Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Windsor Manor Rehabilitation Center,	)	Date: June 29, 2007
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-06-628
	)	Decision No. CR1619
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION GRANTING MOTION FOR SUMMARY DISPOSITION

I grant the motion of the Centers for Medicare & Medicaid Services (CMS) for summary disposition in this case. Consequently, I sustain the remedy that CMS determined to impose against Petitioner, Windsor Manor Rehabilitation Center, a denial of payment for new admissions during a period that began on July 5, 2006 and which ended on July 7, 2006.

I. Background

Petitioner is a skilled nursing facility doing business in the State of California. It participates in the Medicare program. Its participation in Medicare is governed by sections 1819 and 1866 of the Social Security Act and by implementing regulations at 42 C.F.R. Parts 483 and 488.

Petitioner was surveyed for compliance with Medicare participation requirements on April 14 and June 9, 2006 (April and June surveys). The surveyors found a total of 14 deficiencies at the April survey and one additional deficiency at the June survey. Petitioner requested a hearing and the case was assigned to me for a hearing and a decision.

The parties completed pre-hearing exchanges pursuant to which they submitted briefs and exhibits that included the written direct testimony of proposed witnesses. CMS submitted a total of 55 proposed exhibits, which it designated as CMS Ex. 1 - CMS Ex. 55. Petitioner submitted a total of 54 proposed exhibits, which it designated as P. Ex. 1 - P. Ex. 54. I scheduled an in-person hearing. Then, CMS moved for summary disposition and Petitioner opposed the motion.

II. Issues, findings of fact and conclusions of law

A. Issues

The ultimate issue in this case is whether Petitioner failed to comply substantially with one or more Medicare participation requirements during the July 5 - 7, 2006 period. Regulations mandate that I sustain the denial of payment for new admissions that CMS determined to impose if Petitioner manifested a deficiency or deficiencies during this period. *See* 42 C.F.R. § 488.417(a)(1).

There is also a threshold issue in this case of whether it is appropriate to issue summary disposition without holding an in-person hearing. Regulations governing hearings in cases involving CMS do not provide explicitly for summary disposition in such cases. However, administrative law judges and the Departmental Appeals Board have held that summary disposition is appropriate in a case involving CMS where the criteria for summary judgment set forth by Rule 56 of the Federal Rules of Civil Procedure are satisfied.

Rule 56 provides that summary judgment may be imposed where there are no genuinely disputed issues of material fact. Under Rule 56 a "material fact" is a fact which, if it exists, may affect the outcome of a case. A "genuinely disputed" material fact exists when opposing parties advance different versions of an event. The concept of a genuine dispute as to the facts is critical to understanding how summary judgment works. A fact offered by a party is not in dispute simply because the opposing party asserts that it is in dispute. In order for there to be a dispute as to the facts the opposing party must offer a version of events that differs materially from the version offered by the moving party.

Furthermore, Rule 56 draws a distinction between facts and conclusions that are based on facts. A disagreement between parties as to the meaning of facts is not an impediment to summary judgment under Rule 56. The trier of fact always has the authority to draw conclusions from facts, whether the case is disposed of by summary judgment, or after a hearing. Thus, arguments about the meaning of facts – as opposed to disputes as to what facts exist – constitute no impediment to granting summary judgment in a case.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

CMS premised its remedy determination in this case on its determination that Petitioner manifested 14 deficiencies at the April survey and an additional deficiency in June. It is not necessary that I address all or even most of the deficiencies that CMS found or even all or most of those on which CMS based its motion for summary disposition. The presence of even a single deficiency during the July 5 - 7, 2006 period justifies the remedy of denial of payment for new admissions during that period. Consequently, I address only three of the 15 deficiencies cited by CMS. With respect to each of these deficiencies I find that CMS's assertion of noncompliance is supported by the plain meaning of the applicable regulation and by undisputed material facts.[1]

1. The undisputed material facts establish that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.15(h)(2).

The regulation at issue requires that a facility must provide housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior. CMS asserts that, at the April survey, the surveyors adduced facts that establish that Petitioner was not complying substantially with this requirement. Specifically:

- The surveyors observed personal care items such as breathing equipment, urine collection cups, urinals, urine hats, and bedpans stored uncovered on bedside tables, on the floor, and on the tops of toilets in communal bathrooms. CMS Ex. 5, at 3 - 5.

