



Setting the Standard for Building Safety™

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May 5, 2005

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Subject: Comments Proposed Rule RIN 0938-AG82
(70 Fed Reg 6184 et. sec., February 4, 2005)

To whom it may concern:

The International Code Council® (ICC®) submits the following comments regarding the proposed rule issued by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (HHS CMS) (70 Fed Reg 6184) to revise the requirements that end stage renal disease (ESRD) dialysis facilities must meet to be certified under the Medicare Program.

The ICC is a 35,000 + member association dedicated to building safety whose mission is to provide the highest quality codes, standards, products, and services for all concerned with the safety and performance of the built environment. This mission and the activities of the ICC directly relate to Sections 1881 (b)(1) and 1881 (f)(7) of the Social Security Act, as amended by P.L. 95-292, wherein the Secretary of HHS is to prescribe safety requirements for ESRD facilities. The current conditions for coverage of ESRD facilities are to protect patient health and safety. The ICC believes the proposed rule can be modified to further enhance patient health and safety with respect to the building facilities provided to house ESRD services through a reference to the ICC Codes.

The codes developed under the auspices of the ICC serve as a baseline for the design, construction, operation and maintenance of the majority of both public and private sector buildings in the U.S. As such the ICC Codes are readily recognized and understood by building owners, product manufacturers, designers, contractors, code officials and all others involved in building design, construction, approval, and operation. The majority of U.S. state and local government agencies that adopt codes adopt and implement building safety and fire prevention codes developed by the ICC. In addition most federal agencies have building construction policies that require the use of the ICC Codes or those policies refer to the state or local code proximate to the federal facility. This helps fulfill the direction of the National Technology Transfer and Advancement Act (P.L. 104-113), a key point referenced in the supplementary

information pertaining to the proposed rule, requiring federal agencies to participate in the development of and to adopt codes and standards developed in the private sector. In brief, the ICC Codes are the basis for the vast majority of U.S. construction regulations. In using those codes as a basis for its rules HHS CMS would further consistency and uniformity, while reinforcing patient health and safety.

Of particular importance and relevance is the establishment of the ICC by the three U.S. model building code organizations (Building Officials and Code Administrators International, International Conference of Building Officials, and Southern Building Code Congress) in 1994. Prior to that date model codes were developed separately by each of these organizations and state and local government adopted one of the three model codes, and standards referenced therein, on a regional basis. In an effort to unify the U.S. the ICC set out to develop one family of model codes to take the place of these three different sets of model codes. In 2000 the first complete family of the ICC International Codes was published and in 2003 the three model code organizations consolidated their operations as the ICC. This has resulted in one coordinated family of model codes and one supporting organization for those codes - the national uniformity that industry, building owners, regulators and others have demanded. The unification also addressed a concern of federal agencies about the lack of a singular national model code that forced agencies to either choose one of the three model codes over the others or run the risk of applying conflicting codes and standards throughout agency facilities. Federal, state and local governments adopting building regulations have adopted the I-Codes as they undertook to update their regulations that had historically adopted one of the three regional model codes. This has resulted in significant progress toward uniformity in building regulations throughout the U.S.

It is important to point out that this consolidation and focus of the U.S. model code system occurred recently and after current HHS CMS criteria became effective and guiding Federal legislation was signed into law.

General

To fully understand and address ICC's comments it is important to have an understanding of the current situation regarding federal, state and local building regulations. With the publication of the ICC International Codes, federal, state and local government have a singular consolidated solution to addressing building safety and performance issues. With few exceptions federal, state and local government have adopted and are using these codes. Federal agencies are doing so in response to the National Technology Transfer and Advancement Act and the need to update their building-related policies and requirements. State and local agencies are doing so in response to the scheduled updating of their building-related regulations.

As the HHS CMS rules apply to private sector construction that is subject to state and local building and fire safety regulations based on the ICC Codes, the imposition of the proposed rules to ESRD facilities will create an avoidable dilemma. The dilemma created is satisfaction of HHS CMS rules that may conflict with state and local codes and which the property must also satisfy. In the interest of consistency and uniformity between the federal and private sectors the ICC recommends that HHS CMS specifically reference the ICC Codes in the regulations. These codes provide equal or better protection to those cited in the proposed rule. This creates a basis

for uniformity in federal, state and local building regulations as opposed to establishing a situation where HHS CMS rules create a conflict with other rules the private sector must also satisfy. It also ensures that ESRD facilities constructed or operated in areas without codes or with codes not updated to the ICC Codes would meet some minimum provisions as currently established in the proposed rule.

