

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NURSING HOME ENFORCEMENT:
APPLICATION OF
MANDATORY REMEDIES**



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E X E C U T I V E S U M M A R Y

OBJECTIVE

To determine the extent to which the Centers for Medicare & Medicaid Services (CMS) applied the statutorily required “mandatory remedies” for nursing homes not in compliance with Federal quality of care standards.

BACKGROUND

The Omnibus Budget Reconciliation Act of 1987 established a survey and certification process to maintain Federal standards in nursing homes certified for participation in the Medicare and/or Medicaid programs. CMS contracts with States to certify compliance by surveying facilities. When facilities are found to be out of compliance for designated time periods or have deficiencies that are considered to put residents in immediate jeopardy, States are required to refer case information to CMS for enforcement action. Mandatory remedies are enforcement actions that CMS is statutorily required to take to address these particularly egregious or extended cases of noncompliance. Mandatory remedies include termination of the facility’s Medicare contract and the denial of payment for new admissions (DPNA). CMS depends upon the States to inform its regional offices when enforcement action is warranted in time for the regional offices to take action. Therefore, CMS evaluates State performance annually using criteria that measure States’ effectiveness in referring, in a timely manner, cases that require imposition of remedies.

For this inspection, we reviewed all nursing home enforcement cases that required termination in 2000-2002 and all cases that required DPNA remedies in 2002. We also evaluated State Performance Review (SPR) data for 2002-2004 and conducted interviews with State and CMS staff.

FINDINGS

Of the 55 cases requiring termination during 2000-2002, CMS did not apply the mandatory remedy as required in 30 cases (55 percent).

CMS is required to terminate nursing homes that fail to return to “substantial compliance” within 6 months, or have unabated immediate jeopardy deficiencies for 23 days. We found that 23 cases that required termination because they were noncompliant for 6 months were not terminated; these facilities returned to compliance on average 17 days after the termination should have been applied. Seven cases with unabated immediate jeopardy deficiencies were not terminated; these

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facilities removed the immediate jeopardy within 7 days after the termination should have been applied.

Through reviews of surveys following our study period, we found that all of the facilities not terminated had, in subsequent surveys, new cases of noncompliance serious enough to again require referral to CMS for enforcement action. Reasons for not terminating include late referral by States and reluctance by CMS staff to take action that would result in removing residents from the facility.

Of the 706 cases requiring DPNA remedies in 2002, 28 percent were never applied and 14 percent were applied late, largely due to late referral of cases by State survey agencies. CMS is required to apply the DPNA remedy for facilities that fail to return to substantial compliance within 3 months. In those instances for which the mandatory remedy was never applied, the facilities were out of compliance an average of 19 days past the required date to begin denying payments. In those instances in which the mandatory remedy was applied late, the facilities were out of compliance an average of 40 days past the required date to begin denying payments. In both situations, facilities were allowed to receive payment past the required date.

In addition, in 95 percent of cases for which mandatory DPNA was handled inappropriately, States did not refer cases to CMS on time. CMS's SPRs also found late case referral by States. In 2002, our primary study period, the SPR data showed that 38 of the 48 States that had cases requiring the DPNA did not meet the SPR standard of referring 95 percent of these cases on time. After CMS eased the standard in 2003 and again in 2004, 24 States still did not meet the performance standard regarding timely completion of these referral tasks in 2003, and 10 States did not meet the current standard of referring 80 percent of their cases on time in 2004.

RECOMMENDATIONS

CMS should ensure that facilities facing termination either reach compliance or are terminated within required timeframes. This effort could include encouraging State survey agencies to further prioritize termination cases, raising awareness of termination deadlines among CMS and State staff, and special monitoring of pending termination cases by CMS regional offices.

CMS should address late referral of enforcement cases by States to ensure that mandatory remedies are applied as required. CMS should issue a written directive to States to reinforce referral requirements, increase monitoring of State referral timeliness using shared data systems, and promote stronger adherence to the SPR standards regarding case referral. CMS should also strongly consider raising the SPR standards for timely case referral.

AGENCY COMMENTS

While CMS agrees that enforcement and the timely remedy of identified problems in nursing homes are very important, it did not concur with all of our recommendations. In its comments, CMS identifies efforts recently underway or soon to be implemented to address timeliness issues. However, contrary to our recommendation regarding facility termination, CMS notes that it does not expect to make a great deal of change with respect to its implementation of this remedy. Instead, it will continue to apply the remedy in a manner that it believes best protects the well-being of residents.

OFFICE OF INSPECTOR GENERAL RESPONSE

We recognize that since this inspection concluded, CMS has taken a number of positive steps toward ensuring that deadlines are met. However, we are concerned about CMS's implied interpretation that the deadlines for mandatory termination are flexible. While exceptional cases may exist, the 6-month termination requirement is statutory and the 23-day termination is in current regulation. We believe that CMS, through active case management and earlier intervention, can motivate improvements and lasting corrections within the required timeframes for termination of facilities.

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OBJECTIVE

To determine the extent to which the Centers for Medicare & Medicaid Services (CMS) applied the statutorily required “mandatory remedies” for nursing homes not in compliance with Federal quality of care standards.¹

BACKGROUND

This inspection is part of the Office of Inspector General’s (OIG) ongoing evaluation of the quality of care provided to nursing home residents, particularly as measured by CMS’s enforcement of survey deficiencies.

Enforcement Process

Titles 18 and 19 of the Social Security Act (the Act), as amended by the Omnibus Budget Reconciliation Act of 1987, establishes a survey and certification process to verify that Federal standards are maintained in Medicare and/or Medicaid certified nursing homes. The Secretary of the Department of Health and Human Services, through CMS, is responsible for assuring that these requirements and their enforcement “are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys.”² To accomplish this, CMS contracts with State agencies to survey each participating facility no less than once every 15 months to certify compliance.³ Additional surveys are also used to investigate complaints from residents, their families, or the general public.

