnancy if taken within 72 hours after sexual assault.</u> <u>"EMTALA" means the Emergency Medical Treatment and Labor Act (42 USC § 1395dd et seq.)</u> <u>"Follow-up health care" means any physical examination, laboratory tests to determine the presence of STIs, or appropriate medications, including HIV prophylaxis, provided to a SAS or PSAS by a health care professional within 90 days after the date on which treatment or transfer services pursuant to this chapter are first provided.</u> <u>"Forensic medical examination" means health care services provided to a SAS or PSAS that include medical history, physical examination, laboratory testing, assessment for drug-facilitated or alcohol-facilitated sexual assault, collection of evidence in accordance with the requirements of Chapter 1.2 (§ 19.2-11.5 et seq.) of Title 19.2 of the Code of Virginia, discharge and follow-up health care planning necessary to ensure the health, safety, and welfare of the SAS or PSAS, and the collection and preservation of evidence that may be used in a criminal proceeding.</u> <u>"Health care professional" means any person (i) licensed, certified, or registered by a health regulatory board of the Department of Health Professions or (ii) holding a multistate licensure privilege to practice nursing or an applicant</u>		
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	<u>for licensure, certification or registration.</u> <u>"Hospital" means any hospital licensed by the department pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia.</u> <u>"Inspector" means an individual employed by the department and designated by the commissioner to conduct inspections, investigations, or evaluations.</u> <u>"Legal representative" means a PSAS's parent, guardian, or any person who by order of a court of component jurisdiction has legal custody of the PSAS.</u> <u>"OLC" means the Office of Licensure and Certification of the department.</u> <u>"Pediatric health care facility" means a hospital, clinic, or physician's office that provides health care services to pediatric patients.</u> <u>"Physician's office" means the office of one or more physicians, surgeons, or nurse practitioners with autonomous practice privileges. A physician's office does not mean a hospital as defined in § 32.1-123 of the Code of Virginia or a facility directly maintained or operated by the federal government.</u> <u>"Physical evidence recovery kit" or "PERK" has the same meaning as in § 19.2-11.5 of the Code of Virginia.</u> <u>"Plan of correction" means a plan developed by a regulant and approved by the department that is the regulant's written response to inspection findings and details corrective actions to cited violations, who is responsible for implementing corrective actions, how the regulant will prevent</u>		
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	<u>reoccurrence, and specifies the date by which the regulant will correct those deficiencies.</u> <u>"Proposed plan" means a SAS treatment plan, PSAS treatment plan, SAS transfer plan, or PSAS transfer plan that has been submitted pursuant to this chapter to the Department.</u> <u>"PSAS" means a pediatric survivor of sexual assault who is less than 18 years of age.</u> <u>"PSAS transfer plan" means a plan for the transfer of a PSAS to an approved pediatric treatment facility that includes PSAS transfer services and the written agreement of an approved pediatric treatment facility to accept transfer.</u> <u>"PSAS transfer services" means an appropriate medical examination and such stabilizing treatment as may be necessary prior to the transfer of a PSAS from an approved pediatric transfer facility to an approved pediatric treatment facility in accordance with the provisions of a PSAS transfer plan approved by the department.</u> <u>"PSAS treatment plan" means a plan for the treatment of a PSAS at an approved pediatric treatment facility that includes PSAS treatment services and the storage, retention, and dissemination of photographic evidence.</u> <u>"PSAS treatment services" means a forensic medical examination and other health care services provided to a PSAS by an approved pediatric treatment facility in accordance with this chapter.</u> <u>"Rape crisis center" has the same meaning as ascribed in 34 USC § 12291(a)(25).</u> <u>"Regulant" means a treatment hospital, transfer</u>	
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<u>hospital, approved pediatric treatment facility, or approved pediatric transfer facility that has a PSAS treatment plan, PSAS transfer plan, SAS treatment plan, or SAS transfer plan approved by the department.</u> <u>"SAS" means a survivor of sexual assault who is 18 years of age or older.</u> <u>"Sexual assault forensic examiner" or "SAFE" means a sexual assault nurse examiner, physician, physician assistant, nurse practitioner, or registered nurse who has completed training that meets or is substantially similar to the Sexual Assault Nurse Examiner Education Guidelines established by the International Association of Forensic Nurses or its successor.</u> <u>"SAS transfer plan" means a plan for the transfer of a SAS to a treatment hospital that includes SAS transfer services and the written agreement of a treatment hospital to accept transfer.</u> <u>"SAS transfer services" means an appropriate medical examination and such stabilizing treatment as may be necessary prior to the transfer of a SAS from a transfer hospital to a treatment hospital in accordance with the provisions of a SAS transfer plan approved by the department.</u> <u>"SAS treatment plan" means a plan for the treatment of a SAS at a treatment hospital that includes SAS treatment services and the storage, retention, and dissemination of photographic evidence.</u> <u>"SAS treatment services" means a forensic medical examination and other health care services provided to a SAS by a treatment hospital in accordance with this chapter.</u>		
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	<u>"STI" means sexually transmitted infection.</u> <u>"Transfer hospital" means a hospital with a SAS transfer plan approved by the department.</u> <u>"Transportation service" means transportation provided to a SAS or PSAS who is transferred from a transfer hospital, treatment hospital, approved pediatric treatment facility, or approved pediatric transfer facility to a treatment hospital or approved pediatric treatment facility pursuant to a SAS transfer plan or PSAS transfer plan approved in accordance with this chapter.</u> <u>"Treatment hospital" means a hospital with a SAS treatment plan approved by the department to provide SAS treatment services to a SAS who presents with a complaint of sexual assault within the previous seven days or who have disclosed past sexual assault by a specific individual and were in the care of that individual within the previous seven days.</u>		
416-20	<u>12VAC5-416-20. Plans required.</u> <u>A. A hospital shall:</u> <u>1. Develop either a:</u> <u>a. SAS treatment plan that meets the requirements of Part II (12VAC5-416-110 et seq.) of this chapter; or</u> <u>b. SAS transfer plan that meets the requirements of Part IV (12VAC5-416-350 et seq.) of this chapter; and</u> <u>2. Submit any such plan to the department as specified by 12VAC5-416-30.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is that hospitals and pediatric health care facilities know that they must develop and submit plans for VDH's approval and to address hospitals and pediatric health care facilities that are already providing treatment and transfer of SASs and PSASs prior to July 1, 2023. RATIONALE: The rationale of these new requirements is that hospitals and pediatric health care facilities should be directed to where the

