1.	Agency Name & Address:	2. RSA Authority:	RSA 151:9, I(a)-(m) and (o)
		3. Federal Authority:	
	Department of Health & Human Services Bureau of Licensing & Certification Health Facilities Administration 129 Pleasant Street, Brown Bldg. Concord, NH 03301	4. Type of Action:	
		Adoption	
		Repeal	·
		Readoption	
		Readoption w/	amendment X
5	Short Title: Rules for Ambulatory Surgical	Centers	

Rule Number

He-P 812

5. Short Title: Rules for Ambulatory Surgical Centers

2024-26

Notice Number

6. (a) Summary of what the rule says and of any proposed amendments including whether the rule implements a state statute for the first time:

He-P 812 sets forth the licensing requirements for all ambulatory surgical centers (ASC) pursuant to RSA 151:2, I(d).

The Department of Health and Human Services (Department) is proposing to readopt with amendment He-P 812. Amendments to the proposed rule as compared to the existing rule include:

- Updating various provisions of the rule for better clarity, program integrity, and to be consistent with language used in other licensing rules that have been more recently adopted;
- Making no revisions to He-P 812.01 on the purpose of He-P 812;
- Making no revisions to He-P 812.02 on the scope of He-P 812;
- Updating He-P 812.03 on definitions by:
  - Adding the definition of "chemical restraint", "clinical laboratory improvement amendments (CLIA)", "controlling interest", "critical access hospital (CAH)", "direct care", "emergency", "good cause", "health care services", "independent contractor", "laboratory", "material adverse impact", "medication error", "owner", "rehabilitation", "reportable incident", "retention", "service", "service area", "state building code", "state fire code", and "state monitoring";
  - Amending the definition of "abuse" by amending its subcategories of "emotional abuse" and "sexual abuse", "administrator", "advance directive", "area of non-compliance", "assessment", "care plan or treatment plan", "commissioner", "demonstrated competency", "enforcement action", "governing body", "informed consent", "license", "life safety code", "medical staff", "performance-based design", "personal representative", "point of care devices", and "qualified personnel"; and
  - Deleting the definition of "license certificate"; and
- Adding new section He-P 812.04 on notice to critical access hospitals to align with RSA 151:4-a, II, pursuant to 2020, 39:64, effective 7-1-20. This statute is being implemented in He-P 812 for the first time:

- Updating He-P 812.05, formerly He-P 812.04, on initial license application requirements by incorporating by reference the February 2023 edition of the Department Form "Application for Residential, Health Care License or Special Health Care Services" and adding and updating additional requirements for submission with the application;
- Updating He-P 812.06, formerly He-P 812.05, on processing of applications and issuance of licenses by making minor reference revisions and editorial revisions;
- Updating He-P 812.07, formerly He-P 812.06, on license expirations and procedures for renewals by aligning the license expiration with RSA 151:5, updating the requirements of what shall be provided with the renewal application to reflect revisions to RSA 153:5 and Saf-C 6005 of the Department of Safety, and adding what a licensee shall do if they do not submit a complete renewal application prior to expiration and do not intend to cease operation;
- Updating He-P 812.08, formerly He-P 812.07, on ASC construction, modifications, or renovations by adding and amending various requirements for clarity;
- Updating He-P 812.09, formerly He-P 812.08, on ASC requirements for organizational changes by amending the requirements on when the licensee shall apply for a new or revised license from the Department and what documentation that the licensee shall provide to the Department when there is a change in administrator or medical director;
- Updating He-P 812.10, formerly He-P 812.09, on inspections by making clarifying revisions;
- Updating He-P 812.11, formerly He-P 812.10, on waivers by adding that a waiver request shall include the period of time for which the waiver is sought and making other minor editorial revisions;
- Updating He-P 812.12, formerly He-P 812.11, on complaints by adding a warning process for unlicensed facilities and making other minor revisions for clarity;
- Updating He-P 812.13, formerly He-P 812.12, on administrative remedies by clarifying the requirements surrounding plans of correction and updating on when the Department shall impose state monitoring;
- Updating He-P 812.14, formerly He-P 812.13, on enforcement actions and hearings by making minor yet substantive clarifying revisions, adding a fine for failure to notify the Department prior to a change in the administrator or medical director, and clarifying that RSA 541 shall govern further appeals of Department decisions;
- Updating He-P 812.15, formerly He-P 812.14, on duties and responsibilities of all licensees
  by updating and clarifying the duties and obligations of the licensee to include areas of
  policies and procedures, patient decision making, documentation, investigations, and
  reporting to the Department, by updating and clarifying the CLIA-waived laboratory
  testing requirements, and by making additional minor editorial and substantive revisions;
- Making no revisions to He-P 812.16, formerly He-P 812.15, on adverse event reporting;
- Updating He-P 812.17, formerly He-P 812.16, on organization and administration by making minor editorial revisions;

