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Agency of Human Services

February 22, 2018

Senate Health & Welfare Committee
Vermont General Assembly
115 State Street
Montpelier, VT 05633-5301

Re: Written Testimony on S.278, Ambulatory Surgical Centers

To the Committee:

My comments are provided in my role as the Director of Hospital Licensing for the State of Vermont. S.278 proposes to make the Department of Health the licensing authority for Ambulatory Surgical Centers (ASCs).

Should ASCs Be Regulated?

A survey of states shows that 48 states have created requirements for licensing and regulation of ASCs, with Vermont and Wisconsin the two exceptions. I believe the reason why so many states regulate facilities in which surgeries are performed is that the condition and management of the facility can have a profound effect on the health and welfare of the patients who undergo procedures. The near universal establishment of regulation of this category of facilities is to promote public safety. The individual practitioners who perform surgical procedures have an existing requirement to be licensed, but the licensing of health care professionals who conduct procedures does not give rise to inspection of the facilities where they work. The licensing of the providers performing procedures has only an indirect and retrospective impact on a facility, in that there might be an action for unprofessional conduct based on having done a procedure in a substandard facility. It is unrealistic to expect physicians to inspect the facilities they use in the way that a licensing authority would. Even if providers had an obligation to inspect the facilities in which they perform procedures, there are no standards established in Vermont by law or rule for such inspections. It is appropriate for the State of Vermont to promote public safety through the licensing of ASCs, and thus I support the idea of this bill in general. Now I will turn to providing you some more background on this subject that may be helpful for your consideration of the concept and offer more specific observations about the proposed wording.

A first question that might arise is whether Vermont ASCs are subject to any regulation or oversight at all? ASCs may be subject to CMS oversight if they choose to participate in CMS payment programs. And, CMS participation subjects a facility to the requirement to be accredited by a CMS-approved accrediting body (such as the Joint Commission). The only ASC now operating in Vermont does participate in CMS, and thus has federal oversight, but that is a result of decisions made by the ASC's operators. The center offers Lasik eye procedures, as well as cataract surgery. If they limited themselves to elective procedures like Lasik surgery, or opted to accept only private payment, the center would not be regulated in anyway. I've not done research on this point, but I've seen many reports of problems in other states with patient safety in ASCs that perform elective surgeries that are typically paid out-of-pocket by patients. Creation of a licensing requirement will help to avoid harm to the public that might occur if an unregulated ASC was opened in Vermont. Some would argue that the wisdom of state oversight is suggested by the number of states that license ASCs. It is doubtful that 48 states would create and maintain licensure for ASCs if there was little or no benefit. Now I will turn to the question of whether the need for a system of state licensure is affected by the reality that many facilities are subject to federal regulation by virtue of their decision to participate in CMS.

Is There a Role for State Regulation in Addition to CMS Oversight?

Even for those facilities that participate in CMS reimbursement programs, there is justification for having state oversight. In recent years the role of state licensure has become more important. Here, I'm going to shift to information about hospital oversight, but I believe the information applies equally to this discussion of ASCs. Surveys and complaint investigations under CMS authority for Vermont hospitals that participate in CMS are performed by DAIL staff from the Division of Licensing & Protection (L&P). That is consistent with CMS practice nationwide. DAIL is what is referred to as "the designated state agency." The L&P staff who perform that work on behalf of CMS also work with me on the state hospital licensing program, performing surveys and state-based complaint investigations, under an MOU between VDH and DAIL. At some point after the automatic cuts to federal spending that began in March 2013 (known as "sequestration") resulted in reduced federal program support, CMS became more selective in approving investigation of complaints submitted on hospitals. Until approximately 2014, CMS had effectively approved every complaint for investigation and it was rare for there to be a complaint investigation under state authority. Over the past few years, a good number of cases have been rejected by CMS as investigations to be conducted under federal authority, and it is now common for CMS to withhold authority to investigate. When CMS rejects a complaint for investigation, I work with L&P staff to determine if there are any credible allegations that could be an issue under state requirements and authorize a state investigation if appropriate. Presumably, the practice has been similar with complaints about ASCs. If ASC complaints are being rejected for investigation by CMS based upon resource constraints, that would mean some Vermonters who have a complaint about an ASC would not have any means of having their concerns examined by a government authority, and failure to examine patient complaints could prevent or delay the discovery of conditions that might lead to negative outcomes for patients. The number of ASCs is swelling across the country and it is likely that this will continue to grow as an issue for Vermont. The bottom line is that licensure of ASCs would provide for enhanced public safety now and, especially, in the future as the number of ASCs increases.