	<u>B. A hospital may not provide SAS treatment services or SAS transfer services unless the department has granted approval of the proposed plan, except that a hospital may provide SAS treatment services or SAS transfer services prior to approval of its initial proposed plan if the hospital was providing one or more of these services on or before July 1, 2023.</u> <u>C. A pediatric health care facility shall:</u> <u>1. Develop either a:</u> <u>a. PSAS treatment plan that meets the requirements of Part III (12VAC5-416-230 et seq.) of this chapter; or</u> <u>b. PSAS transfer plan that meets the requirements of Part V (12VAC5-416-390 et seq.) of this chapter; and</u> <u>2. Submit any such plan to the department as specified by 12VAC5-416-30.</u> <u>D. A pediatric health care facility may not provide PSAS treatment services or PSAS transfer services unless the department has granted approval of the proposed plan, except that a pediatric health care facility may provide PSAS treatment services or PSAS transfer services prior to approval of its initial proposed plan if the pediatric health care facility was providing one or more of these services on or before July 1, 2023.</u> Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.</u>		minimum plan standards and plan submission process are located within the regulations and to grant some flexibility to hospitals and pediatric health care facilities already providing treatment and transfer of SASs and PSASs prior to July 1, 2023. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants and reduced or eliminated interruptions in the provision of care for hospitals and pediatric health care facilities that are already providing treatment and transfer of SASs and PSASs prior to July 1, 2023.
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416-30	<u>12VAC5-416-30. Request for plan approval.</u> <u>A. An applicant shall transmit to the OLC its proposed plan by electronic mail or postal mail no sooner than 60 calendar days before the applicant's desired effective date for the proposed plan.</u> <u>B. The OLC shall consider a proposed plan submission to be complete when all components of the proposed plan are included in the submission. The OLC may deny approval to an applicant whose proposed plan has been incomplete for more than 180 calendar days.</u> <u>C. An applicant may withdraw a proposed plan at any time prior to the OLC's determination of whether to approve the proposed plan by notifying the OLC in writing of its intent to withdraw.</u> <u>D. The OLC shall notify the applicant of the outcome of its review in writing no more than 30 calendar days after receipt of the proposed plan. If the OLC denies approval of the proposed plan, the OLC shall provide a written statement setting forth the reasons for denial.</u> <u>E. The OLC shall grant the administrator or his designee the opportunity to revise and resubmit a proposed plan that the OLC initially determines to be unacceptable. The administrator or his designee shall resubmit the proposed plan to the OLC no more than 15 calendar days after the OLC has notified the administrator or his designee pursuant to subsection D.</u> Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to describe the plan submission and review process. RATIONALE: The rationale for these new requirements is that a clear process for plan submission and review process will set reasonable expectations for applicants and VDH staff. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and VDH staff.
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416-40	<u>12VAC5-416-40. Review and renewal of plan approval.</u> <u>A. A regulant shall:</u> <u>1. Review its approved plan or plans at least triennially with the administrator or his designee and appropriate clinical staff; and</u> <u>2. Document in writing the triennial review process and any recommendations for updates.</u> <u>B. If a regulant determines that pursuant to subsection A that an update is needed to an approved plan, it shall submit the proposed plan to the OLC in writing no less than 60 days in advance of the proposed plan's implementation date.</u> <u>C. The OLC shall notify the regulant of the outcome of its review in writing no more than 30 calendar days after receipt of the proposed plan. If the OLC denies approval of the proposed plan, the OLC shall provide a written statement setting forth the reasons for denial.</u> <u>D. The OLC shall grant the administrator or his designee the opportunity to revise and resubmit a proposed plan that the OLC initially determines to be unacceptable. The administrator or his designee shall resubmit the proposed plan to the OLC no more than 15 calendar days after the OLC has notified the administrator or his designee pursuant to subsection C of this section.</u> Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure that the plans utilized by hospitals and pediatric health care facilities are up to date with clinical standards and regulatory minimums. RATIONALE: The rationale for these requirements is that both clinical standards and regulatory minimums do change over time and routine regular review of plans will prevent the hospitals and pediatric health care facilities from using out of date standards. LIKELY IMPACT: The likely impact of these requirements is hospitals and pediatric health care facilities are using current clinical standards and meeting regulatory minimums.
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416-50	<u>12VAC5-416-50. Change notification.</u> <u>A. A treatment hospital proposing to transition to a transfer hospital shall:</u> <u>1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to a transfer hospital; and</u> <u>2. Submit a SAS transfer plan with its notification.</u> <u>B. A transfer hospital proposing to transition to a treatment hospital shall:</u> <u>1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to a treatment hospital; and</u> <u>2. Submit a SAS treatment plan with its notification.</u> <u>C. An approved pediatric treatment facility proposing to transition to an approved pediatric transfer facility shall:</u> <u>1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to an approved pediatric transfer facility; and</u> <u>2. Submit a PSAS transfer plan with its notification.</u> <u>D. An approved pediatric transfer facility proposing to transition to an approved pediatric treatment facility shall:</u> <u>1. Notify the OLC in writing no less than 60 calendar days in advance of transitioning to an approved pediatric treatment facility; and</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these requirements is to create a process by which a hospital or pediatric health care facility may transition from transfer to treatment or vice versa. RATIONALE: The rationale for these requirements is that since hospitals and pediatric health care facilities have discretion to choose to treat or transfer, there needs to be a process to do so that allows VDH to review and approve the new plans. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for regulants and VDH staff.
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	<u>2. Submit a PSAS treatment plan with its notification.</u>		
416-60	<u>12VAC5-416-60. Complaints.</u> <u>A. The OLC shall investigate complaints regarding alleged violations of this chapter or Article 8 (§ 32.1-162.15:2 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia. The OLC shall determine if an investigation requires an on-site inspection. In making this determination, the OLC shall consider several factors, to include:</u> <u>1. If the complainant has first-hand knowledge of the alleged incident;</u> <u>2. The regulatory history of the regulant or applicant, including the number of substantiated prior complaints;</u> <u>3. If the OLC has recently inspected the regulant or applicant, and if the incident would have been observed during the prior inspection; and</u> <u>4. The nature of the complaint, including degree of potential serious harm to SASs, PSASs, or other patients.</u> <u>B. The OLC may request records from a regulant or applicant to assist in making a determination pursuant to subsection A. The regulant or applicant shall provide the requested records no more than 5 business days after the OLC makes the request.</u> <u>C. When the investigation is complete, the OLC shall notify the complainant, if known, and the regulant or applicant in</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to give VDH the flexibility to determine whether a complaint warrants an on-site inspection and to describe what happens after an investigation is complete. RATIONALE: The rationale for these new requirements is encouraging efficient and effective use of agency resources in responding to complaints and set expectations about what complainants and regulants after an inspection. LIKELY IMPACT: The likely impact of these new requirements is a more adaptive and efficient complaint process.

	<u>writing of the findings of the investigation.</u> <u>D. For any violation cited during a complaint investigation, the administrator or his designee shall submit a plan of correction in accordance with 12VAC5-416-80.</u> Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, 32.1-162.15:5, 32.1-162.15:6, and 32.1-162.15:10 of the Code of Virginia.</u>		
416-70	<u>12VAC5-416-70. Inspections.</u> <u>A. The OLC may combine an inspection of a treatment hospital or transfer hospital with an inspection conducted pursuant to § 32.1-126 of the Code of Virginia.</u> <u>B. A regulant or applicant shall make available to the inspector any requested records and shall allow access to interview the agents, employees, contractors, and any person under the regulant's or applicant's control, direction, or supervision.</u> <u>1. Upon request of the inspector after the inspector's arrival:</u> <u>a. The treatment hospital or transfer hospital shall provide to the inspector a list of all SASs it treated or transferred in the previous 12 months; and</u> <u>b. The approved pediatric treatment facility or approved pediatric transfer facility shall provide to the inspector a list of all PSASs it treated or</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is describe what responsibilities a regulant or applicant has when an inspection takes place. RATIONALE: The rationale for these new requirements is to set expectations about what applicants and regulants should do during inspection and ensure the privacy of patients. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.

	<u>transferred in the previous 12 months.</u> <u>2. If copies of records are removed from the premises, the regulant or applicant may redact names and addresses of patients contained in such records prior to removal.</u> <u>3. The inspector shall inform the regulant or applicant that it may redact names and addresses of patients prior to the inspector removing copies of records from the premises.</u> <u>C. The OLC shall provide a written inspection report to the administrator. If the OLC cites one or more violations in the written inspection report, the administrator or his designee shall submit a plan of correction in accordance with 12VAC5-416-80.</u>		
416-80	<u>12VAC5-416-80. Plan of correction; directed plan of correction.</u> <u>A. Upon receipt of a written inspection report, the administrator or his designee shall prepare a written plan of correction addressing each violation cited at the time of inspection.</u> <u>B. The administrator shall submit to the OLC a written plan of correction no more than 15 working days after receipt of the inspection report. The plan of correction shall contain for each violation cited:</u> <u>1. A description of the corrective action or actions to be taken and the position title of the</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to create a plan of correction process, including what the consequences of an unacceptable plan of correction are. RATIONALE: The rationale for these new requirements is set expectations about what applicants and regulants should do after inspection if violations are found. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.