Deficiencies identified during a survey are evaluated against a set of factors to determine a scope and severity rating.⁴ CMS created the Scope and Severity Grid (Table 1) so that deficiencies could be ranked in accordance with outcomes, such as harm to patients and prevalence.⁵ The scope and severity level of the highest deficiency is considered in conjunction with the facility’s compliance history to determine the appropriate enforcement actions.⁶

The Act lists several remedies that may be applied when a facility is not in “substantial compliance” with the requirements for participation in the Medicare and Medicaid programs.⁷ A facility is not in substantial compliance if the survey finds deficiencies that pose immediate jeopardy, actual harm, or potential for more than minimal harm to patients.⁸ The shaded portion of Table 1 comprises an additional severity category,

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“substandard quality of care.” This includes deficiencies in resident behavior and facility practices, quality of life, and quality of care.⁹

Table 1			
Scope and Severity Grid for Deficiencies			
Deficiency Severity			
	Isolated	Pattern	Widespread
Actual or potential for death or serious injury (immediate jeopardy)	J	K	L
Actual harm that is not immediate jeopardy	G	H	I
Potential for more than minimal harm	D	E	F
Potential for minimal harm, substantial compliance exists	A	B	C

Source: CMS State Operations Manual, Chapter 7.

To initiate the Act’s enforcement requirements, States must refer enforcement cases to CMS regional offices.¹⁰ An enforcement “case” includes all enforcement activity with respect to a particular facility during a continuous period of noncompliance. Once the State refers a case, CMS determines what enforcement actions are warranted for each case. In addition to mandatory remedies, CMS may choose to apply discretionary, or optional, remedies such as civil money penalties.

Mandatory Remedies

“Mandatory remedies” are enforcement actions that the Act requires CMS to use to address particularly egregious or extended cases of noncompliance.¹¹ For these cases, the Act sets forth the types of remedies that must be applied. For purposes of this report, we use the term “applied” to indicate the action of putting mandatory remedies into effect.

The four circumstances that require mandatory remedies and the remedies that must be applied are as follows:

Immediate Jeopardy. If, within 23 days of the initial finding, a facility fails to eliminate a deficiency deemed to pose immediate jeopardy or fails to reduce the deficiency to the point that it no longer poses a threat of actual harm, CMS must either *terminate* the facility’s Medicare contract or appoint a temporary manager to remove the immediate jeopardy and

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correct the deficiencies.¹² To terminate a facility in this circumstance, the State must refer the case to CMS within 2 days of the finding of immediate jeopardy, conduct a revisit to determine whether the jeopardy was abated, and report its finding to CMS. If the immediate jeopardy condition is not abated, CMS must notify the facility 2 days prior to the termination.¹³

Three Months of Noncompliance. For all facilities that fail to reach substantial compliance within 3 months after the initial deficiency, CMS must apply the mandatory denial of payment for new admissions (DPNA) remedy.¹⁴ Before CMS can apply this remedy, the State must conduct a revisit, and if the facility is still out of compliance, refer the case to CMS. CMS must then notify the facility 15 days prior to application of the remedy, which should occur at the end of the 3-month period.¹⁵

Six Months of Noncompliance. For all facilities that fail to reach substantial compliance within 6 months after the initial deficiency, CMS is required to *terminate* the Medicare contract.¹⁶ This type of case arises when the facility still has not reached compliance after application of the required DPNA at 3 months. To terminate a facility in this circumstance, the State must conduct a revisit, and if the facility is still out of compliance, refer the case to CMS. CMS must then notify the facility 15 days prior to the termination, which should occur at the end of the 6-month period.¹⁷

Repeated Substandard Quality of Care. For all facilities found to have provided substandard quality of care on the last three consecutive standard surveys, CMS must apply the remedies of DPNA and State monitoring of the facility.¹⁸ Additionally, the State must notify the attending physician of each affected resident and the State licensing board.¹⁹ To apply the DPNA, the State must refer the case to CMS following the third finding of substandard quality of care. CMS must then notify the facility 15 days prior to application of the remedy.

Timely Notice to Facilities

CMS must notify nursing homes prior to applying a mandatory remedy.²⁰ For immediate jeopardy cases, notice must occur at least 2 days prior to applying the remedy. For all other cases requiring mandatory remedies, notice must be sent 15 days prior to applying the remedy, e.g., on day 75 for 3 months of noncompliance.

CMS must receive a case referral from the State survey agency in sufficient time prior to the notice period to apply the remedies on time. States must also notify facilities that they have referred the case to CMS and that a particular remedy is mandated. The CMS central office policy

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allows CMS regional offices to approve the State sending a letter that serves as the “official” notice to facilities.²¹

To meet referral deadlines for mandatory DPNA cases specifically, the State Performance Review (SPR) standards in effect during our study period required States to conduct a revisit within 60 days of the initial finding of noncompliance.²² If the revisit reveals that the facility is still noncompliant, in accordance with the SPR, States must refer the case information to CMS within 70 days of the initial finding of noncompliance. Adherence to this timeframe provides CMS with 5 days to send the 15-day notice to facilities (75th day) prior to applying the DPNA on the 90th day of noncompliance.

Applying Mandatory Remedies Late

Based on CMS central office managers’ interpretation of the regulation, as reported in interviews, mandatory remedies can still be applied when CMS regional offices are late in providing notice but only if both of the following criteria are met: (1) the required 2-or 15-day notice was ultimately sent and the notice period has elapsed; and (2) the facility is still out of compliance when the notice period has elapsed. Therefore, mandatory remedies cannot be applied retroactively in cases in which the facility reaches substantial compliance before CMS applies the remedy.²³ In such cases, CMS can still choose to apply a civil money penalty.

