



August 29, 2018

James Jarvis
Regulations and Special Projects Lead
Radiation Program
Department of Public Health and Environment

Dear Mr. Jarvis:

On behalf of its 100 hospital and health system members statewide, Colorado Hospital Association (CHA) thanks the Colorado Department of Public Health and Environment (the Department) for the opportunity to provide feedback on draft proposed changes to Part 2 (Registration of Radiation Machines, Facilities and Services) and Part 6 (X-Ray Imaging in the Healing Arts).

Over the past two months, the Association solicited input from member hospitals and health systems to better understand the operational and financial impact of the proposed changes on health care facilities across Colorado. While CHA supports the overall intent of Part 2 and Part 6, the Association is concerned about the resources needed to operationalize some of the key proposed provisions. CHA recognizes the Department's statutory constraints, which require Colorado radiation regulations to be consistent with the Conference of Radiation Control Program Directors model regulations unless the burden on the community outweighs the intended benefits. The proposed changes, however, create an unreasonable burden for hospitals and health systems – especially for Colorado's 30 critical access hospitals (CAHs) and 12 rural hospitals. The implementation of many of the requirements would be administratively complex, cost prohibitive and ultimately threaten access to timely imaging services in rural and frontier areas of the state.

Section 6.9.1.3: Diagnostic Computed Tomography (CT) System Accreditation Requirement

CHA strongly opposes the proposed provision requiring facilities using CT machines to be accredited by an organization recognized by Medicare or the Department. CHA requests that the Department remove Section 6.9.1.3 entirely for the following reasons:

1. CT Accreditation Standards are Unattainable for Many Rural Facilities

Meeting the national clinical exam accreditation requirements is not feasible for many rural hospitals and CAHs. First, rural facilities invest in CT machines because they provide a critical, often life-saving, health care service to their remote communities. A CT image is a powerful tool that allows a rural clinician to better evaluate whether a patient can continue to receive care locally or must be transferred to a higher level of care.

Due to overall low patient volumes in remote communities, rural facilities often have low CT image volumes compared to their urban counterparts. Further, the volume of images in many of the mountainous communities fluctuates based on the season and tourism patterns. Numerous rural cases are also trauma-related, limiting hospitals' ability to produce high quality images. As a result, many rural facilities do not have the appropriate image mix (i.e. head, sinus, cervical, spine, temporal bones, chest, abdomen, liver, etc.) nor quality (adequate positioning, resolution, labeling, etc.) to qualify for CT accreditation.

Meeting these strict clinical imaging requirements is even more onerous for rural facilities serving low pediatric populations. National accrediting organizations require submission of pediatric images even if the facility only performs occasional pediatric scans. Hospitals work diligently to limit children's exposure to radiation by attempting an ultrasound first and performing a CT scan as a last resort, resulting in very limited pediatric images. As an illustration, one CAH shared with the Association that out of the couple hundred CT images taken in one

calendar year, less than ten were pediatric images – almost all of which corresponded with the start of football season in the local community. Another member shared that their facility previously sought accreditation but had to forgo their efforts due to their inability to meet the pediatric imaging requirements.

In addition to low image mix and volume, many rural facilities cannot meet the national technologist accreditation requirement, which mandates *all* technologists be certified by the American Registry of Radiologic Technologists (ARRT) in CT. Typically, it takes up to two years of training to prepare for the ARRT CT exam. As a recruitment strategy, many rural facilities hire general x-ray certified technologists and will help these technologists obtain their CT certificate through on the job training. Rural facilities frequently experience staffing, recruiting and retention challenges, and this national accreditation requirement would eliminate this successful recruitment tool used in rural areas. Effectively, it would limit the type of technologists hired by hospitals and likely cause staffing shortages in rural Colorado.

2. CT Accreditation is Cost Prohibitive

The cost of accreditation is also a major concern for many rural hospitals, which regularly have lean operating margins. CT systems in rural Colorado are often not revenue generating – due to the low volume of images – and the cost of accreditation could not easily be absorbed by these facilities. As a result, rural facilities would likely need to budget the associated accreditation costs as a fee passed onto the consumer, again increasing overall health care costs in the community. CHA estimates that for the more than 42 rural facilities alone (assuming accreditation costs between \$3,000 - \$6,000 per facility every three years), it would collectively increase rural hospitals costs approximately \$378,000 - \$756,000 in a ten-year period. This rough estimate assumes the national accrediting organizations do not increase their fees in that same time-period. CHA will be requesting a formal cost-benefit analysis from the Department, with a focus on the impact of the regulation on providers.