	<u>employees to implement the corrective action;</u> <u>2. The expected correction date, not to exceed 45 working days from the exit date of the inspection; and</u> <u>3. A description of the measures implemented to prevent a recurrence of the violation.</u> <u>C. A regulant or applicant shall ensure that the person responsible for the validity of the plan of correction signs, dates, and indicates their title on the plan of correction.</u> <u>D. The OLC shall:</u> <u>1. Notify the administrator or his designee if the OLC determines any item in the plan of correction is unacceptable; and</u> <u>2. Grant the administrator or his designee an opportunity to revise and resubmit a plan of correction that the OLC initially determines to be unacceptable. If the administrator or his designee revises and resubmits the plan of correction, the revision is due to the OLC no more than 15 working days after the OLC has notified the administrator or his designee pursuant to subdivision 1 of this subsection.</u> <u>E. The department may impose a directed plan of correction when a regulant or applicant:</u> <u>1. Has one or more violations that warrant directing the regulant or</u>		
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	<u>applicant to take specific actions; or</u> <u>2. Has been cited for the same violation in the most recent prior inspection.</u> <u>F. Upon request of the OLC, a regulant or applicant shall produce evidence that all or part of a plan of correction or directed plan of correction has been implemented. The OLC may conduct an inspection to verify any portion of a plan of correction or directed plan of correction.</u> <u>G. The administrator or his designee shall ensure the plan of correction or directed plan of correction is implemented and monitored so that compliance is maintained.</u> Statutory Authority <u>§§ 32.1-12, 32.1-25, 32.1-162.15:4, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.</u>		
416-90	<u>12VAC5-416-90. Allowable variances.</u> <u>A. The commissioner may authorize a variance only to a specific standard or requirement of this chapter, not to regulations of another agency or to any standards or requirements in federal, state, or local laws. A variance shall:</u> <u>1. Require advance written approval from the commissioner;</u> <u>2. Not be extended to general applicability; and</u> <u>3. Not endanger the health, safety, or well-being of SASS, PSASS, other patients, or the public.</u> <u>B. A regulant may request a variance at any time. The</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to permit the commissioner to grant variances if warranted and to create a clear process by which variances may be requested or modified. RATIONALE: The rationale for these new requirements is to permit the commissioner to address unforeseen circumstances that complicate a regulant's compliance with a requirement in this chapter. LIKELY IMPACT: The likely impact of these new requirements is reduced likelihood of confusion on how a regulant may request

	<u>request for a variance shall describe in writing:</u> <u>1. How compliance with the current standard or requirement is economically burdensome and constitutes impractical hardship unique to the regulant; and</u> <u>2. Proposed alternatives to meet the purpose of the standard or requirement that will ensure the health, safety, and well-being of SASs, PSASs, other patients, and the public.</u> <u>C. The regulant may withdraw a request for a variance at any time by notifying the OLC in writing.</u> <u>D. The commissioner shall notify the regulant in writing of the commissioner's decision on the variance request. If granted, the commissioner may attach conditions to a variance that, in the sole judgment of the commissioner, protects the health, safety, and well-being of SASs, PSASs, other patients, and the public.</u> <u>E. The commissioner may rescind or modify a variance if:</u> <u>1. The impractical hardship unique to the regulant changes or no longer exists;</u> <u>2. Additional information becomes known that alters the basis for the original decision, including if the regulant failed to comply with the standard or requirement prior to receiving a variance;</u> <u>3. The regulant fails to meet any conditions</u>		a variance and clarity on what the commissioner's authority is in regards to granting or modifying a variance.
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	<u>attached to the variance;</u> <u>or</u> <u>4. Results of the variance jeopardize the health, safety, or well-being of SASs, PSASs, other patients, and the public.</u> <u>F. If a variance is denied, expires, or is rescinded, the commissioner or his designee shall enforce the standard or requirement to which the variance was granted.</u> <u>G. The administrator shall develop and document procedures for monitoring the implementation of any variance.</u>		
416-100	<u>12VAC5-416-100. Violations of this chapter.</u> <u>A. A hospital or pediatric health care facility may not violate the provisions of this chapter or Article 8 (§ 32.1-162.15:2 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia.</u> <u>B. The commissioner may:</u> <u>1. For each violation of subsection A of this section by a hospital:</u> <u>a. Deny, revoke, or suspend the license to operate the hospital in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia);</u> <u>b. Refer the hospital for criminal prosecution pursuant to subsection A of § 32.1-27 of the Code of Virginia; or</u> <u>c. Petition an appropriate court for an injunction, mandamus, or other</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to describe the consequences for violating the regulatory requirements or enabling statutes. RATIONALE: The rationale for these new requirements is that applicants and regulants should be informed of the consequences for violations so as to discourage violations. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.

	<u>appropriate remedy or imposition of a civil penalty against the _____ hospital pursuant to subsection B or C of § 32.1-27 of the Code of Virginia; and</u> <u>2. For each violation of subsection A of this section by a pediatric health care facility:</u> <u>a. Report the health care professionals involved in the violation to the appropriate health regulatory board in the Department of Health Professions;</u> <u>b. Refer the pediatric health care facility for criminal prosecution pursuant to subsection A of § 32.1-27 of the Code of Virginia; or</u> <u>c. Petition an appropriate court for an injunction, mandamus, or other appropriate remedy or imposition of a civil penalty against the pediatric health care facility pursuant to subsection B or C of § 32.1-27 of the Code of Virginia.</u> <u>C. If the commissioner determines that a violation of subsection A of this section by a hospital jeopardizes the health or safety of patients, the commissioner may immediately revoke, suspend, or deny a license. Suspension of a license shall in all cases be for an indefinite time.</u>		
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	<u>D. Upon receipt of a completed application and a nonrefundable service charge prescribed by § 32.1-130, the commissioner may issue a new license to the hospital that has had its license revoked if the commissioner determines that:</u> <u>1. The conditions upon which revocation was based have been corrected; and</u> <u>2. The hospital is in compliance with this chapter, Article 8 (§ 32.1-162.15:2 et seq.) of Chapter 5 of Title 32.1 of the Code of Virginia, and all other applicable state and federal law and regulations.</u> <u>E. Upon receipt of a completed application, the commissioner may partially or completely restore a suspended license to the hospital if the commissioner determines that:</u> <u>1. The conditions upon which suspension was based have been completely or partially corrected; and</u> <u>2. The interests of the public will not be jeopardized by resumption of operation.</u> <u>F. The hospital shall submit evidence relevant to subdivisions D 1, D 2, E 1, and E 2 of this section that is satisfactory to the commissioner or his designee. The commissioner or his designee may conduct an inspection prior to making a determination.</u> <u>G. The commissioner may not require an additional fee for restoring a license pursuant to subsection E of this section.</u>	
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416-110	<u>Part II</u> <u>SAS Treatment Plan</u> <u>12VAC5-416-110. Minimum requirements for SAS treatment plan.</u> <u>A treatment hospital shall ensure that its SAS treatment plan meets the minimum standards established in Part II (12VAC5-416-110 et seq.) of this chapter and includes the provision of a forensic medical examination to a SAS when ordered by a health care professional and with the consent of the SAS.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to broadly describe what must be included in the plan. RATIONALE: The rationale for these new requirements is to ensure that applicants and regulants are incorporating all regulatory minimums when developing their plans. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.
416-120	<u>12VAC5-416-120. Staffing and education.</u> <u>A. A treatment hospital shall ensure that at least one SAFE is available during all hours of operation in person.</u> <u>B. A treatment hospital shall ensure that health care professionals providing services in its emergency department annually complete training developed and made available by the department on the topics of:</u> <u>1. Sexual assault;</u> <u>2. Detection of sexual assault;</u> <u>3. Provision of services for SASs and PSASs; and</u> <u>4. Collection of evidence in cases involving alleged sexual assault.</u> <u>C. If the training specified in subsection B is not available, a treatment hospital shall substitute the training for continuing education provided by the treatment hospital or by third</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure that adequately trained staff are available to provide treatment services. RATIONALE: The rationale for these new requirements is that providing treatment services should only be done or directed by someone who has been trained to provide that specialty care and to provide some flexibility to hospitals if training is not available from VDH. LIKELY IMPACT: The likely impact of these new requirements is adequate treatment services and improved clarity for applicants and regulants.

	<u>parties on the same topics identified in this subsection.</u>		
416-130	<u>12VAC5-416-130. Informed consent.</u> <u>A. Except as provided in § 54.1-2970.1 of the Code of Virginia, a treatment hospital shall obtain informed consent from the SAS for:</u> <u>1. Medical evaluation and treatment, including the administration of prophylaxis and emergency contraception, the need for follow-up care, and medical advocacy services and counseling;</u> <u>2. Reporting the alleged crime;</u> <u>3. Performing a forensic medical examination;</u> <u>4. Photodocumentation;</u> <u>5. Evidence collection; and</u> <u>6. Transferal of evidence to law enforcement.</u> <u>B. In obtaining informed consent for evidence collection, a treatment hospital shall inform the SAS that the ability to collect viable evidence declines as time elapses.</u> <u>C. Except as provided in § 54.1-2970.1 of the Code of Virginia, a treatment hospital shall obtain informed consent in writing from the SAS to the maximum extent practicable, provided that if it cannot obtain informed consent in writing, it shall:</u> <u>1. Obtain oral informed consent from the SAS; and</u> <u>2. Document in the SAS's medical records why informed written</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure informed consent is obtained and documented in conformity with recommendations from the American College of Emergency Physicians. RATIONALE: The rationale for these new requirements is that informed consent creates trust between patients and their health care providers and reduces risk. LIKELY IMPACT: The likely impact of these new requirements is patients feeling empowered to make decisions about their care.