State Performance Review

CMS evaluates State survey agency performance in nursing home enforcement by using criteria based in regulation and contained within the SPR.²⁴ The SPR includes three particular measures that are relevant to this inspection:

Timeliness of Referral of Unabated Immediate Jeopardy Cases.²⁵ To meet the expected performance level, States must refer cases within 2 days of an immediate jeopardy deficiency finding and follow all necessary procedures to ensure terminations can occur within the 23-day timeframe in 95 percent of cases in which facilities fail to remove the immediate jeopardy deficiency.²⁶

Timeliness of Referral and Notification in DPNA Cases. During our study period of 2002, State agencies were required to conduct facility revisits by the 60th day of noncompliance, and either send deficiency information to CMS or send an approved notice of the remedy to the facility within 70 days of the end of the survey for 95 percent of cases. Therefore, a

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typical case requiring the DPNA might unfold as follows: the State refers the case on the 70th day, giving CMS up to 5 days to send the facility notice (75th day), which would allow the facility 15 days notice prior to imposing the DPNA within the time required (90th day). In 2003, CMS changed the SPR criteria for referring DPNA cases by lowering the requirement from 95 percent to 80 percent of cases referred on time.²⁷ In 2004, CMS changed the standard further by omitting the requirement that States conduct facility revisits by the 60th day of noncompliance.²⁸

Timeliness of Referral of 6-month Noncompliance Cases. State agencies must follow appropriate termination procedures for 80 percent of applicable cases.²⁹ This requires sending deficiency information to CMS or sending an approved notice of the remedy to the facility within 70 days, allowing for the required 15-day notice period. Therefore, a typical case requiring termination for 6 months of noncompliance might unfold as follows: the State refers the case on the 160th day (70 days after the application of the DPNA on the 90th day), giving CMS up to 5 days to send the facility notice (165th day), which would allow the facility 15 days notice prior to termination within the time required (180th day).

Data Systems

Case information is maintained through data systems shared by CMS and States. Traditionally, CMS has used the Online Survey, Certification, and Reporting (OSCAR) system to record the results of standard, complaint, and revisit surveys. More recently, CMS has employed the Automated Survey Processing Environment (ASPEN), which allows States and CMS to input and access both survey results and enforcement information. State surveyors enter survey findings into a local ASPEN database, then upload the data into a central ASPEN system (and also into OSCAR). Enforcement case information in ASPEN is accessible to CMS regional office staff through the ASPEN Enforcement Module (AEM), implemented in October 2004. The AEM includes several reporting functions that facilitate case monitoring, including reports focused on the DPNA remedy.

METHODOLOGY

Following preliminary analysis of enforcement data, we narrowed the scope of our inspection to focus on the most common circumstances and remedies. This report addresses the three most common circumstances warranting mandatory remedies (immediate jeopardy, 3 months of continued noncompliance, and 6 months of continued noncompliance). We excluded from our review cases of repeated substandard quality of care because only a few occur each year. This study also does not examine cases for which only discretionary remedies were used, those that States failed to refer to CMS for enforcement, or Medicaid-only cases.

For this inspection we reviewed CMS data for all enforcement cases that began in calendar years 2000, 2001, and 2002 to identify cases that required mandatory remedies. We found 55 cases warranting termination during the study period and 2,140 cases warranting mandatory DPNA remedies. We reviewed all 55 termination cases and limited our analysis of mandatory DPNA cases to the 706 cases begun in 2002. We then collected documentation for all cases for which data indicated that CMS did not apply remedies as required, and interviewed CMS regional and central office staff regarding procedures for applying mandatory remedies. To verify our findings regarding State referral of enforcement cases, we evaluated all State Agency Performance Evaluation records for 2002 and for its successor, the SPR, in 2003 and 2004. Because we analyzed all cases and not a sample, all data reported within this report represent actual cases, not estimates or projections. A detailed methodology is included in Appendix A.

Standards

We conducted this inspection in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

► FINDINGS

CMS did not terminate the facility in 30 of the 55 cases requiring termination during our study period of 2000–2002

CMS must terminate facilities that remain out of substantial compliance for more than 6 months or do not remove an immediate jeopardy deficiency within 23 days. Few

facilities warranted termination during our study period. However, termination did not occur in 30 of the 55 cases in which it was required (55 percent). Twenty-three of the thirty cases involved facilities that were out of substantial compliance for 6 months, and the other seven cases involved facilities that had not succeeded in removing immediate jeopardy deficiencies within 23 days.

Reasons for not terminating as required include late referral by States and CMS staff reluctance to displace facility residents

While we are not able to determine the exact cause of CMS's failure to terminate in each case, several factors appear to contribute to the lack of action. In a number of cases, States did not refer cases to CMS sufficiently in advance of the required date and the facilities were allowed to return to compliance late. States referred cases late in 5 of the 7 immediate jeopardy cases and in 4 of the 23 6-month noncompliance cases. Even when referrals were timely, CMS staff reported that procedural delays could occur for a number of reasons, such as the handling of cases by multiple staff members.

Also, some CMS regional office staff reported that, in their reluctance to displace residents, they might opt to delay termination if they believed the facility would soon come back into compliance. Indeed, facilities that CMS did not terminate as required did return to compliance shortly after the date they should have been terminated. The 23 cases that were not terminated after continued noncompliance returned to substantial compliance an average of 17 days after the 6-month mark, and all 7 cases that were not terminated after uncorrected immediate jeopardy deficiencies reached compliance within 7 additional days.

All facilities not terminated were found to be out of compliance again

For the 29 facilities involved in the 30 cases that were not terminated as required, we reviewed all available subsequent surveys through May 31, 2005. We found that all of the facilities that were not terminated had new cases of noncompliance serious enough to again require referral to CMS for enforcement action, including cases of extended noncompliance and immediate jeopardy to residents. Ten of the twenty-nine facilities were subsequently cited with immediate jeopardy deficiencies, and in one case the facility was cited with an immediate jeopardy deficiency four

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times in consecutive years. Additionally, many of the facilities required referral to CMS multiple times—14 of the 29 facilities had deficiencies that warranted referral to CMS in 3 or more subsequent surveys.

Of the 706 DPNA cases in 2002, 28 percent were never applied and 14 percent were applied late, due largely to late referral by States

CMS must apply the DPNA for facilities that fail to return to substantial compliance within 3 months. The remedy denies Medicare

payment for residents newly admitted while the facility is out of compliance. Delays in applying denials of payment allow facilities more time than regulation permits to return to compliance and avoid the remedy.