- The uncovered storage of personal care items violated Petitioner's own policy governing the storage of such items. Petitioner's policy required that personal items be labeled and stored in a bedside cabinet or on a bathroom shelf. CMS Ex. 50, at 99.

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[1] The fact that I do not address the other twelve deficiencies cited by CMS does not mean that CMS would not prevail on one or more of these other deficiencies at a hearing or even that CMS might not be entitled to summary disposition as to one or more of them. However, it is unnecessary that I address them here because the presence of even one deficiency during the July 5 - 7, 2006 period justifies the remedy of denial of payment for new admissions.

- The surveyors smelled strong odors of urine and feces in Petitioner's facility. They observed brown smears on residents' toilets. CMS Ex. 5, at 5.

The foregoing facts, if not disputed, establish a violation of 42 C.F.R. § 483.15(h)(2). The presence of odors of urine and feces in and of themselves are a basis for finding noncompliance. No interpretation of the regulation would excuse a facility from subjecting its residents to such odors. The storage of personal items uncovered and in violation of Petitioner's own personal item storage policy is a violation of the regulation because such storage is neither sanitary nor orderly. CMS Ex. 50, at 99.

Petitioner makes the following arguments against summary disposition:

- It asserts that only by imposing a "strict liability standard" of compliance would the facts offered by CMS support a finding of noncompliance with the regulation. Petitioner argues that it cannot be held responsible for every offensive sight, sound, or smell on its premises. Petitioner's response to CMS's motion (response) at 9. On the other hand, according to Petitioner, it cannot be required to restrain, unduly isolate or control its incontinent residents' movements to the extent that there is never a misplaced item, foul odor, or a smudge on a toilet. *Id.*

- There is a dispute as to the significance of the surveyors' findings of items not properly stored because CMS has not offered evidence establishing that these items had been misplaced for any significant period of time or that they were misplaced by facility staff or residents. Response at 10.

- CMS has not made any allegation that the items observed by the surveyors were not "sanitized as needed." Response at 10.

- CMS has not proven that unlabeled items belonged to any particular resident. Response at 11.

- Contrary to CMS's allegations Petitioner in fact has a policy that provides for the safe storage and labeling of residents' bedside equipment. Response at 11.

- The surveyors' smelling urine and/or feces in the facility and their observations of brown smears on a resident's toilet demonstrate nothing more than the fact that Petitioner houses elderly residents who, from time to time, have episodes of incontinence. Response at 11.

Petitioner disputes none of the facts relied on by CMS. Petitioner does not assert that the surveyors' findings are inaccurate or that the surveyors did not see what they contend to have seen. Furthermore, Petitioner offers no facts of its own to counter those offered by CMS. It has not offered any facts that would place CMS's facts into a context that is favorable to Petitioner's position.

Petitioner seems to be contending – without offering a single fact to support its contention – that the surveyors' findings constitute, at most, observations of a brief moment in time when there happened to be disorder and foul odors in Petitioner's facility. The heart of Petitioner's argument against summary disposition is that these observations cannot be used to characterize the state of Petitioner's facility because they do not depict a long-term or ongoing situation. Ultimately, according to Petitioner, the facts presented by CMS add up to nothing more than proof that incontinent residents are at times incontinent. Moreover, according to Petitioner, it would be unreasonable to require Petitioner to assure that its facility was free from the consequences of incontinence, including stains and odors. It asserts that some odors and unsanitary conditions are simply part of the business of taking care of incontinent residents.

I find this argument to be unpersuasive. The facts presented by CMS are, to be sure, a snapshot of Petitioner's operation. That snapshot establishes both disorder and unsanitary conditions at the facility. It is entirely reasonable to conclude from these facts that problems with sanitation and disorder typified Petitioner's operation. Moreover, it is the *only* reasonable conclusion that I may draw based on the undisputed material facts because Petitioner offered no facts to suggest that anything else is the case. Nor has Petitioner suggested that, somehow, a hearing would produce evidence that contradicts in any respect the facts that CMS presented in support of its motion.

