Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Rosewood Care Center of Rockford
(CCN: 145891),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-74

Decision No. CR2440

Date: October 4, 2011

DECISION

I sustain the determination of the Centers for Medicare and Medicaid Services (CMS) to impose remedies against Petitioner, Rosewood Center of Rockford, consisting of:

- civil money penalties of $3,050 per day for each day of a period beginning on August 6, 2010 and running through August 12, 2010;

- civil money penalties of $200 per day for each day of a period beginning on August 13, 2010 and running through October 27, 2010; and

- denial of payment for new Medicare admissions for each day of a period beginning on September 27, 2010 and running through October 27, 2010.

I. Background

Petitioner is a skilled nursing facility that is located in Rockford, Illinois. It participates in the Medicare program. Its participation in Medicare is governed by

sections 1819 and 1866 of the Social Security Act (Act) and by implementing regulations at 42 C.F.R. Parts 483 and 488. Its hearing rights in this case are governed by regulations at 42 C.F.R. Part 498.

Petitioner requested a hearing to challenge a determination by CMS to impose the remedies that I cite in the opening paragraph of this decision. CMS premised its determination on findings of noncompliance with Medicare participation requirements that were made at surveys conducted of Petitioner's facility on September 2, 2010 (September Survey) and October 27, 2010 (October Survey). The noncompliance findings included a finding that Petitioner had contravened participation requirements to the extent that residents were in immediate jeopardy. "Immediate jeopardy" means noncompliance that is so egregious as to cause, or be likely to cause, serious injury, harm, impairment, or death to a resident or residents of a skilled nursing facility. 42 C.F.R. § 488.301.

The case was assigned to me for a hearing and a decision. I ordered the parties to exchange proposed exhibits, including the written direct testimony of all witnesses, and pre-hearing briefs. The parties complied with that order, and I scheduled the case for an in-person hearing to be held on August 22, 2011. Petitioner moved for partial summary judgment. CMS then cross-moved for partial summary judgment. I denied the parties' motions.[1] The parties then informed me that they agreed that this case could be decided based on their written submissions. I afforded the parties the opportunity to file final briefs.

CMS filed a total of 19 proposed exhibits that it identified as CMS Exhibit (Ex.) 1 – CMS Ex. 19. Petitioner filed a total of 16 proposed exhibits that it identified as P. Ex. 1 – P. Ex. 16. I receive all of the parties' exhibits into the record.

II. Issues, Findings of Fact, and Conclusions of Law

A. Issues

The issues in this case are whether:

1. Petitioner failed to comply substantially with Medicare participation requirements; and

[1] I ruled on the parties' motions at a telephone pre-hearing conference. I ruled that there were disputed issues of fact that precluded me from entering summary judgment in favor of Petitioner. I ruled that CMS filed its motion too close in point of time to the August 22 hearing date for me to rule on it prior to the hearing. This decision memorializes my rulings. I also denied the parties' motion to continue the hearing.

2. CMS's remedy determinations are reasonable.

B. Findings of Fact and Conclusions of Law

I make the following findings of fact and conclusions of law (Findings).

1. Petitioner failed to comply substantially with Medicare participation requirements.

a. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(m)(2).

From August 6 through August 12, 2010, Petitioner manifested immediate jeopardy level noncompliance with the requirements of 42 C.F.R. § 483.25(m)(2), which requires that a skilled nursing facility must ensure that its residents are free from significant medication errors. Petitioner's noncompliance with this participation requirement, at a level of noncompliance that is less egregious than immediate jeopardy, continued through October 27, 2010.

Petitioner concedes that, on August 6, 2010, it manifested immediate jeopardy level noncompliance with the requirements of 42 C.F.R. § 483.25(m)(2). The undisputed facts graphically establish that noncompliance. On that date, at 3:30 in the afternoon, Petitioner admitted a resident who is identified as R2. This resident's medical problems included a history of malignant hypertension, in other words, potentially lethal high blood pressure. CMS Ex. 9 at 16-17. The resident came to the facility with prescriptions for several anti-hypertensive medications. *Id.* Notwithstanding, Petitioner's staff failed to administer these medications to the resident on August 6. *Id.* at 8. Petitioner did not have the necessary medications on hand. *Id.* at 20. At 8:30 on the evening of August 6 – five hours after the resident was admitted – Petitioner's staff asked a pharmacy to rush the needed medications to Petitioner. The staff anticipated administering the medications to R2 at some point during the next nursing shift, or early on the morning of August 7, 2010. *Id.* at 20. The record does not show that the resident received the necessary medications at Petitioner's facility, either on the evening of August 6 or during the early morning hours of August 7, 2010.