Forty-two percent of DPNA remedies were never applied or were applied late

Of the 706 cases in 2002 which should have received a DPNA remedy, CMS applied the remedy on time in 58 percent of cases. CMS never applied the remedy in 28 percent of cases; these facilities came back into compliance after the required date, but before CMS took action. The facilities were out of compliance an average of 111 days (19 days past the required 3-month effective date of the remedy), allowing the facilities the opportunity to erroneously receive payment for newly admitted residents during the interim period.³⁰ In the remaining 14 percent of cases, the facilities were still out of compliance when CMS acted to put the remedy into effect, so the required DPNA was applied late. These late remedies were applied after an average of 132 days of noncompliance (40 days past the required 3-month effective date of the remedy) also allowing the facilities the opportunity to erroneously receive payment.

Despite not applying this remedy on time in 42 percent of the cases, CMS and State staff reported in interviews that they consider denial of payment to be a very effective tool in enforcing nursing home standards. Staff reported that, unlike other remedies such as civil money penalties, denial of payment can cause facilities to turn away new residents and is therefore likely to affect the image of the facility in the community and among medical facilities that may refer clients.

Late referral of cases by States was the primary cause when DPNA remedies were never applied or were applied late

In the 196 cases for which the DPNA was never applied, facilities returned to compliance after the deadline but before notice was sent or the notice period had elapsed. Case documents showed that late referral by States caused delays in 92 percent of these cases (Table 2).

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Referrals in these cases were sent an average of 28 days late, with the latest case sent 101 days after the required date.³¹ For the remaining 8 percent of cases, States referred the cases on time, but CMS regional offices still did not apply the mandatory DPNA remedies. In interviews, CMS staff reported a number of possible problems, including notice letters not sent to facilities and staff turnover interrupting case tracking.

In the 102 cases for which the DPNA was applied late, the facilities were still out of compliance when the case was referred to CMS by the State. Late referral by State survey agencies was a cause of delay in 97 percent of these cases. Referrals in these cases were sent an average of 18 days late, with the latest case sent 82 days after the required date.³² Once CMS received referrals from States for these cases, it began the DPNA remedy after the required 15-day notice period to facilities.

Table 2	
DPNA Remedies Never Applied or Applied Late	
Reasons for Never Applying	196 Cases
Late referral by State	92%
- <i>Late referral by State the only reason</i>	- 87%
- <i>Late action by both State and CMS regional office</i>	- 5%
Late action by CMS regional office only	8%
Reasons for Applying Late	102 Cases
Late referral by State	97%
Late action by CMS regional office	3%

Source: OIG analysis of 706 cases warranting DPNA remedy in 2002.

State staff were not able to document a cause for all late referrals in 2002, but a late revisit by surveyors to the facility was the cause mentioned most frequently by staff during case reviews and interviews. Other, less prominent, causes for late referral reported by State or CMS regional office staff include transmission errors when referrals are made electronically, insufficient survey documentation that requires States to resubmit case information, and State staff misunderstanding regarding referral requirements.³³ Two CMS regional offices reported ad hoc efforts to track referrals through the ASPEN system, but no regional offices reported routine, comprehensive monitoring of current enforcement cases to determine if referrals were made by States when required.

F I N D I N G S

State Performance Reviews by CMS confirm that States have problems referring enforcement cases on time

The SPR data for 2002 reveals that 38 of the 48 States that had cases warranting a mandatory DPNA remedy did not meet the standard for timely referral of cases.³⁴ In 2002, the SPR protocol required States to conduct a revisit of facilities by the 60th day of noncompliance, then to either send deficiency information to CMS or send an approved notice of the remedy to the facility by the 70th day. To meet this standard, States had to accomplish these tasks in 95 percent of cases warranting a mandatory DPNA remedy.

Despite easing these SPR standards in 2003 and 2004, CMS reviews still found a substantial number of States to be underperforming.³⁵ In 2003, 24 States did not meet the standard for timely case referral although CMS lowered the standard from 95 percent to 80 percent of applicable cases. In 2004, 10 States still did not meet the performance standard although CMS further changed it by requiring only that States refer 80 percent of cases by the 70th day and omitting the requirement to conduct revisits within the 60th day of noncompliance.³⁶

While the variable SPR standards make it inappropriate to compare State performance across 2002-2004, it is evident that some States continue to have problems with late referrals, and that even States passing the current SPR standard could have late referrals in up to 20 percent of cases. CMS has the ability to impose a variety of remedies and sanctions on States that fail SPR criteria; yet six States failed the criteria for referral timeliness in all 3 years we reviewed without CMS seeking any remedies or sanctions.³⁷

► R E C O M M E N D A T I O N S

Timely application of mandatory remedies encourages facilities to achieve and sustain compliance with Federal quality standards and is essential to CMS efforts to address noncompliance. However, facility terminations did not occur as required in 55 percent of cases in 2000-2002, due to both late case referral by States and CMS staff reluctance to impose this severe remedy. All of these facilities were later referred to CMS for new findings of noncompliance or immediate jeopardy. CMS also did not apply the DPNA as required in 42 percent of cases in 2002. Late referral of enforcement cases caused nearly all errors in applying mandatory DPNA remedies. These errors allowed facilities the opportunity to receive payment by Federal programs while out of compliance with resident care standards.

To address these issues, OIG recommends the following:

CMS should ensure that all facilities facing termination either reach compliance or are terminated within required timeframes

To strengthen its effectiveness in addressing these egregious or extended cases of noncompliance, CMS should focus attention on termination cases to better ensure that facilities reach compliance by the required date, or, failing that, are terminated as required. This effort could include encouraging State survey agencies to further prioritize termination cases, raising awareness of termination deadlines among State and CMS staff, and conducting special monitoring of pending terminations.

CMS should address late referral of nursing home enforcement cases by States to ensure that mandatory remedies are applied as required

Guidance to States. CMS should make addressing the timely referral of enforcement cases an organizational priority. CMS should issue a program transmittal or other written guidance to reinforce for States the Federal requirements for referring enforcement cases on time. This directive should emphasize completing revisits on time, which was identified as a common cause of late referral.