If Petitioner wanted to argue that the facts offered by CMS depict aberrant circumstances, it had the burden of offering something affirmative to counter those facts. For example, if Petitioner wanted to contend that episodes of incontinence and their aftereffects are simply momentary events that are attended to immediately and efficiently by its staff, it could offer testimony or documentary evidence showing how the staff responds to such episodes. But, in response to CMS's motion, Petitioner offered nothing of the kind. Petitioner has offered nothing – literally, no facts whatsoever – that would serve as an impediment to concluding that the disorder and lack of sanitation observed by the surveyors was an ongoing problem.

Nor am I persuaded by Petitioner's argument that odors, stains, and a certain level of poor sanitation are inevitable when it comes to caring for incontinent residents. The regulation does not build in a margin of error when it comes to caring for incontinent

residents. Obviously, unfortunate accidents will from time to time occur in a facility that cares for the incontinent. But, the regulation presumes that such accidents will be attended to immediately by staff and that there will be no lingering odors or residues. The uncontradicted facts offered by CMS are strong proof that Petitioner did not live up to this standard.

Petitioner's assertions that CMS has failed to show that items were not "sanitized as needed" is an unreasonable characterization of what CMS's burden is in this case. CMS does not have to account for every possible fact scenario in order to prevail here. Its burden is to present a set of facts that show a failure by Petitioner to comply with a participation requirement. It is *Petitioner's* obligation to offer facts that would negate or neutralize those presented by CMS. Petitioner has the obligation to show that it "sanitizes" items as needed if it contends that such action is a reasonable way to assure that residents are provided with clean and safe incontinence products. But, Petitioner has offered no facts to show that it takes such action.

Petitioner's assertion that CMS failed to offer facts to show that unlabeled products belong to a particular resident similarly lacks merit. First, it is unclear to me why having such products labeled or unlabeled matters in the context of CMS's noncompliance allegations. There is no dispute that these products were being used to provide care to residents. And, Petitioner has offered nothing to dispute the facts offered by CMS showing that these products were stored in an unsafe and potentially unsanitary manner. Residents might be exposed to even greater health hazards if CMS were to offer facts showing that Petitioner's staff commingled these products and used them interchangeably on different residents without properly sanitizing them. But, that allegation is not necessary to CMS's case.

Petitioner's assertion that it has a policy for safe storage and labeling of residents' bedside equipment begs the question of its compliance. CMS is not alleging that Petitioner lacked such a policy. To the contrary, CMS offered undisputed facts that Petitioner *violated* its storage and labeling policy.

2. The undisputed material facts establish that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(h)(1).

The applicable regulation mandates that a facility ensure that its resident environment remains as free of accident hazards as possible. The regulation's intent is clear. It requires a participating facility to eliminate from its physical plant all known or foreseeable hazards that might pose a threat of injury to residents. Such hazards include defective or poorly maintained equipment and access to locations that might prove

dangerous to residents. CMS Ex. 52, at 80. A facility must take into account the physical and mental conditions of its residents in researching and eliminating hazards. Residents of skilled nursing facilities are by definition impaired individuals, often having severe mental and/or physical handicaps. Environmental factors which might pose minimal danger to young and healthy individuals could be life-threatening to nursing facility residents. Consequently, each facility must exercise extraordinary vigilance to assure that its residents are housed safely.

CMS relies on the following fact assertions to support its argument that I should enter summary disposition against Petitioner for failing to maintain a hazard-free facility:

- The surveyors who conducted the April survey found that one of the resident's rooms (Room 101B) had poorly maintained bedside furniture equipment and splintered door frames. CMS Ex. 42. Additionally, they found that in Room 109 there was a splintered and rough overbed table. None of the broken furniture had been replaced by Petitioner in accordance with its policy. CMS Ex. 50, at 99.

- At the April survey a surveyor observed an unsecured outdoor chemical storage locker that residents could obtain access to through a nearby unlocked door. Petitioner's maintenance supervisor told the surveyor that the storage locker should have been locked. CMS Ex. 41.

The conclusion that I draw from these facts, if there is nothing to contradict them, is that Petitioner's premises were not free from accident hazards. The risk of exposure to chemicals is particularly evident here, in a facility which houses frail and demented individuals.