Early on the morning of August 7, 2010, R2 complained of a stomachache and headache. Her blood pressure was recorded at 210/100. CMS Ex. 9 at 18. The resident was brought by ambulance to a hospital emergency room at about 3:50 on the morning of August 7. The emergency room physician concluded that R2 suffered from:

> [p]ulmonary edema likely secondary to hypertensive emergency. Likely her high blood pressure may have resulted from skipped doses of her blood pressure medications in the nursing home, but in the remote possibility that there could be other possible causes of her pulmonary edema . . . .

CMS Ex. 9 at 10. The resident remained in the hospital, in intensive care, for six days before being discharged. CMS Ex. 7 at 31.

I draw three conclusions from these undisputed facts. First, and obviously, Petitioner's staff endangered the life of R2 by failing to give her blood pressure medications that were necessary to treat her malignant hypertension. Equally obviously, the staff failed to comprehend the extreme danger that their inaction posed for R2. It was not until five hours after the resident was admitted to Petitioner's facility that the staff recognized that they were lacking medication that was necessary to protect R2 from potentially lethal consequences. Even then – and notwithstanding the fact that the staff made a rush order for the medication – the staff failed to comprehend that additional delays were putting the resident at extreme risk. The rush order that the staff made at 8:30 on the evening of August 6, 2010 anticipated several hours' additional delay before the resident would receive her medications. Yet her orders indicate that these medications were supposed to be given to her twice a day at 8 am and 4 pm. CMS Ex. 9 at 16.

Third, it is also obvious that Petitioner had no mechanism in place for assessing the urgent medication needs of newly admitted residents, and no mechanism for assuring that newly admitted residents would receive necessary medication. These deficiencies are made manifest by the failures to perceive the risks that R2 was being exposed to, and by the failure to address her medication needs.

Petitioner, while conceding immediate jeopardy level noncompliance on August 6, 2010, makes two arguments aimed at limiting its liability. First, Petitioner asserts that it ended its jeopardy, indeed, that it completely abated its noncompliance, on August 7, 2010. Thus, according to Petitioner, there exists no basis to impose any remedies against it after August 6.

Second, Petitioner asserts that the surveyors who conducted the September Survey cited Petitioner's noncompliance as "past" noncompliance; that is to say, noncompliance that was present and completely abated prior to the September Survey. For that reason, according to Petitioner, no remedies may be imposed against it after August 6.

I find both of these arguments to be unpersuasive. Petitioner's first argument notwithstanding, it has not offered proof establishing that it abated its immediate

jeopardy level noncompliance by August 7, 2010. Nor has it proven that it abated all noncompliance before October 27, 2010. Indeed, and as I shall discuss, there is affirmative proof showing that Petitioner continued to be out of compliance with the requirements of 42 C.F.R. § 483.25(m)(2) as late as the October Survey.

As to Petitioner's second argument, I find it to be irrelevant. Petitioner premises its argument about "past" noncompliance on its interpretation of some language in the report of the September Survey. Seizing on that language, it acts as if CMS's advocacy in this case is set in stone by the choice of words in the survey report. That argument misrepresents the role of the survey report and misstates the function of the de novo administrative hearing that I conduct in this case. Moreover, Petitioner's asserted interpretation of the language in the survey report is at variance with what the report actually says.

Petitioner argues that CMS's determination that immediate jeopardy was not abated prior to August 12, 2010 is unsupported. According to Petitioner:

> neither the surveyors, the . . . [Illinois State survey agency], nor CMS offer any explanation as to why all the steps taken by the facility through August 13, 2010, were necessary to abate the . . . [immediate jeopardy]. That is, the surveyor offers no reason why the completion of the investigation by the facility and inservice by the pharmacist were necessary to abate the . . . [immediate jeopardy].