In summary, if the state of Colorado mandates accreditation of all CT machines, and rural hospitals subsequently cannot meet the national standards or afford the accreditation costs, facilities would likely eliminate this vital service in their community. In turn, this proposed regulation would unintentionally create significant barriers to radiology care in rural communities. CHA and its member hospitals and health systems have worked diligently to ensure that *where* someone lives never determine *if* they live. The Association urges the Department to not impose unreasonable and burdensome regulations that would roll back the gains Colorado has made in safeguarding access to care across the state.

3. There is Insufficient Evidence to Justify the Need for CT Accreditation

The Centers for Medicare and Medicaid Services (CMS) accreditation requirement for advanced diagnostic imaging suppliers does not currently apply to hospitals, as highlighted below:

“Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275) amended section 1834(e) of the Social Security Act (the Act). This amendment requires suppliers of the technical component of advanced diagnostic imaging (ADI) services to be accredited by a designated accrediting organization in order to receive Medicare reimbursement. This accreditation requirement for ADI suppliers was effective January 1, 2012. CMS has the statutory authority to designate accrediting organizations which accredit suppliers furnishing the technical component of ADI services. **These requirements do not apply to hospitals or critical access hospitals.**”¹

CHA has seen insufficient evidence to justify why Colorado regulations should go beyond what CMS currently requires in MIPPA. At this time, it remains unclear what specific quality concerns, especially as they relate to over exposure to radiation, the Department is attempting to solve with the proposed CT accreditation requirement. Consequently, **CHA strongly urges the Department to remove section 6.9.1.3 entirely from the proposed regulations and allow hospitals and health systems to continue offering excellent services to their community without further regulatory burden.**

¹ CMS Accreditation of Advanced Diagnostic Imaging Suppliers :<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Accreditation-of-Advanced-Diagnostic-Imaging-Suppliers.html>

Section 6.9.3.3: CT Radiation Protocol Committee Requirement

Our members are generally supportive of the proposed CT Radiation Protocol Committee (RPC), as they see value in the committee's intended purpose of overseeing quality standards. The RPC requirements, however, must ensure sufficient flexibility for those facilities with limited resources and staff.

As drafted, the RPC requirements appear to be aimed at hospitals with larger staff pools and who do not have financial constraints. Most rural hospitals do not have the appropriate staff (i.e. Lead CT radiologist, Lead CT technologist, CT medical physicist, Radiation Safety Officer) to form the RPC. For example, requiring a radiologist to participate as a member is *not* feasible for a rural facility that only has a radiologist visit the facility twice a month. If the radiologist were to be required to participate in the RPC, it would ultimately interfere with patient care.

Further, physicists often only visit rural facilities once per year to recertify and survey the equipment. Many rural facilities currently struggle to afford a physicist's hourly rate for the equipment inspection and must split the cost of time and travel with a neighboring rural hospital. Requiring rural facilities to include both a radiologist and physicist is an onerous and cost prohibitive mandate, especially when RPC members must "meet as often as necessary to conduct business". As such, **CHA strongly urges the Department to ensure sufficient flexibility to allow hospitals to develop RPC membership based on a facility's unique staffing and financial limitations.**

Section 6.5.1.5: Fluoroscopically-guided Interventional (FGI) Case Review Committee

Our members shared similar concerns with the proposed provision requiring facilities performing FGI procedures to form a Case Review Committee (CRC) consisting of a supervising physician, medical physicist and lead technologist. Some rural hospitals offer pain management injections under FGI guidance. This service generates very little revenue, but it is a service that is needed for those community members who cannot travel the distance to metro areas to receive care. One rural member shared that their facility would not be able to continue performing this procedure with the new CRC requirement, because the cost of paying for the new committee would significantly outweigh reimbursement. Again, **CHA urges the Department to consider the financial constraints many facilities will face when struggling to comply with onerous regulations.**

Section 6.3.3.5: Credential Requirement Changes

The Association is hopeful that permitting physician assistants and nurse practitioners to supervise or use x-ray machines will help in building a stronger health care workforce in Colorado. As such, **CHA supports expanding the scope of persons able to supervise and authorize an x-ray exam, provided that such activity is within the acceptable scope of practice and authorized by the regulations and requirements of the licensing body.**

In summary, Colorado hospitals and health systems remain dedicated to providing quality imaging care to their patients. CHA commends the Department's undertaking of this significant regulatory overhaul of Colorado's radiation regulations. The Association, however, urges the Department to fully evaluate the potential adverse outcomes of the proposed changes before moving forward. CHA is optimistic that future iterations of the proposed rule will not create an unreasonable burden for hospitals and health systems. Thank you for your consideration of our comments and your continued partnership.

Sincerely,



Amber Burkhart
Policy Analyst, Colorado Hospital Association