Routine Monitoring. CMS should actively monitor pending nursing home enforcement cases. In interviews, no CMS regional office reported routine use of ASPEN to monitor enforcement case referrals from States. To accomplish this, CMS should make full use of the monitoring capabilities of the ASPEN data management system. According to CMS staff, the ASPEN system allows input and access by CMS central office, its regional offices, and States, and includes enforcement case information in its ASPEN enforcement module. Proactive use of ASPEN to monitor current

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enforcement cases would allow regional offices to address problems with specific cases before it is too late to take action.

CMS regional offices should regularly utilize the reporting functions available in ASPEN, including reports that can identify cases approaching the DPNA deadlines. In addition, CMS should consider developing an automated function in ASPEN that alerts both CMS caseworkers and State staff when cases have reached the 70th day of noncompliance. Such an automated alert or indicator would serve as a reminder to State staff to refer the case and as a prompt for CMS staff to ask States if they have sent the expected case documentation. Finally, ASPEN allows CMS staff to review survey data online at any time, including before a case is referred to the regional office. While not practical in every case, this access could allow CMS staff to monitor the status of facilities with particularly troublesome histories.

Use of State Performance Review. As part of the effort to address late referrals, CMS should also promote stronger adherence to the SPR standards. The SPR provides a potentially valuable tool for enforcing State referral requirements, yet it is evident that some States have continued to have problems with late referrals well after the time period of our primary analysis (2002). CMS regional offices should fully enforce the case referral standards contained in the SPR, including employing the prescribed remedies and sanctions when States fall below the SPR standards for timely referral. CMS should also consider focusing efforts on underperforming States.

Finally, we believe that recent changes in the SPR standards regarding referral timeliness make the SPR a less effective tool for identifying States with problems referring cases. Currently, States could refer up to 20 percent of cases late, yet still pass the SPR standard. Considering that late referrals are the primary cause when CMS does not apply DPNA remedies as required, the SPR should promote a higher level of State performance regarding this critical function. By restoring the performance standard to 95 percent, CMS could further draw State attention to correcting the problem, while still allowing for late referrals under exceptional circumstances.

AGENCY COMMENTS

While CMS agrees that enforcement and the timely remedy of identified problems in nursing homes are very important, it did not concur with all of our recommendations.

In its comments, CMS identifies efforts recently underway or soon to be implemented to address timeliness issues. First, CMS affirms that the new ASPEN Enforcement Management System has improved its ability to manage enforcement cases resulting in more mandatory DPNAs being implemented timely. Additional changes to the State performance standards and the strengthening of the Special Focus Facility program signal the importance CMS places on nursing home quality of care. CMS plans to begin a new internal triage review geared to strategically assess individual cases at the 5-month point to identify any additional actions that might help bring a facility back into compliance before the termination deadline. CMS will also test a process to streamline the required notification process to alleviate the difficulties associated with timely implementation of the mandatory denial of payments for new admissions.

Contrary to our recommendation regarding facility termination, CMS notes that it does not expect to make a great deal of change with respect to its implementation of this remedy. Instead, it will continue to apply the remedy in a manner that it believes best protects the well-being of residents. CMS cited specific difficulties in meeting the 6-month timeframe for termination. These include new unrelated deficiencies identified during the survey just prior to the termination date, the desire to both meet the 15-day public notice requirement and to maximize the facility's opportunity to achieve compliance, and retention of the benefit of what it terms the "crisis environment" in the final hours before termination. CMS argues that imminent termination is instrumental in making positive reforms by causing the facility to apply more resources to correct deficiencies that led to termination.

The full text of CMS's comments is presented in Appendix B.

R E C O M M E N D A T I O N S

OFFICE OF INSPECTOR GENERAL RESPONSE

We recognize that since this inspection concluded, CMS has taken a number of positive steps toward ensuring that deadlines are met. These new steps, in addition to the planned actions, should assist CMS in meeting the mandatory enforcement requirements on time in future cases. However, we are concerned about CMS's implied interpretation that the deadlines for mandatory termination are flexible. While exceptional cases may exist, the 6-month termination requirement is statutory and the 23-day termination is in current regulation. Consequently, we see no room for discretion in the application of this remedy.

CMS supported its position on two fundamental grounds: (1) that it is difficult to meet all scheduled timeframes and provide all reasonable opportunities for the facility to achieve compliance prior to termination and (2) that termination would be unnecessarily detrimental to the nursing home residents, particularly when compliance was achieved shortly after the termination deadline.

First, we believe that actions similar to those CMS plans to implement for mandatory denials of payment, combined with active case management can reduce the number of missed deadlines in termination cases. For example, notification requirements can be streamlined so that they do not impede surveyors' abilities to conduct a final revisit. Additionally, CMS can maintain the benefits of the "crisis environment," which it believes promotes corrective action, by beginning sooner in the process to make it clear to facilities that decisive action will be taken. Second, we believe the pattern of noncompliance observed for the facilities that achieved compliance after the deadline, and thus were not terminated as required, deserves attention. One facility in this inspection that received additional time to achieve compliance was cited with an immediate jeopardy deficiency in each of its next four consecutive surveys. Nine others were cited with immediate jeopardy deficiencies during their very next survey.

Given these considerations, we believe that CMS, through active case management and earlier intervention, can motivate improvements and lasting corrections within the required timeframes for termination of facilities.

► E N D N O T E S

¹ While the Social Security Act (the Act) does not use the term “mandatory remedies,” CMS and the States use this term to distinguish between those remedies that must be imposed under certain circumstances and those remedies that CMS has the discretion to impose.

² The Act, § 1819(f)(1).

³ 42 CFR §§ 488.308 and 488.330.

⁴ 42 CFR §§ 488.404, 488.406, and 488.408; Department of Health and Human Services, Centers for Medicare & Medicare Services, State Operations Manual (SOM), Chapter 7, § 7400E1 (2004).

⁵ The SOM, Chapter 7, § 7400E1.

⁶ 42 CFR § 488.404.