For the reasons stated above, the ICC comments focus on the basic premise that HHS CMS should adopt by reference a coordinated set of codes as a foundation for rules on ESRD facility design, construction, renovation, and operation. The ICC Codes are that coordinated set of provisions. They have been widely adopted throughout the U.S. and apply to other federal facilities such as those of the General Services Administration, Department of State and Department of Defense, as well as state and local facilities and private sector facilities throughout the U.S. The ICC Codes are the baseline codes and include by reference a large number and wide range of standards developed by many organizations, including many from NFPA, ASME, etc. To impose codes and standards for ESRD facilities that are not based on the same foundation as other federal, state and local requirements fosters non-uniformity and will likely increase the costs of construction and facility operation. It can also foster a decrease in worker and patient safety wherein what is "standard" elsewhere is not applied in ESRD facilities. For example, private sector interests subject to state and local codes but wishing to participate in HHS CMS programs will likely pass along the expense in time and construction cost associated with multiple and conflicting rules in the costs of providing health care, if they can even comply with multiple sets of conflicting regulations.

With this overarching concept of building upon an existing foundation of consistent federal, state and local rules the following specific comments are offered for HHS CMS consideration.

Specific Comments

The following specific comments are offered in response to questions raised in the proposed rule.

- The last paragraph under “D, Establishment of Central Requirements” on page 6187 requests public comment on improving the fundamental shift toward performance based regulations while not adversely affecting patient health and safety. With respect to building design, construction, renovation and operation the ICC Codes, and all federal, state and local codes based on the ICC Codes, have a path to compliance that is based on performance. As long as what is proposed is no more hazardous nor less safe than something specifically provided by the code then the alternative can be approved on the basis of performance equivalency. We would encourage HHS CMS to embrace the acceptance of building designs and construction on the basis of equivalent performance to any minimum prescribed criteria.
- The first paragraph under “7, Updating Existing ESRD Standards” on page 6190 refers to the NTTAA and OMB Circular A-119 as the basis for federal agencies using private sector technical standards. The ICC Codes satisfy such directives and support performance-based design while design-specific technical specifications. On this basis federal agencies have adopted and/or rely on the ICC Codes and a reference to the ICC

Codes by HHS CMS for ESRD facilities would reinforce federal uniformity.

- With respect to “compliance with federal, state and local laws and regulations” on page 6191 the ICC notes that a requirement that ESRD facilities be in compliance with federal, state and local laws and regulations pertaining to fire safety, equipment and other relevant health and safety issues (42 CFR 494.20 proposed) and a requirement to satisfy the Life Safety Code is generally duplicative, highly impractical and creates a significant problem for state and local government and ESRD facility owners and operators. As private sector operations, ESRD facilities must comply with state and/or local building and fire safety regulations as a condition for initial construction and continued occupancy. To impose a duplicative and unnecessarily conflicting set of HHS CMS requirements on such facilities for their initial design and construction as well as their operation essentially leaves two outcomes: operation in violation of state and/or local law; or failure to qualify for HHS CMS programs. To eliminate this conflict the ICC recommends that the rule be revised to provide an option for facility design, construction and operation in accordance with state or local building and fire safety codes that are no less stringent than the latest edition of the ICC Codes.
- With respect to “physical environment” on page 6197 the ICC notes that in adopting the ICC Codes a number of the issues raised would be addressed. The issue of comfort is addressed in the International Building and Mechanical Codes and the International Energy Conservation Code addresses lighting design. Note also the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) have a standard to address human comfort (ASHRAE 55) and the Illuminating Engineering Society of North America (IES NA) has standards addressing illumination levels and lighting quality. In relying on state or local codes as suggested above and adopting ASHRAE and IES standards as a minimum alternative in the absence of state or local codes based on the ICC Codes, HHS CMS need not be silent on these aspects related to patient comfort. As stated in proposed 42 CFR 494.60, the ICC Codes provide a basis for satisfaction of the performance statements therein related to the building and patient care environment. To establish such performance oriented objectives and then later in the rule mandate one approach (the Life Safety Code) appears to be at odds with the intent of the proposed rules. ICC also notes that the ICC Codes provide clear detail on addressing natural disasters that would address the issue of emergency preparedness.
- With respect to “physical environment” on page 6199 the ICC recommends also adopt the ICC Codes and allow its use in lieu of the Life Safety Code. As stated above this ensures some consistency and uniformity with state and local codes applicable to such facilities, allows for performance-based alternatives, ensures patient safety and health, is fully consistent with NTTA and OMB directives to federal agencies, and fully meets the intent of the rule to provide for patient health and safety. The ICC realizes that a state can currently request of HHS CMS that the state code be allowed to be applied to ESRD facilities in lieu of the Life Safety Code. Unfortunately HHS CMS does not have any guidelines in place for such a request and the one request they have received from a state has been burdened by the lack of such guidelines. The direct reference to the ICC Codes in the rule would eliminate considerable time, manpower and federal resources in