Petitioner's Closing Brief at 6-7. The argument assumes, incorrectly, that CMS has a burden of proof to establish why a facility's corrective actions are insufficient to abate immediate jeopardy. That argument stands the parties' burdens on their heads. In fact, it is Petitioner's duty to prove why its corrective actions abated immediate jeopardy. These actions were, after all, what Petitioner elected to implement to address a problem that Petitioner concedes it caused. Having caused the problem, Petitioner must prove that it effectively addressed it.

Second, Petitioner seems to be saying that it should not be held accountable for completing certain corrective actions that it elected to take because CMS cannot prove that they were, in fact, necessary. I find that position to be puzzling. Petitioner's management decided that certain actions were necessary to eliminate immediate jeopardy at the facility. It was imperative that the actions be implemented given that these are what Petitioner opted for to address the problem that it created.

Petitioner also contends that it abated its immediate jeopardy by no later than August 7, 2010, because it took affirmative actions on that date to remove immediate jeopardy. These actions – which Petitioner asserts convinced the

surveyors who conducted the September Survey that immediate jeopardy had been abated immediately – are recited in the September Survey Report and consist of the following:

- On August 7, Petitioner's director of nursing began investigating what had occurred and determined that all of a resident's medications needed to be secured as soon as possible upon the resident's admission and/ or used from the convenience box as necessary.

- The director of nursing began in-servicing the nurses. In-servicing and monitoring were ongoing as of September 2, 2010.

- R2's admitting nurse was suspended pending the outcome of the investigation into what had occurred.

- The director of nursing assured that all new residents' medications were accounted for and properly administered from the previous day.

CMS Ex. 1 at 18-19.

Despite Petitioner's assertion, there is nothing in the report of the September Survey that supports a conclusion that immediate jeopardy was abated effective August 7, 2010. The survey report does not conclude that immediate jeopardy was abated on that date; rather, it concludes that the immediate jeopardy persisted until August 13, 2010. CMS Ex. 1 at 14, 20-22.

Thus, Petitioner mischaracterizes the survey report. Moreover, Petitioner's argument that it abated its immediate jeopardy immediately is not supported by the evidence. The steps, recited by the surveyors, that Petitioner took on August 7, 2010, may have been actions that were necessary to abate immediate jeopardy. But, the fact that Petitioner's director of nursing determined that these steps were necessary, and even began to implement them as of August 7, 2010, does not mean that they were *completely implemented* by that date. For example, determining that a newly admitted resident's medications needed to be secured as soon as possible is not proof that this determination, even after it was communicated to the staff, was immediately and effectively implemented by the staff.

Similarly, in-servicing the nurses (retraining them as to their obligations and duties) may have been a necessary measure. But proof that in-service training was conducted is not proof that it was absorbed by the staff and that the lessons taught in that training were implemented by them. Moreover, and as the survey report

states, in-servicing was only *begun* on August 7, it was not *completed* on that date. Indeed, some staff members were still being in-serviced as of September 2, 2010.

As I have discussed above, CMS determined that Petitioner did not completely abate its non-immediate jeopardy level noncompliance with 42 C.F.R. § 483.25(m)(2) prior to October 27, 2010. CMS predicates this determination to some extent on its conclusion that, as of October 27, Petitioner continued to fail to comply with the regulation's requirements. CMS Ex. 2.

The evidence offered by CMS pertains to a resident who is identified in the report of the October Survey as R14. This resident was admitted to Petitioner's facility on October 19, 2010 with a prescription for a cardiac medication, Diltiazem. CMS Ex. 2 at 1. The staff failed to obtain the medication from the pharmacy on that date, and, consequently, the resident did not receive the medication on the date of admission. *Id.*

The noncompliance established by this episode is, but for the level of harm involved, factually indistinguishable from what happened to R2 on August 6-7, 2010. Again, there is proof that Petitioner admitted a resident with a prescription for a medication, but that its staff failed to obtain the medication and to administer it timely to the resident. It is compelling evidence of continuing noncompliance by Petitioner.