⁷ The Act, §§ 1819(h) and 1919(h). See also 42 CFR §§ 488.400, 488.406, and 488.408, and the SOM, Chapter 7, § 7400A.

⁸ 42 CFR § 488.301.

⁹ “Substandard quality of care means one or more deficiencies related to participation requirements under § 483.15, Quality of life, or § 483.25, Quality of care of this chapter, which constitute either immediate jeopardy to resident health or safety; a pattern of widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.” 42 CFR § 488.301.

¹⁰ While there are circumstances in which an enforcement action can be referred to the State Medicaid agency, e.g., cases involving Medicaid-only facilities, this study examined only those cases in which the enforcement action was referred to CMS. CMS guidelines set forth three case types for referral: (1) immediate jeopardy cases, (2) cases in which facilities are not given an opportunity to correct, but do not involve immediate jeopardy, and (3) opportunity to correct cases which have failed to achieve subsequent compliance. The SOM, Chapter 7, §§ 7308A, 7316A, and 7316B.

¹¹ The Act, §§ 1819(h)(1)(A), 1819(h)(2)(D), 1819(h)(2)(C), and 1819(h)(2)(E).

¹² 42 CFR § 488.410(a), the SOM, Chapter 7, § 7301A.

¹³ The SOM, Chapter 7, §§ 7305B(3)(a) and 7309A.

¹⁴ The Act, § 1819(h)(2)(D); 42 CFR §§ 488.412(c) and 488.417(b); the SOM, Chapter 7, §7506C

¹⁵ The remedy is to be applied at the end of 3 full months, rather than after a certain number of days. For example, if the deficiency is cited on January 1, the denial of payment should be applied on April 1. “Policies about Verification of Compliance and Setting 3-and 6-month Remedy Effective Dates,” Memorandum S&C01-10, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, 2001.

¹⁶ The Act, § 1819(h)(2)(c); 42 CFR §§ 488.412(a) and (b); the SOM, Chapter 7, § 7556C

¹⁷ 42 CFR §§ 488.402(f)(4) and 488.456(c)(2); the SOM, Chapter 7, § 7305B3(b)

¹⁸ The Act, § 1819(h)(2)(E); 42 CFR §§ 488.414(a) and 488.417(b)(2). Certain types of deficiencies may not fall within the definition of substandard quality of care because they do not relate to resident behavior and facility practices or quality of life or quality of care.

¹⁹ The Act, § 1819(g)(5)(C); 42 CFR § 488.410(e).

²⁰ 42 CFR § 488.402(f).

²¹ The [CMS] regional office or State Medicaid agency must provide formal notice of the remedies imposed unless official notice has already been provided by the State, as authorized by CMS and/or the State Medicaid agency. The SOM, Chapter 7, § 7316B(4).

²² Centers for Medicare & Medicaid Services, Survey and Certification Group, Center for Medicaid and State Operations, “State Agency Performance Standards for Fiscal Year 2002,” (Standard 4, Emphasis B), REF: S&C-02-28 and “State Agency Performance Standards for Fiscal Year 2003,” (Standard 4, Emphasis B), REF: S&C-03-27.

²³ To understand this interpretation of policy, CMS staff in interviews pointed to the following two regulations: 42 CFR § 488.417(d) states that

“ . . . [w]hen a facility does not have repeated instances of substandard quality of care, payments to the facility or, under Medicaid, CMS payments to the State on behalf of the facility, resume prospectively on the date that the facility achieves substantial compliance, as indicated by a revisit or written credible evidence acceptable to CMS (under Medicare) or the State (under Medicaid) . . . ” and 42 CFR §§ 488.402(f)(3) and (4) state that “ . . . for all remedies imposed when there is immediate jeopardy, the notice must be given at least 2 calendar days before the effective date of the enforcement action.” and “ . . . notice must be given at least 15 calendar days before the effective date of the enforcement action in situations in which there is no immediate jeopardy.” CMS staff explained that mandatory remedies therefore (1) cannot be applied to facilities that are in substantial compliance, and (2) cannot be applied without proper notice.

²⁴ The Act, § 1864, Article II(J); the SOM, Chapter 8, §§ 8000C and 8000D.

²⁵ Immediate jeopardy deficiencies that are downgraded to a scope and severity level below immediate jeopardy upon citation are considered “abated” and are not subject to these referral guidelines. Some CMS regional offices request that States refer all immediate jeopardy cases, and may choose to apply discretionary remedies, even in cases that were fully corrected.

²⁶ OIG analysis of the SPR results revealed that in 2004, 31 of the 33 States (94 percent) that had unabated immediate jeopardy cases met the standard of 95 percent referral as required.

²⁷ Centers for Medicare & Medicaid Services, Survey and Certification Group, Center for Medicaid and State Operations, “State Agency Performance Standards for Fiscal Year 2002,” (Standard 4, Emphasis B), REF:S&C-02-28 and “State Agency Performance Standards for Fiscal Year 2003,” (Standard 4, Emphasis B), REF: S&C-03-27.

²⁸ Centers for Medicare & Medicaid Services, Survey and Certification Group, Center for Medicaid and State Operations, “State Agency Performance Standards for Fiscal Year 2003,” (Standard 4, Emphasis B), REF: S&C-03-27 and “FY 2004 State Performance Review Protocol Guidance,” (Standard 4, Emphasis B), REF: S&C-04-47.

²⁹ Centers for Medicare & Medicaid Services, Survey and Certification Group, Center for Medicaid and State Operations, “State Agency Performance Standards for Fiscal Year 2003,” (Standard 4, Emphasis B), REF: S&C-03-27

and “FY 2004 State Performance Review Protocol Guidance,” (Standard 4, Emphasis B), REF: S&C-04-47.

³⁰ Denial of payment for new admissions is to be applied at the end of 3 full months. (“Policies about Verification of Compliance and Setting 3- and 6-month Remedy Effective Dates,” Memorandum S&C01-10, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, 2001.) We used 92 days for calculating expected application dates.

³¹ Due to incomplete data, average and maximum referral times are based on 171 of the 196 cases in which denial of payment was never applied.