- Updating He-P 812.18, formerly He-P 812.17, on personnel by updating the criminal background check requirements, updating the timeframe on when the personnel shall complete their orientation, and making other minor editorial revisions;
- Updating He-P 812.19, formerly He-P 812.18, on required services by updating the revision date from 2018 to 2022 of the "Guidelines for Design and Construction of Outpatient Facilities" incorporated by reference and making other minor editorial revisions;
- Making no revisions to He-P 812.20, formerly He-P 812.19, on patient records;
- Making no revisions to He-P 812.21, formerly He-P 812.20, on infection control;
- Updating He-P 812.22, formerly He-P 812.21, on quality assessment and performance improvement by making minor citation revisions;
- Updating He-P 812.23, formerly He-P 812.22, on sanitation by updating the revision date from 2018 to 2022 of the "Guidelines for Design and Construction of Outpatient Facilities" incorporated by reference;
- Making no revisions to He-P 812.24, formerly He-P 812.23, on pharmacy and medications;
- Updating He-P 812.25, formerly He-P 812.24, on physical environment by making minor revisions, both substantive and editorial, for rule clarity and updating the revision date from 2018 to 2022 of the "Guidelines for Design and Construction of Outpatient Facilities" incorporated by reference;
- Updating He-P 812.26, formerly He-P 812.25, on life safety and fire safety procedures making minor clarifying revisions; and
- Updating He-P 812.27, formerly He-P 812.26, on emergency preparedness making minor clarifying revisions.
- 6. (b) Brief description of the groups affected:

Groups affected by this rule include operators of ASC's, clients who receive ASC services, and their families.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

Rule	Specific State or Federal Statutes the Rule Implements
He-P 812.01 – He-P 812.03	RSA 151:9, I(a) and (b)
He-P 812.04	RSA 151:4-a, II
He-P 812.05 – He-P 812.08	RSA 151:2, I and II and RSA 151:9,I
He-P 812.09	RSA 151:9, I(a)
He-P 812.10	RSA 151:9, I(e) and RSA 151:6-a
He-P 812.11	RSA 151:9, I(a) and (b)
He-P 812.12	RSA 151:9, I(e) and RSA 151:6
He-P 812.13	RSA 151:9, I(f), (g), (l), and (m)
He-P 812.14	RSA 151:9, I(f), (h), and (l)
He-P 812.15 – He-P 812.27	RSA 151:9, I(a)

	Name:	Allyson Ra	admae	Title:	Administrator- Administrative Rules Unit				
	Address:	Dept. of Health and Human Services Administrative Rules Unit 129 Pleasant Street, 2 <sup>nd</sup> Floor	Phone #:	(603) 271-9604					
			Fax#:	(603) 271-5590					
		Concord, NH 03301		E-mail:	Allyson.E.Raadmae@dhhs.nh.gov				
				TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)					
The proposed rules may be viewed and downloaded at: <a href="https://www.dhhs.nh.gov/doing-business-dhhs/legal-services/administrative-rules/nh-administrative-rules-public-comment">https://www.dhhs.nh.gov/doing-business-dhhs/legal-services/administrative-rules/nh-administrative-rules-public-comment</a>									
8.									
	⊠ Fax		⊠ E-mail		Other format (specify):				
9.	Public hearing scheduled for:								
	Date and Time: Tuesday, April 2, 2024 at 1:00 pm  Physical Location: DHHS Brown Bldg., Auditorium, 129 Pleasant St., Concord, NH								
	Electron	ic Access (if	applicable): N/A						
10.	10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant):								
	FIS#	2	24:010 , dated _	Februa	ry 14, 2024				
	1. Comparison of the costs of the proposed rule(s) to the existing rule(s):  When compared to the existing rules, the proposed rules may increase costs to independently owned businesses by an indeterminable amount.								
	2. Cite the Federal mandate. Identify the impact on state funds:  No federal mandate, no impact on state funds.								
	3. Cost and benefits of the proposed rule(s):  The Department of Health and Human Services states that He-P 812.04 is a direct result of RSA 151:4-a, II, which establishes notice requirements for licensure near critical access hospitals. Accordingly, any costs or benefits are attributable to statute and rather than to the rule.								
	A. To State general or State special funds: None.								
	B. To State citizens and political subdivisions: None.								

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

## C. To independently owned businesses:

The Department of Health and Human Services has identified the following potential costs to facilities licensed under the proposed rule: This list does not include costs ultimately attributable to RSA 151:4-a, II, as noted in response to (3) above.

- (1) If a licensee opts to perform CLIA-waived laboratory testing, there may be an indeterminable cost as a result of complying with additional requirements including infection prevention, protocols, and training.
- (2) Facilities may incur administrative costs as a result of daily operation, recordkeeping, and reporting requirements.
- (3) Any issuance of a fine to a facility would be a cost to that facility. The Department notes that fines are a rare occurrence and can be avoided through compliance with this rule and applicable law.
- (4) Any training requirements that must be met may have a cost to the facility.

## 11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rule modifies an existing program or responsibility, but does not mandate any fees, duties, or expenditures on the political subdivisions of the state, and therefore does not violate Part I, Article 28-a of the N.H. Constitution.