Petitioner offers no evidence to counter what I have just described. In effect, it concedes the facts and concedes the noncompliance. It argues, however, that this noncompliance is not proof of continuing noncompliance by Petitioner after August 6, 2010. Rather, it characterizes it as an isolated incident, separated by the passage of many weeks from the noncompliance that was uncovered at the September Survey.

As support for this argument, Petitioner asserts that the surveyors found only "past" noncompliance at the September Survey. In Petitioner's eyes, the surveyors absolved Petitioner of any liability because they found that the noncompliance relating to R2 ended almost as soon as it occurred. Petitioner relies on the following language in the September Survey report:

> The facility became aware of R3's medication omission on 8/7/10 and completed a thorough investigation of the circumstances. The facility implemented corrective actions and completed these on 8/13/10.

CMS Ex. 1 at 14. As I discuss above, this argument is both factually and legally incorrect. First, the language cited by Petitioner does not mean that the surveyors

found that *all* noncompliance with 42 C.F.R. § 483.25(m)(2) was abated by August 13, 2010. In citing this language, Petitioner omits to cite the first sentence of the relevant paragraph:

> The Immediate Jeopardy was removed on August 13, 2010 when the surveyor determined that the facility took immediate action to ensure that the harm is not likely to recur . . . .

CMS Ex. 1 at 14. That language makes it obvious that what the surveyors were talking about in the September Survey report was abatement of *immediate jeopardy*. They found that immediate jeopardy was abated by August 13, 2010, a position that is entirely consistent with CMS's determination and the evidence. They made no finding that all noncompliance with the regulation, including non-immediate jeopardy level noncompliance, was abated by that date.

However, even a surveyor finding that all noncompliance was abated by August 13 would be irrelevant as a matter of law. The surveyors do not make the final determination of noncompliance, CMS does. Moreover, this is a de novo proceeding. CMS has given notice to Petitioner that it determined that noncompliance continued through October 27, 2010. That notice supersedes any conclusion that the surveyors may have made. And, it puts the issue of date of compliance before me de novo. I therefore base my decision on when compliance was obtained on the objective evidence and not on what a surveyor or surveyors may or may not have said at some point in the past.

As I have discussed, there is compelling, unrebutted evidence that Petitioner continued to be noncompliant as of October 27, 2010. That evidence is sufficient for me to infer that noncompliance at the non-immediate jeopardy level continued after August 13. Furthermore, Petitioner's own corrective actions did not envision immediate completion of corrections. As I have discussed, as of the September Survey, Petitioner's in-servicing activities were still ongoing.

b. Petitioner failed to comply substantially with the requirements of 42 C.F.R. §§ 483.20(k)(3)(i), 438.25(g)(2), and 483.75(l)(1).

There were additional noncompliance findings made at the September Survey. These included findings that Petitioner failed to comply substantially with the requirements of: 42 C.F.R. § 483.20(k)(3)(i), which requires that services provided or arranged by a skilled nursing facility meet professional standards of quality; 42 C.F.R. § 483.25(g)(2), which requires that a facility ensure that a resident who is fed by naso-gastric tube or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea,

vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers, and to restore, if possible, normal eating skills; and 42 C.F.R. § 483.75(l)(1), which requires a facility to maintain clinical records for each of its residents in accordance with accepted professional standards and practices that are complete, accurately documented, readily accessible, and systematically organized.

I find that the evidence overwhelmingly sustains CMS's determinations that Petitioner failed to comply substantially with the requirements of these regulations.

i. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.20(k)(3)(i).

CMS offered unrebutted evidence concerning the care that Petitioner provided to a resident who is identified in the September Survey report as R1. The failure to provide care to R1 that met professional standards of quality is made evident by the fact that R1 suffered the consequences of improper placement of a gastrostomy tube during her stay at Petitioner's facility. On July 19, 2010, a gastrostomy feeding tube was surgically inserted into the resident's stomach. CMS Ex. 1 at 2. Difficulties with keeping the tube unblocked were encountered subsequently, while R1 resided at Petitioner's facility. On July 29, 2010, the resident's surgeon ordered that the tube be changed. A nurse practitioner replaced the tube with a smaller diameter tube than had originally been implanted. Furthermore, the tube was not placed properly. On July 31, 2010, the resident was hospitalized. The resident received emergency surgery to address a dislodged gastrostomy tube and to deal with complications resulting from the improper placement of the tube. CMS Ex. 8 at 45-49.