³² Due to incomplete data, average and maximum referral times are based on 75 of the 102 cases in which denial of payment was never applied.

³³ Timeliness is not the only problem with the State referral process. In the report, “State Referral of Nursing Home Enforcement Cases” (OEI-06-02-00400), OIG found that while States referred most nursing home cases warranting enforcement during the study period, an estimated 8 percent of cases were not referred. Primary causes of nonreferral included State staff misunderstanding referral requirements and attempted referrals that were not recognized as such by CMS staff.

³⁴ OIG analysis of the 2002 State Agency Performance Evaluation results provided by CMS regional offices.

³⁵ OIG analysis of the 2003 and 2004 State Performance Review results, provided by CMS central office.

³⁶ OIG analysis of the SPR results includes 50 States and the District of Columbia for a total of 51.

³⁷ These potential remedies and sanctions include submitting a corrective plan of action, undergoing supplemental training, meeting with State officials, and ultimately, facing reductions in Federal financial participation and even the termination of their contract to survey facilities. The SOM, Chapter 8, § 8000G, (2004).



Detailed Methodology

We reviewed all nursing home enforcement cases that began in calendar years 2000, 2001, and 2002 to identify those that required mandatory remedies as a result of one of the four statutorily required conditions: immediate jeopardy, noncompliance lasting 3 months, noncompliance lasting 6 months, or a third instance of substandard quality of care.

We identified enforcement cases from CMS's Online Survey, Certification, and Reporting (OSCAR) system, and determined enforcement activity from the Long Term Care Enforcement Tracking System (LTC). The OSCAR system contains information collected during nursing home surveys and complaint investigations conducted by State agencies. This information includes survey dates, the type of survey, cited deficiencies and the scope and severity of those deficiencies, as well as demographic and historical information about individual facilities. The LTC database is a compilation of each CMS region's nursing home enforcement case files. It contains basic facility descriptors, as well as data from all stages of the enforcement process—from receipt of a case in the CMS regional office to final disposition.

Because the LTC database includes only cases that States have referred to CMS, our analysis did not examine cases where the facility successfully corrected its deficiencies after being given an opportunity to correct or any cases not referred by States. We used State survey data from OSCAR to identify the date a deficiency was found and enforcement data from the LTC database to determine the date remedies were applied.

For immediate jeopardy cases, we reviewed scope and severity ratings in OSCAR and included any case which had not returned to compliance or been terminated by the end of the 23rd day following the first day of the survey visit. For cases requiring termination at the end of 6 months, we included those which were still out of compliance after 185 days instead of 180 days because there are 5 months which contain 31 days. Similarly, for cases requiring the DPNA remedies after 3 months, we allowed 92 days. (Because of the large number of cases requiring the DPNA remedies, we narrowed our examination to cases in 2002.) Finally, we also used OSCAR deficiency data to identify facilities that were cited for a third instance of substandard quality of care.

From this universe of cases, we identified those which required mandatory remedies. We found a total of 55 cases requiring termination. These included 20 cases in which an immediate jeopardy deficiency was identified during a survey, yet had not been corrected by the 23rd day and 35 cases for which the facility was subject to termination for failure to return to compliance within 6 months between 2000 and 2002. We initially identified 750 cases in 2002 requiring the DPNA remedies. However, 44 were exempted from the remedy as a result of settlements, informal dispute resolution, or because they were terminated from the Medicare program altogether due to other, more severe, enforcement cases, effectively sanctioning them for failing to return to compliance. This exemption reduced the number of mandatory DPNA cases for review to 706.

Once we identified the cases, we requested additional information from States and CMS regional offices about cases for which no record of the remedy existed in the data. We reviewed these cases further to confirm that they met our criteria and warranted additional analysis. We then considered additional LTC and OSCAR data elements and State and CMS responses to ensure the remedies had not been rescinded as the result of an appeal or informal dispute resolution.

Because there are many explanations for a case not facing a remedy that might not be captured in administrative databases, we also requested additional information from CMS regional offices to explain what happened with each of the cases in this subset. Further, we conducted structured interviews with CMS regional office staff to determine why required remedies were not applied.

To verify our findings regarding State referral of enforcement cases, we evaluated all State Agency Performance Evaluation records for 2002 and all records for its successor, the SPR, in 2003 and 2004.

This study does not examine Medicaid-only cases, cases for which only discretionary remedies were indicated, or those that States failed to refer to CMS for enforcement.

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: DEC 27 2005
TO: Daniel R. Levinson
Inspector General
Office of Inspector General
FROM: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

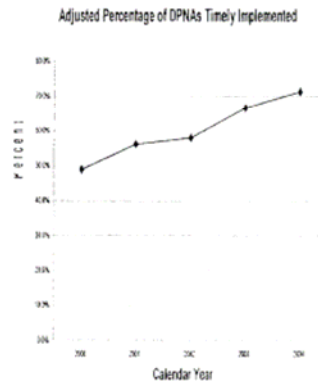
Mark B. McClellan

RECEIVED
 2005 DEC 27 10:21
 OFFICE OF THE INSPECTOR
 GENERAL
 DEPARTMENT OF HEALTH & HUMAN SERVICES

SUBJECT: Office of Inspector General (OIG) Draft Report: "Nursing Home Enforcement: Application of Mandatory Remedies" (OEI-06-03-00410)

Thank you for the opportunity to review and comment on the subject OIG draft report. The report focused on whether certain nursing home enforcement actions (terminations and denial of payment for new admissions (DPNAs)) were implemented in a timely manner.

The OIG study, while still very useful, involved a survey period (2000-2002) that pre-dated significant improvements we made in the enforcement system. The effects of such improvements are therefore not included in findings of the OIG report. Such positive results can be seen in this graph, depicting the trend line for DPNAs that were implemented in a timely manner for years 2000-2004.¹



With regard to termination of nursing homes from Medicare and Medicaid, it is worth noting that most of the nursing homes in question (ones that would otherwise have been terminated) did, in fact, achieve substantial compliance with the Medicare/Medicaid requirements shortly after the intended termination date. Those average compliance times are shown in the chart below.