	<u>consent was not obtained.</u> <u>D. A treatment hospital shall maintain documentation of compliance with this section in the SAS's medical records.</u>		
416-140	<u>12VAC5-416-140. Documentation.</u> <u>A treatment hospital shall ensure that all findings of the forensic medical examination are comprehensively and objectively documented.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure the findings are complete. RATIONALE: The rationale for these new requirements is that inadequately documented findings may compromise any future criminal investigation or prosecution. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.
416-150	<u>12VAC5-416-150. Medical history.</u> <u>A. A treatment hospital shall document specific information related to the alleged sexual assault, including:</u> <u>1. Time, date, and place of the alleged sexual assault;</u> <u>2. The SAS's ability to give consent to the reported sexual activity;</u> <u>3. Alleged use of force, threats of force, weapons, coercion, drugs, or alcohol to facilitate the sexual assault;</u> <u>4. Types or means of the alleged sexual assault;</u> <u>5. Number of alleged assailants;</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to describe the minimum medical history and alleged sexual assault information to be captured for SASs in conformity with recommendations from the American College of Emergency Physicians. RATIONALE: The rationale for these new requirements is that inadequately documented findings may compromise any future criminal investigation or prosecution. LIKELY IMPACT: The likely impact of these new requirements is improved

	6. <u>The occurrence of penetration of any body part with a penis, finger, or other object;</u> 7. <u>Whether the SAS voided, removed or inserted a tampon, douched, wiped or cleaned the genital area, bathed, showered, gargled, brushed teeth, smoked, ate, drank, chewed gum, changed clothes, or took medications after the alleged sexual assault;</u> 8. <u>Whether the SAS bit an alleged assailant or was bitten by the alleged assailant; and</u> 9. <u>Any other relevant information as determined by the health care professional who is providing care.</u> <u>B. To the maximum extent practicable, a treatment hospital shall ensure that:</u> 1. <u>Information documented pursuant to subsection A includes direct quotations from the SAS describing the alleged sexual assault; and</u> 2. <u>Information solicited pursuant to subsection A is through the use of open-ended, non-leading questions that encourage free narrative from the SAS.</u> <u>C. A treatment hospital shall document the SAS's medical history, including:</u> 1. <u>Use of contraceptives and which type the SAS uses;</u> 2. <u>Last menstrual period, if applicable;</u>	chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.
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	<u>3. Last consensual intercourse;</u> <u>4. Pregnancy status, if applicable;</u> <u>5. History of anogenital surgery; and</u> <u>6. Any other relevant information as determined by the health care professional who is providing care.</u>		
416-160	<u>12VAC5-416-160. Physical examination, laboratory testing, and evidence collection.</u> A. A treatment hospital shall ensure that health care professionals conducting the forensic medical examination or collecting the PERK: <u>1. Are specially educated and clinically trained to perform these tasks;</u> <u>2. Clearly document all findings; and</u> <u>3. Prevent cross contamination of evidence by changing gloves whenever cross contamination could occur.</u> B. A treatment hospital shall ensure that in conducting a forensic medical examination: <u>1. A clean sheet is placed on the floor to be a barrier for the collection paper before the SAS undresses;</u> <u>2. A SAS is permitted to remove and place each piece of clothing being collected in a separate paper bag; and</u> <u>3. A health care professional:</u> <u>a. Conducts an appropriate</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure that the collection of evidence for a PERK is complete and done in conformity with recommendations from the American College of Emergency Physicians. RATIONALE: The rationale for these new requirements is that improper evidence collection can jeopardize or destroy the potential for criminal investigation or prosecution. LIKELY IMPACT: The likely impact of these new requirements is improved chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.

	<u>evaluation to determine the SAS's risk of infection or STIs, including HIV, resulting from the alleged sexual assault;</u> <u>b. Documents the presence of any physical injury, biological evidence, or foreign debris;</u> <u>c. Photographs and recovers any trace evidence, including sand, soil, leaves, grass, and biological secretions;</u> <u>d. Documents the location on the body from which trace evidence is collected;</u> <u>e. Performs appropriate photodocumentation of collection sites and injuries before evidence collection;</u> <u>f. Recovers debris, moist secretions, and dry secretions in accordance with best practices; and</u> <u>g. Documents the location, size, and complete description of any trauma, including bite marks, strangulation injuries, or areas of point tenderness, including those occurring around the mouth, breasts, thighs, wrists, upper arms, legs, back, and anogenital region.</u> <u>C. If drug-facilitated or alcohol-facilitated sexual assault</u>		
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	<u>is suspected, a treatment hospital shall ensure that blood or urine or both are collected with the consent of the SAS.</u> <u>D. A treatment hospital shall ensure that health care professionals performing a forensic medical examination conduct all necessary laboratory testing.</u> Statutory Authority <u>§§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.</u>		
416-170	<u>12VAC5-416-170. Chain of custody.</u> <u>A. A treatment hospital shall ensure that the chain of custody is maintained for all samples collected during the forensic medical examination.</u> <u>B. A treatment hospital shall ensure that all specimens are properly sealed, initialed, and labeled with:</u> <u>1. The name of the treatment hospital;</u> <u>2. The SAS's name and patient identification number;</u> <u>3. Date and time of specimen collection;</u> <u>4. Description and location of the body part of the origin of the specimen;</u> <u>5. The name and signature of the person collecting the specimen; and</u> <u>6. Any other information that may be required by law.</u> <u>C. A treatment hospital shall ensure that all transfers in the custody of evidence are documented in a written record of:</u> <u>1. The name, title, and signature of the person</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure that chain of custody is maintained in conformity with recommendations from the American College of Emergency Physicians and local law enforcement. RATIONALE: The rationale for these new requirements is that mishandling evidence or breaking the chain of custody can jeopardize or destroy the potential for criminal investigation or prosecution. LIKELY IMPACT: The likely impact of these new requirements is improved chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.

	<u>receiving the evidence;</u> <u>and</u> <u>2. Date and time of transfer.</u> <u>D. A treatment hospital may designate a secured location to store evidence and maintain chain of custody, provided the treatment hospital has consulted with local law enforcement on the location, security, and policies and procedures for storage.</u>		
416-180	<u>12VAC5-416-180. Prophylaxis and contraception.</u> <u>A. A treatment hospital shall provide appropriate oral and written information regarding:</u> <u>1. The possibility of infection or STIs, including HIV resulting from the alleged sexual assault;</u> <u>2. Accepted medical procedures and medications for the prevention or treatment of infection or STIs;</u> <u>3. The indications, contraindications, and potential risks of medical procedures or medications for the prevention or treatment of infection or STIs;</u> <u>4. The possibility of pregnancy resulting from the alleged sexual assault;</u> <u>5. Medically and factually accurate oral and written information about emergency contraception;</u> <u>6. The indications, contraindications, and potential risks associated with the use of emergency contraception; and</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to describe the information to be provided to a patient and the care to be provided or arranged for with regard to STIs and emergency contraception, subject to certain exclusions. RATIONALE: The rationale for these new requirements is that treatment for STIs and emergency contraception are often clinically indicated for alleged sexual assaults and patients should be provided adequate information to make informed choices. Also, VDH recognizes that some hospitals may object to emergency contraceptive on religious grounds and has provided an exception. LIKELY IMPACT: The likely impact of these new requirements is patients feeling empowered to make decisions about their care.