Petitioner's defense to the evidence that I have just recited is that the nurse practitioner, who improperly replaced R1's gastrostomy tube, was not an employee of Petitioner, but an independent contractor. Petitioner contends that it has no legal responsibility for the performance of this individual because she was not an employee.

I disagree. On its face, 42 C.F.R. § 483.20(k)(3)(i) applies to more than services that are provided by a facility's employee. It applies to services that are "provided or arranged" by a facility. The plain meaning of the regulation is that it applies to all services that are given to a resident under the aegis of a skilled nursing facility, not just to those that are provided by employees.

The language of the regulation is entirely consistent with the intent of the Act and its implementing regulations. The Act applies to skilled nursing facilities and to the services that they provide. It does not distinguish between facilities and their

employees or facilities and independent contractors who provide services on facilities' premises. The act defines a "skilled nursing facility" to be an institution, or a distinct part of an institution, which is primarily engaged in providing skilled nursing care and related services or rehabilitation services to covered beneficiaries. Act § 1819(a)(1)(A), (B). The Act states additionally that:

> A *skilled nursing facility* must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident.

Act § 1819(b)(1)(A). Thus, a skilled nursing facility is responsible for everything that happens on its premises, whether what happens is the consequence of actions by its employees or whether it is the consequence of independent providers who are performing services on the premises.

If Petitioner's argument were taken to its logical end, the Act and implementing regulations could be made meaningless by any facility that desires to immunize itself from liability. Using Petitioner's logic, a facility could hire contractors to perform all of its services and escape liability for the contractors' actions on the basis that the contractors and their employees are not employees of the facility. That plainly violates both the intent and the plain meaning of the Act.

ii. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(g)(2).

CMS bases its assertion that Petitioner failed to comply with the requirements of this regulation on the evidence that I discussed pertaining to R1 and also on evidence pertaining to an additional resident, identified in the report of the September Survey as R4. In the case of R4, the evidence establishes that, on July 6, 2010, Petitioner's staff discovered that the resident had a clogged feeding tube. CMS Ex. 10 at 5-6. The resident needed hospitalization to address the problem. At the hospital, it was determined that the resident's feeding tube was dislodged due to feeding tube mismanagement. *Id.* at 37-38.

The evidence offered by CMS thus shows mismanagement of feeding tubes of two of Petitioner's residents. In the case of R1, the mismanagement consisted of a botched effort at replacing the tube, coupled with use of a tube that was smaller than that which had been ordered by the resident's physician. In the case of R4, the mismanagement consisted of dislodging the resident's feeding tube in the course of attempts to unclog it.

In responding to this evidence, Petitioner makes the same arguments about the care provided to R1 that I have discussed and rejected previously. I need not

address those arguments again. As respects R4, it is Petitioner's contention that the resident's clogged tube was essentially unavoidable and that it should not be held responsible for that event. It argues also that its staff followed facility policies in attempting to unclog the resident's tube.

For purposes of this decision, I will assume that the resident's clogged tube was an unavoidable development and that its staff used approved facility policies to attempt to unclog it. That, however, does not absolve Petitioner from mismanaging the efforts to unclog the tube. The resident was hospitalized in part because the feeding tube had become dislodged. The staff should have been able to protect the resident against that development, even if the tube's clogging was an unavoidable event and even if they followed facility protocol in attempting to unclog it.

Petitioner argues that the hospital records, showing that the tube was dislodged, do not establish that the tube became dislodged at Petitioner's facility. Petitioner's Pre-Hearing Brief at 14. In fact, the reasonable inference is that the tube did become dislodged, while R4 was at the facility. Petitioner has offered no evidence to show that the resident was away from the facility during the time when she experienced problems with her feeding tube, nor has Petitioner offered a plausible alternative explanation for the tube becoming dislodged other than mismanagement of the tube by Petitioner's staff.

iii. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.75(l)(1).