developing and considering what could easily be 20 or more individual state requests all based on the same ICC Codes. Also of relevance to this issue is the significant role the CEO or administrator will play in the overall success of the facility in providing patient care, safety and health. Given all the operational issues of importance to HHS CMS, it appears to ICC that burdening the CEO or administrator with the task of satisfying state and local codes concurrently with differing HHS CMS building standards will detract from as opposed to reinforce patient health and safety. Recognition of the ICC Codes and permitting of the facility as per state or local regulations would allow the facility CEO or administrator to focus his/her attention on items related to patient care, health and safety that may not already be covered by state or local law. Another statement supporting a reference to the ICC Codes is found on page 6240 of the Federal Register notice. In indicating that the proposed rule requires the facility meet the 2000 Life Safety Code HHS CMS indicates that most dialysis facilities meet this document “because of state and local building codes”. Those building codes do not reference nor adopt the Life Safety Code but instead adopt the ICC Codes and in the past the model codes that preceded the ICC Codes. This recognition by HHS CMS that state and local codes sufficiently provide a firm foundation for patient health and safety with respect to facility construction and operation would seem to support ICC’s recommendation to reference the ICC Codes in the rule.

- With respect to “special purpose renal dialysis facilities” on page 6219 the ICC notes that such facilities are approved on a short term (currently 8 month basis). The application of state and local codes would have applied to buildings intended to house such facilities when initially constructed and as a condition for a change of use. This is another example where the ICC Codes should be specifically recognized in the rule. Consider the situation where a facility is converted for a short term basis to serve renal dialysis patients and after securing state and local building code approval must then attempt to comply with the Life Safety Code. This would seem counterproductive to serving the short term need and might not likely be accomplished in the 8 month window associated with a short term use.
- In discussing the alternatives considered under item 1 on page 6243 HHS CMS notes that the current regulations inhibit the ability for the agency to ensure better patient care outcomes and that the proposed regulations address that issue by eliminating numerous processes and procedural requirements. As noted above, the lack of clear direction with respect to how a state should prepare a request for and document the acceptability of a state code is in fact a process and procedural requirement that in reality may hinder patient safety and health. A clear indication by HHS CMS in the rule that state and local codes based on the ICC Codes are acceptable in lieu of the referenced Life Safety Code would in actuality eliminate processes and procedural requirements that exist today and would continue to exist under the proposed rule.

Closing Comments

The ICC believes that the best way to address patient safety in ESRD facilities is to adopt the same requirements for protection of public health and safety already widely adopted, applied and enforced by federal, state and local government agencies. This ensures that all those involved with the design, construction, renovation and use of such facilities are able to technically and administratively work from the same baseline, especially considering the ESRD facility owner must already comply with state and/or local building and fire safety codes. Consistency between the baseline HHS CMS requirements and such state and local codes will benefit everyone involved in ESRD facility design, construction, operation and maintenance.

The ICC appreciates the opportunity to provide comments and hopes HHS CMS will consider the opportunity it has to further solidify the uniformity and consistency of U.S. building regulation. Should additional information be needed please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink that reads "Sara C. Yerkes". The signature is written in a cursive, flowing style.

Sara C. Yerkes
Senior Vice President of Government Relations