	<u>7. The availability of emergency contraception for SASs.</u> <u>B. Unless the prophylaxis is medically contraindicated or the SAS refuses to consent to the administration of prophylaxis, the treatment hospital shall provide, or arrange for, the administration to a SAS of prophylaxis for STIs in accordance with the:</u> <u>1. Sexually Transmitted Infections Treatment Guidelines, July 2021 (U.S. Centers for Disease Control and Prevention); and</u> <u>2. Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, January 2020 (U.S. Centers for Disease Control and Prevention).</u> <u>C. Unless emergency contraceptive is medically contraindicated or the SAS refuses to consent to the administration of emergency contraceptive, the treatment hospital shall provide, or arrange for, the administration to a SAS of emergency contraceptive.</u> <u>D. The provisions of subsection C of this section may not apply to a treatment hospital operated under the auspices of a religious institution objecting to the administration or arrangement of administration for emergency contraceptive on religious grounds.</u>		
416-190	<u>12VAC5-416-190. Anonymous PERK.</u> <u>A. If a SAS who undergoes a forensic medical examination elects not to report the offense to law enforcement, the treatment hospital shall ensure that the</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to describe what a hospital must do when a patient

	<u>health care professional informs the SAS:</u> <u>1. The PERK will be forwarded to DCLS for storage as an anonymous PERK;</u> <u>2. The anonymous PERK will be stored by DCLS;</u> <u>3. The SAS has the right to object to the destruction of the anonymous PERK;</u> <u>4. How the SAS can have the anonymous PERK released to a law enforcement agency at a later date; and</u> <u>5. The rights of the SAS pursuant to § 19.2-11.11 of the Code of Virginia.</u> <u>B. The treatment hospital shall ensure that the health care professional forwards the anonymous PERK to DCLS in accordance with the policies and procedures established by DCLS.</u>		declines to report the offense to law enforcement. RATIONALE: The rationale for these new requirements is that patients should be adequately informed about what happens next to their PERK and their ability to change their mind in the future. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what will happen to their PERK and for applicants and regulants about their obligations.
416-200	<u>12VAC5-416-200. Medical advocacy services.</u> <u>A. A treatment hospital shall:</u> <u>1. Enter into a memorandum of understanding with at least one rape crisis center; and</u> <u>2. Adopt procedures to ensure compliance with mandatory reporting requirements pursuant to §§ 63.2-1509 and 63.2-1606 of the Code of Virginia.</u> <u>B. A treatment hospital shall review its memorandums of understanding with rape crisis centers at least triennially and shall document the outcome of this review in writing.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent for these new requirements is to meet the statutory requirements for memoranda of understanding (MOUs) with rape crisis centers and provision of information to patients about medical advocacy, and to ensure the MOUs are regularly reviewed. RATIONALE: The rationale for these new requirements is that Chapter 725 (2020 Acts of Assembly) mandates these MOUs, that regular review ensures the MOU continues to serve the

	<u>C. A treatment hospital shall provide written and oral information to the SAS about medical advocacy services provided by a rape crisis center with which the hospital has entered into a memorandum of understanding pursuant to this section.</u>		purposes of legislation and the contracting parties, and that patients are adequately informed of non-hospital services that may be of assistance. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what community resources are available and for applicants and regulants about their obligations.
416-210	<u>12VAC5-416-210. Discharge and follow-up health care.</u> <u>A. A treatment hospital shall ensure that a SAS is provided with oral and written medical discharge instructions that include:</u> <u>1. A summary of the examination, which includes:</u> <u>a. Evidence collected;</u> <u>b. Tests conducted;</u> <u>c. Medication prescribed or provided;</u> <u>d. Information provided during the examination; and</u> <u>e. Treatment received;</u> <u>2. Medication doses to be taken, if any;</u> <u>3. Recommended examinations and laboratory tests to determine the presence or absence of STIs;</u> <u>4. Follow-up care related to HIV prophylaxis;</u> <u>5. Any other follow-up health care appointments needed or scheduled; and</u> <u>6. Referrals.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to meet the statutory requirements for follow-up health care. RATIONALE: The rationale for these new requirements is that care for patients who have experienced an alleged sexual assault does not end after the initial hospital encounter and adequate instructions and follow-up care should be provided. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what next steps they need to take for their care and for applicants and regulants about their obligations.

	<u>B. A treatment hospital shall provide to a SAS contact information and the hours of operation for local advocacy programs.</u> <u>C. A treatment hospital shall inform a SAS in writing that the SAS is not required to disclose the alleged sexual assault to other health care professionals to receive follow-up health care.</u> <u>D. The follow-up health care appointments that a treatment hospital may schedule or recommend to a SAS include:</u> <u>1. For patients with evidence of acute trauma, a short-term follow-up appointment to reexamine and document the development of visible findings and photograph areas of injury, and an exam two to four weeks later to document resolution of findings or healing of injuries; and</u> <u>2. For all patients, a repeat examination for STIs in accordance with the policies and procedures of the treatment hospital and with best practices.</u> Statutory Authority <u>§§ 32.1-12 and 32.1-162.15:4 of the Code of Virginia.</u>		
416-220	<u>12VAC5-416-220. Reporting requirements.</u> <u>A treatment hospital shall report to the department by December 1 of each year:</u> <u>1. The total number of SASs to whom a forensic medical examination was provided; and</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to meet the statutory requirements for hospital reporting. RATIONALE: The rationale for these new requirements is that the regulations should

	<u>2. The total number of PERKs offered and completed.</u>		be in conformity with the enabling statutes. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants about their obligations and increased knowledge about treatment services.
416-230	Part III PSAS Treatment Plan <u>12VAC5-416-230. Minimum requirements for PSAS treatment plan.</u> <u>An approved pediatric treatment facility shall ensure that its PSAS treatment plan meets the minimum standards established in Part III (12VAC5-416-230 et seq.) of this chapter and includes the provision of a forensic medical examination to a PSAS when ordered by a health care professional and with the assent of the PSAS and consent of the PSAS's legal representative.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to broadly describe what must be included in the plan. RATIONALE: The rationale for these new requirements is to ensure that applicants and regulants are incorporating all regulatory minimums when developing their plans. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.
416-240	<u>12VAC5-416-240. Pediatric staffing.</u> <u>An approved pediatric treatment facility shall ensure that at least one SAFE is available during all hours of operation in person.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure that adequately trained staff are available to provide treatment services. RATIONALE: The rationale for these new requirements is that providing treatment services should only be done or directed by someone who has been trained to provide that specialty care. LIKELY IMPACT: The likely impact of these new requirements is adequate treatment services and

			improved clarity for applicants and regulants.
416-250	<u>12VAC5-416-250. Informed assent and consent for treatment.</u> <u>A. An approved pediatric treatment facility:</u> <u>1. Shall ensure that all necessary and reasonable efforts are made to obtain informed assent of PSASs who are six years of age or older prior to and during treatment, unless the attending health care professional reasonably believes that the PSAS lacks the developmental and linguistic capacity to give informed assent;</u> <u>2. May obtain informed assent of PSASs who are less than six years of age prior to and during treatment, if the attending health care professional reasonably believes that the PSAS has the developmental and linguistic capacity to give informed assent; and</u> <u>3. Shall ensure that the attending health care professional documents in the PSAS's medical record the informed assent or the attending health care professional's judgment that the PSAS lacks the developmental and linguistic capacity to give informed assent.</u> <u>B. Except as provided in § 54.1-2970.1 of the Code of Virginia, an approved pediatric health care facility shall obtain informed consent from the PSAS's legal representative for:</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure informed assent and consent is obtained and documented, subject to certain age and capacity restrictions. RATIONALE: The rationale for these new requirements is that informed assent and consent creates trust between patients and their health care providers and reduces risk. LIKELY IMPACT: The likely impact of these new requirements is patients and their legal representatives feeling empowered to make decisions about the patient's care.