The evidence relied on by CMS to establish noncompliance with this regulation pertains to the care that Petitioner's staff provided to a resident who is identified as R5 in the September Survey report.[2] R5 was a diabetic resident admitted to Petitioner's facility from a local hospital on June 30, 2010. The resident had a prescription for insulin injections according to a schedule. CMS Ex. 1 at 21. However, the resident failed to receive the prescribed injection on the morning of July 1, 2010. This was due to a transcription error by Petitioner's staff. In preparing the resident's July medication administration record (MAR), the staff failed to transfer over from the June MAR the orders that the resident receive insulin. *Id.* at 21-22.

[2] The care that Petitioner's staff gave to R5 was also cited in the September Survey report as non-immediate jeopardy level noncompliance with the requirements of 42 C.F.R. § 483.25(m)(2). I did not address this evidence with respect to that regulation because of Petitioner's concession that it had contravened the regulation's requirements at the immediate jeopardy level of noncompliance.

The documentation error that I have just described was plainly serious. As a consequence of staff error, a resident failed to receive a dose of prescribed medication. The error is an obvious violation of the regulation, which requires that records be accurately documented.

Petitioner does not dispute any of the evidence that I have just cited, nor does it contend that the error committed by its staff was not serious. Its sole defense is that this noncompliance was "past" noncompliance and should not be a basis for imposition of remedies against it. Petitioner's Pre-Hearing Brief at 15. I have addressed and rejected that argument previously. It is unnecessary that I address it again.

2. CMS's remedy determinations are reasonable.

a. Civil money penalties of $3,050 per day for the period beginning August 6 and running through August 12, 2010 are reasonable as a matter of law.

The minimum daily civil money penalty amount that CMS may impose to remedy immediate jeopardy level noncompliance is $3,050 per day. 42 C.F.R. § 488.438(a)(1)(i). CMS imposed the minimum amount to remedy Petitioner's immediate jeopardy level noncompliance, and, therefore, it is reasonable as a matter of law.

b. Civil money penalties of $200 per day for the period beginning August 13 and running through October 27, 2010 are reasonable.

The permissible range for daily civil money penalties that are imposed to remedy non-immediate jeopardy level deficiencies is from $50 to $3,000 per day. 42 C.F.R. § 488.438(a)(1)(ii). A decision as to where within that range a penalty should fall depends on factors specified by regulation that include: the seriousness of a facility's noncompliance; its compliance history; its culpability; and its financial condition. 42 C.F.R. §§ 488.438(f)(1) – (4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)).

The civil money penalties of $200 per day are minimal, constituting only six percent of the maximum allowable daily penalties for non-immediate jeopardy level noncompliance. I find that they are amply justified by the seriousness of Petitioner's noncompliance. Indeed, the continuing noncompliance by Petitioner with the requirements of 42 C.F.R. § 483.25(m)(2) would justify the entire penalty amount without consideration of Petitioner's other, non-immediate jeopardy level noncompliance.

Petitioner does not challenge the reasonableness of the penalty amount. It argues that no penalties should be imposed against it, reiterating its past noncompliance argument and its assertion that it corrected all deficiencies by August 7, 2010. I have addressed those arguments elsewhere.[3]

c. Denial of payment for new Medicare admissions for the period beginning September 27 and running through October 27, 2010 is authorized by regulation.

CMS is authorized by regulation to impose denial of payment for new Medicare admissions for any date on which a facility is not substantially complying with Medicare participation requirements. 42 C.F.R. § 488.417(a). Whether to do so is a matter of discretion that a facility may not challenge.

Here, there is justification for CMS's imposition of the remedy for each day of the September 27 – October 27, 2010 period. Petitioner was not complying substantially with Medicare participation requirements during this period. That is sufficient to justify CMS's imposition of the remedy.

Petitioner again makes its past noncompliance argument to assert that there is no basis for CMS to deny payment for new admissions. I have addressed that argument previously and will not revisit it here.

/s/
Steven T. Kessel
Administrative Law Judge

[3] Petitioner argues that it corrected all of its non-immediate jeopardy level noncompliance by September 2, 2010. I do not find it necessary to address whether Petitioner abated its noncompliance with regulations other than 42 C.F.R. § 483.25(m)(2) prior to October 27, 2010, because I find that its noncompliance with that regulation continued through October 27.