In response to CMS's motion Petitioner asserts the following:

- The surveyors' findings that pieces of furniture were rough or splintered does not automatically qualify the furniture as broken or unsafe. Response at 12. According to Petitioner, there are no facts showing that a resident ever complained about the furniture or that the furniture was in a location that was likely to come into contact with residents' skin. Petitioner argues also that CMS did not prove that Petitioner failed promptly to repair the broken furniture when its presence was brought to Petitioner's attention. *Id.*

- CMS has not offered facts showing for how long the chemical storage locker was unlocked nor has CMS shown that Petitioner's staff was unaware of the open locker. Response at 12. Also, according to Petitioner, the facts offered by CMS do not suggest that residents had access to the open locker or that the locker posed a threat to residents' safety. *Id.*

Petitioner also asserts that there are disputed material facts. It argues that, contrary to CMS's assertions, Petitioner's policy governing replacement of broken or damaged items does not cover replacement of broken or splintered furniture. Response at 13. It argues also that there is a "triable issue of fact" as to whether the wear and tear described by surveyors demonstrated that furniture needed to be replaced. With respect to the unlocked storage locker, Petitioner asserts that CMS concedes that the locker was outdoors and out of Petitioner's common areas, thereby again raising a triable issue of fact as to whether the locker posed a hazard.[2]

I find that none of these arguments serve as an impediment to granting summary disposition. To begin with, Petitioner does not challenge any of the fact findings made by the surveyors. It does not dispute that there were rough and splintered furniture and door frames in residents' rooms. Nor does it dispute that there was an unlocked chemical storage locker on its premises. And, it says nothing about the surveyors' findings that residents had access to the locker through an unlocked door.

Nor has Petitioner offered any facts of its own to challenge CMS's fact assertions. For example, it has not offered facts showing that, contrary to the surveyors' finding, residents did not have access to Petitioner's unlocked chemical storage locker. Neither has it offered any facts to show that furniture and door frames were not, in fact, rough and splintered.

Furthermore, the arguments offered by Petitioner consist essentially of speculation about possible scenarios that are simply unsupported by any facts. There is *nothing* to show that Petitioner's staff promptly repaired broken furniture and door frames. Nor has Petitioner advanced any facts to show that Petitioner's staff was aware of the unlocked chemical storage locker and took actions to protect residents from the unlocked locker.

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[2] Petitioner asserts also that there is a fact dispute concerning residents' access to an oxygen tank storage area. Response at 13. However, resident access to the oxygen tank storage area was not a basis for CMS's motion for summary disposition concerning Petitioner's noncompliance with 42 C.F.R. § 483.25(h)(1).

Petitioner's assertions notwithstanding, the only reasonable conclusion that I can draw from the unchallenged facts presented by CMS is that splintered furniture and door frames in residents' rooms posed a hazard to residents. An overbed table, for example, is an object that a resident would come in contact with more or less constantly. Similarly, a splintered door frame would pose a risk to a resident each time that resident passed through it. And, Petitioner is simply wrong in arguing that CMS failed to offer facts showing that residents had access to the unlocked chemical storage locker. The unchallenged facts offered by CMS are that residents had access to the locker through an unlocked door.

3. The undisputed material facts establish that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.60(a).

The applicable regulation requires that a facility:

> provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

CMS contends that Petitioner failed to comply with this requirement based on the following facts:

- During the April survey a surveyor observed in a refrigerator three expired Novalog flex pen prefilled syringes of insulin that had been prescribed for one of Petitioner's residents who is identified as Resident # 14. The expiration date for the pens was March 2006 and one of the pens had been opened and used. CMS Ex. 39, at 22-23; CMS Ex. 5, at 31- 32. No other supplies of insulin for the resident were present.

- Novalog insulin had been prescribed to Resident # 14 for administration in March and April 2006. Between April 1 and April 8, 2006 Resident # 14 was administered Novalog insulin at least once, and, on occasion, twice daily. CMS Ex. 14, at 2.

- The surveyor observed an additional vial of insulin, prescribed to another resident, Resident # 2, that had been opened on March 2, 2006, more than 30 days before the April survey. The surveyor was told by a nurse on Petitioner's staff that Petitioner's policy was to dispose of insulin 30 days after it is opened. CMS Ex. 39, CMS Ex. 14, CMS Ex. 49, at 43.

- Petitioner's policy required that expired drugs be stored separately, away from use, until destroyed or returned to the provider. CMS Ex. 25, at 11. However, Petitioner was not storing the expired Novalog insulin away from other drugs.

- Manufacturer's instructions for Novalog require that it be discarded after 28 days. The manufacturer also instructs that an opened Novalog flex pen should not be refrigerated. www.novonordisk-us.com; CMS Ex. 34, at 4.