	1. <u>Medical evaluation and treatment, including the administration of prophylaxis and emergency contraception, the need for follow-up care, and medical advocacy services and counseling;</u> 2. <u>Reporting the alleged crime;</u> 3. <u>Performing a forensic medical examination;</u> 4. <u>Photodocumentation;</u> 5. <u>Evidence collection; and</u> 6. <u>Transferal of evidence to law enforcement.</u> C. <u>In obtaining informed consent for evidence collection, an approved pediatric treatment facility shall inform the PSAS and the PSAS's legal representative that the ability to collect viable evidence declines as time elapses.</u> D. <u>Except as provided in § 54.1-2970.1 of the Code of Virginia, an approved pediatric treatment facility shall obtain informed consent in writing from the PSAS's legal representative to the maximum extent practicable, provided that if it cannot obtain informed consent in writing, it shall:</u> 1. <u>Obtain oral informed consent from the PSAS's legal representative; and</u> 2. <u>Document in the PSAS's medical records why informed written consent was not obtained.</u> E. <u>An approved pediatric treatment facility shall maintain documentation of compliance with this section in the PSAS's medical records.</u>		
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	<u>F. If a PSAS refuses to grant informed assent and the PSAS's legal representative gives informed consent, an approved pediatric treatment facility that is a hospital:</u> <u>1. May not proceed with PSAS treatment services and shall only screen, treat, and stabilize the PSAS in accordance with EMTALA; and</u> <u>2. May attempt to obtain a PSAS's informed assent at a later time.</u> <u>G. If a PSAS refuses to grant informed assent and the PSAS's legal representative gives informed consent, an approved pediatric treatment facility that is not a hospital:</u> <u>1. May not proceed with PSAS treatment services and shall only screen or treat serious medical injury, pain, or trauma to stabilize the PSAS; and</u> <u>2. May attempt to obtain a PSAS's informed assent at a later time.</u> Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.</u> <u>12VAC5-416-260.</u> <u>Documentation.</u> <u>An approved pediatric treatment facility shall ensure that all findings of the forensic medical examination are comprehensively and objectively documented.</u> Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.</u>		
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416-260	<u>12VAC5-416-260. Documentation.</u> <u>An approved pediatric treatment facility shall ensure that all findings of the forensic medical examination are comprehensively and objectively documented.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure the findings are complete. RATIONALE: The rationale for these new requirements is that inadequately documented findings may compromise any future criminal investigation or prosecution. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.
416-270	<u>12VAC5-416-270. Medical history.</u> <u>A. An approved pediatric treatment facility shall document specific information related to the alleged sexual assault, including:</u> <u>1. Time, date, and place of the alleged sexual assault;</u> <u>2. The PSAS's ability to give consent to the reported sexual activity;</u> <u>3. Alleged use of force, threats of force, weapons, coercion, drugs, or alcohol to facilitate the sexual assault;</u> <u>4. Types or means of the alleged sexual assault;</u> <u>5. Number of alleged assailants;</u> <u>6. The occurrence of penetration of any body part with a penis, finger, or other object;</u> <u>7. Whether the PSAS voided, removed or inserted a tampon, douched, wiped or</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to describe the minimum medical history and alleged sexual assault information to be captured for PSASs in conformity with recommendations from the American College of Emergency Physicians. RATIONALE: The rationale for these new requirements is that inadequately documented findings may compromise any future criminal investigation or prosecution. LIKELY IMPACT: The likely impact of these new requirements is improved chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.

	<u>cleaned the genital area, bathed, showered, gargled, brushed teeth, smoked, ate, drank, chewed gum, changed clothes, or took medications after the alleged sexual assault;</u> <u>8. Whether the PSAS bit an alleged assailant or was bitten by the alleged assailant; and</u> <u>9. Any other relevant information as determined by the health care professional who is providing care.</u> <u>B. To the maximum extent practicable, an approved pediatric treatment facility shall ensure that:</u> <u>1. Information documented pursuant to subsection A includes direct quotations from the PSAS describing the alleged sexual assault; and</u> <u>2. Information solicited pursuant to subsection A is through the use of open-ended, non-leading questions that encourage free narrative from the PSAS.</u> <u>C. An approved pediatric treatment facility shall document the PSAS's medical history, including:</u> <u>1. Use of contraceptives and which type the PSAS uses;</u> <u>2. Last menstrual period, if applicable;</u> <u>3. Last consensual intercourse;</u> <u>4. Pregnancy status, if applicable;</u> <u>5. History of anogenital surgery; and</u>		
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	6. Any other relevant information as determined by the health care professional who is providing care.		
416-280	<u>12VAC5-416-280. Physical examination, laboratory testing, and evidence collection.</u> <u>A. An approved pediatric treatment facility shall ensure that health care professionals conducting the forensic medical examination or collecting the PERK:</u> <u>1. Are specially educated and clinically trained to perform these tasks;</u> <u>2. Clearly document all findings; and</u> <u>3. Prevent cross contamination of evidence by changing gloves whenever cross contamination could occur.</u> <u>B. An approved pediatric treatment facility shall ensure that in conducting a forensic medical examination:</u> <u>1. A clean sheet is placed on the floor to be a barrier for the collection paper before the PSAS undresses;</u> <u>2. A PSAS is permitted to remove and place each piece of clothing being collected in a separate paper bag; and</u> <u>3. A health care professional:</u> <u>a. Conducts an appropriate evaluation to determine the PSAS's risk of infection or STIs, including HIV,</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure that the collection of evidence for a PERK is complete and done in conformity with recommendations from the American College of Emergency Physicians. RATIONALE: The rationale for these new requirements is that improper evidence collection can jeopardize or destroy the potential for criminal investigation or prosecution. LIKELY IMPACT: The likely impact of these new requirements is improved chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.

	<u>resulting from the alleged sexual assault;</u> <u>b. Documents the presence of any physical injury, biological evidence, or foreign debris;</u> <u>c. Photographs and recovers any trace evidence, including sand, soil, leaves, grass, and biological secretions;</u> <u>d. Documents the location on the body from which trace evidence is collected;</u> <u>e. Performs appropriate photodocumentation of collection sites and injuries before evidence collection;</u> <u>f. Recovers debris, moist secretions, and dry secretions in accordance with best practices; and</u> <u>g. Documents the location, size, and complete description of any trauma, including bite marks, strangulation injuries, or areas of point tenderness, including those occurring around the mouth, breasts, thighs, wrists, upper arms, legs, back, and anogenital region.</u> <u>C. If drug-facilitated or alcohol-facilitated sexual assault is suspected, an approved pediatric treatment facility shall ensure that blood or urine or both</u>	
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	are collected with the assent of the PSAS. <u>D. An approved pediatric treatment facility shall ensure that health care professionals performing a forensic medical examination conduct all necessary laboratory testing.</u> Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.</u>		
416-290	<u>12VAC5-416-290. Chain of custody.</u> <u>A. An approved pediatric treatment facility shall ensure that the chain of custody is maintained for all samples collected during the forensic medical examination.</u> <u>B. An approved pediatric treatment facility shall ensure that all specimens are properly sealed, initialed, and labeled with:</u> <u>1. The name of the approved pediatric treatment facility;</u> <u>2. The PSAS's name and patient identification number;</u> <u>3. Date and time of specimen collection;</u> <u>4. Description and location of the body part of the origin of the specimen;</u> <u>5. The name and signature of the person collecting the specimen; and</u> <u>6. Any other information that may be required by law.</u> <u>C. An approved pediatric treatment facility shall ensure that all transfers in the custody of evidence are documented in a written record of:</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure that chain of custody is maintained in conformity with recommendations from the American College of Emergency Physicians and local law enforcement. RATIONALE: The rationale for these new requirements is that mishandling evidence or breaking the chain of custody can jeopardize or destroy the potential for criminal investigation or prosecution. LIKELY IMPACT: The likely impact of these new requirements is improved chances that criminal investigation or prosecution is successful and improved clarity for applicants and regulants.

	<u>1. The name, title, and signature of the person receiving the evidence; and</u> <u>2. Date and time of transfer.</u> <u>D. An approved pediatric treatment facility may designate a secured location to store evidence and maintain chain of custody, provided the approved pediatric treatment facility has consulted with local law enforcement on the location, security, and policies and procedures for storage.</u>		
416-300	<u>12VAC5-416-300. Prophylaxis and contraception.</u> <u>A. An approved pediatric treatment facility shall provide appropriate oral and written information regarding:</u> <u>1. The possibility of infection or STIs, including HIV resulting from the alleged sexual assault;</u> <u>2. Accepted medical procedures and medications for the prevention or treatment of infection or STIs;</u> <u>3. The indications, contraindications, and potential risks of medical procedures or medications for the prevention or treatment of infection or STIs;</u> <u>4. The possibility of pregnancy resulting from the alleged sexual assault;</u> <u>5. Medically and factually accurate oral and written information about emergency contraception;</u> <u>6. The indications, contraindications, and</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to describe the information to be provided to a patient and the care to be provided or arranged for with regard to STIs and emergency contraception, subject to certain exclusions. RATIONALE: The rationale for these new requirements is that treatment for STIs and emergency contraception are often clinically indicated for alleged sexual assaults and patients should be provided adequate information to make informed choices. Also, VDH recognizes that some pediatric health care facilities may object to emergency contraceptive on religious grounds and has provided an exception. LIKELY IMPACT: The likely impact of these new requirements is patients feeling empowered to make decisions about their care.

