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January 23, 2006

Mark B. McClellan  
Administrator, Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Mark.mcclellan@cms.hhs.gov

Re: Part D and nursing home residents

Dear Dr. McClellan:

Your recent correspondence with the American Health Care Association and the American Association of Homes and Services for the Aging advises the two national nursing home trade associations of CMS' expectation that Part D plans will pay for all covered charges during the transition to Part D and that, as a result, CMS does "not expect nursing homes to be responsible for these payments." Your January 11 letter does not advise the nursing home industry about what its members must do if CMS' expectations are *not* met and if residents' prescription drug costs are *not* all paid for by Part D plans. It also does not describe facilities' obligations *after* the transition period.

A CMS training video for surveyors, "Medicare Part D Impact on Nursing Home Surveys" (Nov. 4, 2005), filled in these blanks. It confirmed that the 1987 Nursing Home Reform Law and the federal nursing home survey process have not been changed by Part D. All the requirements of the Reform Law and regulations, in particular 42 C.F.R. §483.25(l) (unnecessary drugs), 42 C.F.R. §483.25(m) (medication error), and 42 C.F.R. §483.60 (pharmacy services), as well as survey guidelines for these Requirements of Participation, continue. Surveyors were advised that, as before, facilities must ensure distribution of the right medication to the right resident at the right dose, at the right time, and in the right route. They must assure that residents not receive duplicative medications or inappropriate doses. If a resident does not get medically necessary medications, the facility may be cited with a deficiency in quality of care, pharmacy, professional standards of care, or other Requirements of Participation.

The Nursing Home Reform Law requires that facilities provide residents with all services they need, including drugs, whether or not there is a source of payment for those services. The preamble to the final Requirements of Participation for facilities confirms that requirement in the following question and answer:

*Comment:* We received numerous comments requesting clarification of the facility's responsibility to pay for the items and services discussed in §483.25(b), particularly with regard to Medicaid facilities and services that are not covered under a State's Medicaid program.

*Response:* . . . If a service appears in the applicable portion of the Act [42 U.S.C. §§1395i-3(b)(4)(A)(i)-(vii), 1396r(b)(4)(A)(i)(vii)] the facility is obligated to provide it to all residents who need the service; the nonavailability of program funding for private pay residents, for example, does not relieve the facility of this obligation. The sole exception would be routine dental services in Medicaid NFs, . . . .

56 Fed. Reg. 48,826, at 48,850 (Sep. 26, 1991).

We ask that you send a letter to each Medicare or Medicaid certified nursing home, setting out the points in CMS' training video for surveyors and confirming that skilled nursing facilities and nursing facilities are obligated to assure that residents promptly receive all the prescription drugs they need, whether or not there is a source of payment for those drugs under Part D.

We ask that the letter also confirm additional responsibilities that CMS has identified for facilities under Part D, including

- informing physicians and residents' families about Part D, including their rights and responsibilities, and
- providing factual information to residents and families about their Part D options.

In addition, CMS must remind facilities that they are obligated to provide over-the-counter drugs without charge to residents.

Problems in implementation of Part D will continue and will likely intensify after the initial transition period. Once plans have provided beneficiaries with the *first-fill* during the transition period, formulary limitations and utilization management tools will become legally relevant and will add new complexities.

It is important for CMS to advise nursing facilities about their obligations under both Part D and the Nursing Home Reform Law.

Thank you.

Sincerely,

Toby S. Edelman