Does the Bill Present an Appropriate Framework for Licensure of ASCs?

Yes, however the bill is not perfect. In some respects, it seems to go too far. One might get the impression that the purpose is not to regulate operation of ASCs, but to deter them from entering the marketplace. That is because the bill includes many requirements for licensure not put on Vermont hospitals as license requirements and that do not reflect matters typically viewed as within the scope of public protection associated with facility licensure. It is my understanding that those unexpected provisions reflect conditions mentioned in the certificate of need issued by the Green Mountain Care Board. My recommendation is to modify the bill to more closely resemble the obligations of licensure imposed on Vermont hospitals. By including the conditions from the CoN in the statute, the bill would impose those same conditions on any ASC that might arise, limiting the discretion of the GMCB to determine appropriate conditions based upon the information in the application before it.

On page 3, line 16, it mandates that facilities participate in CMS. Mandating participation in a federal program is going too far. No such provision is found in the hospital licensing statute. 26 V.S.A. § 1905. Participation in CMS forces facilities to be accredited by the Joint Commission, or other CMS-approved accrediting bodies. That process is quite costly, and unnecessary because the state is capable of conducting adequate surveys to determine if facilities meet standards to operate safely. For those facilities that do not want to operate as CMS providers, gaining CMS status is a costly and time-consuming process that is not necessary to promote public safety. Such a requirement could effectively hamper access to care for patients seeking elective procedures.

Additionally, on page 5, line 19, a provision mandates that each physician operating at the ASC certify that he or she will accept patients without regard to payer type, insurance status, or ability to pay for services. Similarly, at page 6, line 3 it mandates each ASC have a policy for charity care. There are no comparable provisions in the requirements for hospital licensing; such requirements are outside the scope of licensing regulation, which is focused on patient safety, not financial matters.

On page 6, line 12, it mandates maintenance of accounting records for 20 years; records retention costs money and should not be mandated in the absence of justification. 20 years is much longer than the longest civil statute of limitations (6 years) and, as business records, not medical records, would in no way enhance patient care.

On page 7, line 3, the bill proposes making ASCs subject to the Bill of Rights for Hospitalized Patients (18 V.S.A. § 1852). That is something of a non-sequitur, as by its terms the Bill of Rights for Hospitalized Patients applies to inpatients only, defining "patient" as a person admitted on an inpatient basis. 18 V.S.A. § 1851(2). Unless the law was changed to make it apply to all patients (including hospital patients who are not admitted as inpatients), it would be illogical and an unjustified disparity in treatment of facilities. Additionally, it would be open to debate whether all the rights listed in 18 V.S.A. § 1852 should be extended to those who are not inpatients.

At page 10, line 3, there is a requirement for disclosure of pricing for procedures. Again, there is no comparable requirement as a condition of licensure for hospitals, and financial practices are not the focus of licensing regulation.

Finally, some of the financial burdens seem disproportionate given the number of ASCs and their scale, as compared to hospitals and health insurers, but that is a discussion for the Committee, GMCB, and other stakeholders. The fee proposed for the license seems reasonable. Compared to the hospital fee, the fee is appropriate and sufficient to cover the limited amount of work added with the program. Being a small fraction of the hospital fee, I would say it's not excessive. The goal with setting licensing fees is to cover the cost of regulation. The amount set in the bill, $2,000, is a good estimate what those costs will be to run a program for the two facilities that would be initially licensed, including costs that might be incurred to investigate complaints.

Fiscal Implications for State Agencies

VDH will need to create rules and provide a staff member to act as the Director. It should be possible to do this with existing staff. Generally, time spent on a new fee-based program would be allocated to the program and shifted from existing programs. The program should be self-sustaining on the same model as the existing hospital licensing program; start-up demands may present an initial resource challenge, but in the long run fiscal implications should be minimal and only proportionate to growth in the number of facilities in this category. As with hospital licensing, a substantial portion of licensing fees would be used to fund an MOU with DAIL to obtain staff services by nurse surveyors from the Division of Licensing & Protection.

Conclusion

Thank you for this opportunity to provide input on S.278. I hope you find this input helpful to your discussion of the proposal to regulate ASCs. Please don't hesitate to ask if you have any questions about this bill.

Sincerely yours,

David K. Herlihy
Director of Hospital Licensing