	potential risks associated with the use of emergency contraception; and 7. The availability of emergency contraception for PSASs. B. Unless the prophylaxis is medically contraindicated, the PSAS refuses to assent to the administration of prophylaxis, or the PSAS's legal representative refuses to consent to the administration of prophylaxis, the approved pediatric treatment facility shall provide, or arrange for, the administration to a PSAS of prophylaxis for STIs in accordance with the: 1. Sexually Transmitted Infections Treatment Guidelines, July 2021 (U.S. Centers for Disease Control and Prevention); and 2. Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, January 2020 (U.S. Centers for Disease Control and Prevention). C. Unless emergency contraceptive is medically contraindicated, the PSAS refuses to assent to the administration of emergency contraceptive, or the PSAS's legal representative refuses to consent to the administration of emergency contraceptive, the approved pediatric treatment facility shall provide, or arrange for, the administration to a PSAS of emergency contraceptive. D. The provisions of subsection C of this section may not apply to an approved pediatric treatment facility operated under the auspices of a		
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	<u>religious institution objecting to the administration or arrangement of administration for emergency contraceptive on religious grounds.</u>		
416-310	<u>12VAC5-416-310. Anonymous PERK.</u> <u>A. If a PSAS who undergoes a forensic medical examination elects not to report the offense to law enforcement, the approved pediatric treatment facility shall ensure the health care professional informs the PSAS or the PSAS's legal representative:</u> <u>1. The PERK will be forwarded to DCLS for storage as an anonymous PERK;</u> <u>2. The anonymous PERK will be stored by DCLS;</u> <u>3. The PSAS has the right to object to the destruction of the anonymous PERK;</u> <u>4. How the PSAS can have the anonymous PERK released to a law enforcement agency at a later date; and</u> <u>5. The rights of the PSAS and PSAS's parent or guardian under § 19.2-11.11 of the Code of Virginia.</u> <u>B. The approved pediatric treatment facility shall ensure the health care professional forwards the anonymous PERK to DCLS in accordance with the policies and procedures established by DCLS.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to describe what a hospital must do when a patient declines to report the offense to law enforcement. RATIONALE: The rationale for these new requirements is that patients should be adequately informed about what happens next to their PERK and their ability to change their mind in the future. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what will happen to their PERK and for applicants and regulants about their obligations.
416-320	<u>12VAC5-416-320. Medical advocacy services.</u> <u>A. An approved pediatric treatment facility shall:</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent for these new requirements is to meet

	<u>1. Enter into a memorandum of understanding with at least one rape crisis center; and</u> <u>2. Adopt procedures to ensure compliance with mandatory reporting requirements pursuant to § 63.2-1509 of the Code of Virginia.</u> <u>B. An approved pediatric treatment facility shall review its memorandums of understanding with rape crisis centers at least triennially and shall document the outcome of this review in writing.</u> <u>C. An approved pediatric treatment facility shall provide written and oral information about medical advocacy services provided by a rape crisis center with which the approved pediatric treatment facility has entered into a memorandum of understanding pursuant to this section.</u>		the statutory requirements for memoranda of understanding (MOUs) with rape crisis centers and provision of information to patients about medical advocacy, and to ensure the MOUs are regularly reviewed. RATIONALE: The rationale for these new requirements is that Chapter 725 (2020 Acts of Assembly) mandates these MOUs, that regular review ensures the MOU continues to serve the purposes of legislation and the contracting parties, and that patients are adequately informed of non-hospital services that may be of assistance. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what community resources are available and for applicants and regulants about their obligations.
416-330	<u>12VAC5-416-330. Discharge and follow-up health care.</u> <u>A. An approved pediatric treatment facility shall ensure that a PSAS and the PSAS's legal representative is provided with oral and written medical discharge instructions that include:</u> <u>1. A summary of the examination, which includes:</u> <u>a. Evidence collected;</u> <u>b. Tests conducted;</u> <u>c. Medication prescribed or provided;</u> <u>d. Information provided during the examination; and</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to meet the statutory requirements for follow-up health care. RATIONALE: The rationale for these new requirements is that care for patients who have experienced an alleged sexual assault does not end after the initial hospital encounter and adequate instructions and follow-up care should be provided. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients about what next steps they need to

	e. <u>Treatment received;</u> 2. <u>Medication doses to be taken, if any;</u> 3. <u>Recommended examinations and laboratory tests to determine the presence or absence of STIs;</u> 4. <u>Follow-up care related to HIV prophylaxis;</u> 5. <u>Any other follow-up health care appointments needed or scheduled; and</u> 6. <u>Referrals.</u> B. <u>An approved pediatric treatment facility shall provide to a PSAS and the PSAS's legal representative contact information and the hours of operation for local advocacy programs.</u> C. <u>An approved pediatric treatment facility shall inform a PSAS and the PSAS's legal representative in writing that the PSAS is not required to disclose the alleged sexual assault to other health care professionals to receive follow-up health care.</u> D. <u>The follow-up health care appointments that an approved pediatric treatment facility may schedule or recommend to a PSAS and the PSAS's legal representative include:</u> 1. <u>For patients with evidence of acute trauma, a short-term follow-up appointment to reexamine and document the development of visible findings and photograph areas of injury, and an exam two to four weeks later to document resolution of findings or healing of injuries; and</u>	take for their care and for applicants and regulants about their obligations.
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	<u>2. For all patients, a repeat examination for STIs in accordance with the policies and procedures of the approved pediatric treatment facility and with best practices.</u>		
416-340	<u>12VAC5-416-340. Approved pediatric treatment facilities with limited capacity.</u> <u>A. In cases in which an approved pediatric treatment facility is not able to provide the full range of treatment services required by Part III (12VAC5-416-230 et seq.) of this chapter, the PSAS treatment plan shall include:</u> <u>1. The specific PSAS treatment services that the approved pediatric treatment facility will provide for a PSAS;</u> <u>2. Provisions for PSAS transfer services for a PSAS; and</u> <u>3. The written agreement of an approved pediatric treatment facility to accept transfer of a PSAS who cannot be treated by the originating approved pediatric treatment facility.</u> <u>B. If the approved pediatric treatment facility does not provide services 24 hours per day, seven days per week, it shall:</u> <u>1. Inform the public regarding the need to seek an alternative source of treatment, including emergency medical services; and</u> <u>2. Post conspicuous signage on its premises, including in an area</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to meet the statutory requirements for pediatric health care facilities with limited capacity. RATIONALE: The rationale for these new requirements is that Chapter 725 (2020 Acts of Assembly) mandates these pediatric health care facilities include certain elements in their plans and that patients and their legal representatives know a non-24/7 pediatric health care facility will not be available to provide care after hours. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for patients and their legal representatives about where to seek care after hours and for applicants and regulants about their obligations if they are a pediatric health care facility with limited capacity or pediatric health care facilities that does not operate 24/7.

	<u>readily visible and accessible to the public from the exterior of the approved pediatric treatment facility.</u> <u>C. An approved pediatric treatment facility's provision of PSAS transfer services pursuant to subdivision A 2 of this section shall comply with Part V (12VAC5-416-390 et seq.) of this chapter.</u> Statutory Authority <u>§§ 32.1-12, 32.1-162.15:4, and 32.1-162.15:6 of the Code of Virginia.</u>		
416-350	<u>Part IV</u> <u>SAS Transfer Plan</u> <u>12VAC5-416-350. Minimum requirements for SAS transfer plan.</u> <u>A transfer hospital shall ensure that its SAS transfer plan meets the minimum standards established in Part IV (12VAC5-416-350 et seq.) of this chapter.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to broadly describe what must be included in the plan. RATIONALE: The rationale for these new requirements is to ensure that applicants and regulants are incorporating all regulatory minimums when developing their plans. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.
416-360	<u>12VAC5-416-360. Screening.</u> <u>A. A transfer hospital shall screen patients for sexual assault, as deemed appropriate by a qualified health care professional in accordance with EMTALA.</u> <u>B. A transfer hospital shall adopt procedures to ensure compliance with mandatory reporting requirements pursuant to §§ 63.2-1509 and 63.2-1606 of the Code of Virginia.</u>	EMTALA	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure that the hospitals appropriately screen for sexual assault. RATIONALE: The rationale for these new requirements is that not all patients will disclose they are survivors of an alleged sexual assault