These facts, if unchallenged, establish a failure by Petitioner to comply with the requirements of the regulation. They show that Petitioner: retained insulin after its expiration date; stored expired insulin commingled with other, non-expired medications; and improperly refrigerated opened syringes of insulin. Additionally, the facts support only one conclusion concerning Petitioner's administration of insulin to Resident # 14, and that is that the resident was administered expired and improperly stored insulin. That is because there were no insulin supplies present for the resident that were unexpired.

Petitioner disputes none of these facts. It does not deny that it retained expired insulin, that it refrigerated opened insulin contrary to the manufacturer's directions, or that it commingled expired with unexpired drugs. And, significantly, it offers no facts to refute the conclusion that Resident # 14 received expired insulin. It did not allege, for example, that there were other supplies of insulin maintained separately for the resident.

Petitioner makes the following arguments in opposition to CMS's motion for summary disposition on this deficiency:

- There is no evidence that Resident # 14 received expired insulin or that the insulin maintained by Petitioner for the resident had degraded to the extent that it was ineffective. Response at 21. Further, there is no documentation that Resident # 14 actually received insulin from the opened syringe. *Id.* at 22.

- There is no evidence that Resident # 2 was administered insulin after its expiration date. Nor is there evidence that expired insulin that had been prescribed for Resident # 2 degraded. Response at 22.

- The regulation governs the "acquiring, receiving, dispensation, and administration of drugs" and not their storage. Consequently, there is no basis for finding Petitioner deficient even if all of CMS's allegations are true. Response at 22.

I find these arguments to be unpersuasive. First, and as I discuss above, the *only* reasonable conclusion that one may draw from the undisputed facts offered by CMS is that Resident # 14 was receiving expired insulin. That is because the surveyors found no supply of insulin for the resident other than the expired Novalog syringes and because Petitioner has offered no facts to show that it maintained an additional supply. Second, it is not CMS's burden to prove that the expired insulin had degraded to the extent that it was ineffective. The only reasonable conclusion one may draw from the fact that Petitioner was administering expired insulin to a resident is that it was administering a medication in a way that contradicted the manufacturer's instructions. That is, on its face, a failure by Petitioner to administer medication in a way that is consistent with its residents' needs. Similarly, the fact that Petitioner stored expired insulin for another Resident, Resident # 2, leads inescapably to the conclusion that it was administering expired insulin to this resident. I note also that Petitioner has offered no facts to counter CMS's allegations that it was refrigerating opened insulin contrary to the manufacturer's instructions.

I disagree with Petitioner's argument that CMS's allegations, even if true, do not amount to a failure to comply with regulatory requirements. CMS does not allege only that Petitioner stored medications improperly. It has presented undisputed facts showing that it administered insulin that had been stored improperly. That practice is covered by the explicit language of the regulation at issue. Moreover, I find that the language of the regulation is sufficiently broad to extend to improper storage and maintenance of drugs because storage of medications is an essential element of the process by which medications are administered and dispensed.

> ***4. The only reasonable conclusion that I may draw from the undisputed material facts is that Petitioner's noncompliance with 42 C.F.R. §§ 483.15(h)(2), 483.25(h)(1), and 483.60(a) persisted until July 7, 2006.***

Petitioner argues that summary disposition is inappropriate because CMS:

> fails completely to offer any evidence of . . . whether any of the acts/omissions of purported noncompliance cited during the April survey continued through July 5, 2006, the date of the imposition of . . . [the remedy of denial of payment for new admissions].

Response at 2.

However, CMS has no burden of coming forward with facts showing a continuing state of noncompliance after the April survey. A finding of noncompliance by a facility establishes a presumption of continuing noncompliance until CMS determines that the facility has re-attained compliance or until the facility proves by the preponderance of the evidence that it has done so. Here, Petitioner has offered no facts to show that it corrected its noncompliance with the three participation conditions that I discuss at Findings 1, 2, and 3 of this decision, prior to July 7, 2006, the date on which CMS determined that Petitioner had re-attained compliance.[3]

/s/

Steven T. Kessel
Administrative Law Judge

[3] If Petitioner corrected one or two of the three deficiencies prior to July 7 the remaining uncorrected deficiency would, standing alone, justify imposition of denial of payment for new admissions.