			and health care professionals need to be cognizant of these patients. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants about when to screen patients for sexual assault.
416-370	<u>12VAC5-416-370. Acute injuries.</u> <u>A transfer hospital shall ensure that a SAS is screened, treated, and stabilized in accordance with EMTALA prior to initiating any transfer.</u>	EMTALA	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure that a hospital's actions under this regulatory chapter comply with EMTALA. RATIONALE: The rationale for these new requirements is to avoid hospitals misunderstanding their obligations under this regulatory chapter when it intersects with their obligations under EMTALA. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.
416-380	<u>12VAC5-416-380. Transfer coordination.</u> <u>A. A transfer hospital shall comply with EMTALA in coordinating transfer with a receiving treatment hospital.</u> <u>B. A transfer hospital shall communicate with the receiving treatment hospital to confirm the availability of a SAFE to provide SAS treatment services to ensure minimal or no delay in the provision of a forensic medical examination.</u> <u>C. A transfer hospital shall provide a SAS with:</u>	EMTALA	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure adequate coordination for patient transfers and to ensure patients receive information about emergency contraception. RATIONALE: The rationale for these new requirements is that adequate transfer coordination is needed to ensure patients receive timely care from the receiving hospital and that

	<u>1. Written and oral information about:</u> a. <u>Emergency contraception;</u> b. <u>The indications, contraindications, and potential risks associate with the use of emergency contraception; and</u> c. <u>The availability of emergency contraception; and</u> <u>2. A copy of the SAS's medical record from the encounter, _____ as appropriate.</u>		patients are adequately informed about emergency contraception. LIKELY IMPACT: The likely impact of these new requirements is patients will be informed about emergency contraception and improved clarity for applicants and regulants.
416-390	<u>Part V</u> <u>PSAS Transfer Plan</u> <u>12VAC5-416-390. Minimum requirements for PSAS transfer plan.</u> <u>An approved pediatric transfer facility shall ensure that its PSAS transfer plan meets the minimum standards established in Part V (12VAC5-416-390 et seq.) of this chapter.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to broadly describe what must be included in the plan. RATIONALE: The rationale for these new requirements is to ensure that applicants and regulants are incorporating all regulatory minimums when developing their plans. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.
416-400	<u>12VAC5-416-400. Screening.</u> <u>A. An approved pediatric transfer facility that is a hospital shall screen pediatric patients for sexual assault, as determined to be appropriate by a qualified health care professional in accordance with EMTALA.</u> <u>B. An approved pediatric transfer facility that is not a hospital shall:</u>	EMTALA	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure that the pediatric health care facilities appropriately screen for sexual assault and have policies in place for mandatory reporting.

	<u>1. Screen pediatric patients for sexual, as determined to be appropriate by a qualified health care professional; and</u> <u>2. Have a written policy and procedure specifying the qualifications of the health care professionals at the approved pediatric transfer facility who may make the determination specified in subdivision B 1 of this section.</u> <u>C. An approved pediatric transfer facility shall adopt procedures to ensure compliance with mandatory reporting requirements pursuant to § 63.2-1509 of the Code of Virginia.</u> <u>D. If an approved pediatric treatment facility does not provide services 24 hours per day, seven days per week, it may not refuse to screen a PSAS solely on the basis that the PSAS arrived before the impending cessation of its daily operations. For the purposes of this subsection, "daily operations" means the publicly posted hours that the approved pediatric treatment facility provides services to patients.</u>		RATIONALE: The rationale for these new requirements is that not all patients will disclose they are survivors of an alleged sexual assault and health care professionals need to be cognizant of these patients, as well as ensuring non-24/7 pediatric health care facilities do not turn away patients on that basis they arrived close to—but not after—close of business. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants about when to screen patients for sexual assault.
416-410	<u>12VAC5-416-410. Acute injuries.</u> <u>A. An approved pediatric transfer facility that is a hospital shall ensure that a PSAS is screened, treated, and stabilized in accordance with EMTALA prior to initiating any transfer.</u> <u>B. An approved pediatric transfer facility that is not a hospital shall ensure that a PSAS is screened, treated, and</u>	EMTALA	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure that pediatric health care facilities stabilize and treat acute injuries, communicate as appropriate with child protective services or local law enforcement, and comply with EMTALA, as applicable.

	<u>stabilized prior to initiating any transfer.</u> <u>C. If an approved pediatric transfer facility reasonably believes that the PSAS's legal representative has abused or neglected the PSAS, the approved pediatric transfer facility shall consult with child protective services or local law enforcement immediately.</u> <u>D. If the PSAS's legal representative refuses to grant consent to treatment of an acute injury, the approved pediatric transfer facility shall consult with child protective services or local law enforcement immediately.</u>		RATIONALE: The rationale for these new requirements is to ensure patients get adequate care prior to any transfers, to alert child protective services or local law enforcement in cases where a patient may be in danger, and to avoid pediatric health care facilities that are hospitals misunderstanding their obligations under this regulatory chapter when it intersects with their obligations under EMTALA. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.
416-420	<u>12VAC5-416-420. Transfer coordination.</u> <u>A. An approved pediatric transfer facility that is a hospital shall comply with EMTALA in coordinating transfer with a receiving approved pediatric treatment facility.</u> <u>B. An approved pediatric transfer facility shall communicate with the receiving approved pediatric treatment facility to confirm the availability of a SAFE to provide PSAS treatment services to ensure minimal or no delay in the provision of a forensic medical examination.</u> <u>C. When making a transfer, the approved pediatric transfer facility shall:</u> <u>1. Ensure the transfer does not unduly burden the PSAS;</u> <u>2. Take precautions to minimize the loss of forensic evidence; and</u> <u>3. Provide a copy of the PSAS's records, including reports of any</u>	EMTALA	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure adequate coordination for patient transfers. RATIONALE: The rationale for these new requirements is that adequate transfer coordination is needed to ensure patients receive timely care from the receiving hospital and that pediatric health care facilities that are hospitals should continue to comply with EMTALA. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.

	<u>treatment administered or testing performed, to the approved pediatric treatment facility.</u>		
416-430	<u>12VAC5-416-430. Required transfer disclosures.</u> <u>A. Prior to initiating a transfer, an approved pediatric transfer facility shall discuss with the PSAS and the PSAS's legal representative the reasons for the transfer.</u> <u>B. An approved pediatric transfer facility shall ensure that a PSAS and the PSAS's legal representative are advised of the impact of accepting or declining a transfer to assist the PSAS in making an informed decision on transfer to include the effect on quality of care, the usefulness of evidence collection, and any criminal investigation or prosecution.</u> <u>C. An approved pediatric transfer facility shall provide a PSAS and the PSAS's legal representative with:</u> <u>1. Written and oral information about:</u> <u>a. Emergency contraception;</u> <u>b. The indications, contraindications, and potential risks associated with the use of emergency contraception; and</u> <u>c. The availability of emergency contraception; and</u> <u>2. A copy of the PSAS's medical record from the encounter, as appropriate.</u> Statutory Authority <u>§§ 32.1-12, 32.1-162.15:5, and 32.1-162.15:6 of the Code of Virginia.</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to ensure to ensure patients and their legal representatives receive information about the transfer and emergency contraception. RATIONALE: The rationale for these new requirements is that patients and legal representatives need adequate information to make decisions about receiving timely care from the receiving facility and about emergency contraception. LIKELY IMPACT: The likely impact of these new requirements is patients and their legal representatives will be informed about transfer and emergency contraception, and improved clarity for applicants and regulants.

DIBR	<u>Documents Incorporated by Reference (12VAC5-416)</u> <u>Recommendations for Providing Quality Sexually Transmitted Diseases Clinical Services, January 2020 (U.S. Centers for Disease Control and Prevention).</u> <u>Sexually Transmitted Infections Treatment Guidelines, July 2021 (U.S. Centers for Disease Control and Prevention).</u>	None	CHANGE: The Board is proposing to promulgate this section. INTENT: The intent of these new requirements is to list the documents incorporated by reference. RATIONALE: The rationale for these new requirements is that the concepts and information found in the documents incorporated by reference are too length and detailed to be replicated in regulation. LIKELY IMPACT: The likely impact of these new requirements is improved clarity for applicants and regulants.
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