Average Time to Achieve Compliance After Last Chance Due Date

Reason	# Cases	Avg. Time to Achieve Compliance After "Last Chance" Due Date
Immediate Jeopardy Not Abated within 23 Days	7	7 days
Substantial Compliance Not Achieved within 6 Months	23	17 days

¹ The percentages above were calculated using CMS' data, adjusted to match OIG's presumed edits applied to the data (the trend is the same without the adjustments).

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Had the State Agencies and Centers for Medicare & Medicaid Services' (CMS) not worked with those nursing homes up to the very last minute, thousands of nursing home residents would have been forced to relocate even though the problems were abated within a few weeks. Other legitimate concerns for the welfare of nursing home residents, as well as competing legal requirements, also mean that terminations may not be executed exactly on the date specified. We explain those considerations in more detail later in this reply.

We expect that the improvements we made in our enforcement management system, together with the new State performance standards system and related efforts, will continue to enable further progress. In particular, CMS' new ASPEN Enforcement Manager (AEM) is a comprehensive enforcement data system that allows States and regions to track and monitor all nursing home survey and enforcement activity. Unlike the previous "paper" data system, AEM is a completely electronic, real-time system that eliminates delays between the States and CMS that have occurred in the past as a result of mailing time, misplaced paperwork, etc.

Additionally, AEM is capable of generating reports which States and CMS can use to track and monitor the real-time status of any enforcement case at any time. Data collection from this new system is designed to ensure a higher rate of conformance with timely and proper imposition of mandatory sanctions.

Although the study period for the OIG report pre-dated most of the above improvements, we find that the study is still quite useful and will help us to take more actions that can advance enforcement actions. Below are some immediate, additional steps we are taking, matched with the OIG recommendations, designed to best promote the well-being of nursing home residents.

OIG Recommendation

The CMS should ensure that all facilities facing termination either reach compliance or are terminated within required timeframes.

Background to OIG Recommendation

The nursing home reform laws of 1987 require that mandatory enforcement action be taken when facilities have immediate jeopardy (IJ), uncorrected, or extended noncompliance for specified periods of time. Specifically:

- **DPNA at 3 Months:** The DPNA sanction must be imposed when a facility has not achieved substantial compliance within 3 months from a finding of noncompliance;
- **DPNA after 3 Consecutive Surveys:** The DPNA sanction and State monitoring must be imposed when a facility has provided substandard quality of care, as defined in Federal regulations at section 488.301, on 3 consecutive standard surveys. *NOTE:* Since this circumstance does not occur as frequently as the others listed above, it was excluded from this study;

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- **Termination at 6 Months:** A facility’s participation in the Medicare and Medicaid programs must be terminated when the facility has not achieved substantial compliance within 6 months from the finding of noncompliance;
- **Termination at 23 Days with Unabated IJ:** A facility’s participation in the Medicare and Medicaid programs must be terminated when the facility’s noncompliance constitutes IJ. (To accommodate the administrative activities that must occur to effectuate a termination action, CMS’ operational guidance provides that termination will occur no later than 23 days after the IJ is identified).

The OIG study found that, for 30 of 55 cases, termination was not applied within the 6-month time period. Of the 30 cases, 7 were due to failure to remedy IJ within 23 days, and 23 were due to failure to achieve substantial compliance within 6 months (or findings of new violations within that time period). As reported by OIG, the facilities that were not terminated achieved compliance shortly after the 6-month time period. For the 7 cases in which immediate jeopardy was not abated within the required 23 days, the problems were confirmed as abated within an average of 7 days later. For the 23 other facilities that did not achieve substantial compliance within the required 6 months, the additional time to achieve compliance averaged 17 days.

CMS Response

Legitimate factors often influence the timeliness of a termination action. CMS regulations require a 15-day advance notice to facilities prior to effectuating sanctions in non-immediate jeopardy cases. CMS tries to accommodate both the 15-day notice requirement and the mandatory 6-month termination requirement. The effort to ensure the 15-day prior notice sometimes leads to terminations that lapse for short periods beyond the 6-month deadline. When a final revisit just prior to termination finds a new, unexpected deficiency that prevents the facility from being in substantial compliance (even though previously-cited deficiencies were corrected), the 15-day advance publication date cannot be met and the termination will overstep the 6-month time period.

In addition, the crisis environment that surrounds the imminent termination is usually instrumental in making positive reforms; more resources are applied by the facility, improvements occur, and systemic barriers are changed. In response to these “final” hours of concentrated effort, State Survey Agencies are responsibly applying revisit energies up to the very last moment in the process. If the onsite visit indicates that the facility has achieved substantial compliance, the desired result of the pending sanction has been realized: quality is improved, the residents benefit, termination action is withheld, and resident relocation is not needed.

If, instead, the facility’s best efforts prove inadequate, due process requirements are initiated and termination is effective. The decision to perform a final revisit rather than to automatically proceed to termination is rational in most cases. While these last-minute visits can delay the issuance of the 15-day “due process” notice which informs the facility of the date of the imposition of the sanction, the OIG report also found that facilities whose terminations were not effectuated timely were able to abate the remaining quality problem(s) within days after the termination date.

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Termination of a facility from Medicare and Medicaid is a serious action that has weighty consequences for the residents. While the law requires that mandatory actions occur at specified times and under specific circumstances, it also contemplates that sanctions will be used to motivate improvements and lasting corrections. Where these expectations may be in conflict, we seek to resolve the conflict with the solution that best protects the well-being of the resident. Consequently, we do not expect a great deal of change with regard to the dates at which facilities are terminated, but we are adopting some additional techniques to sharpen the action planning at a critical “improve or terminate” time period.

CMS Action: In addition to (1) the new enforcement management system and (2) the state performance standards system that were put in place after the OIG data period, and (3) a strengthened “Special Focus Facility” program adopted in late 2004², we will also (4) institute a new internal CMS “triage review” of each case at the 5-month mark (or earlier if needed). This “triage” will be a strategic assessment of each situation to determine if any additional actions are warranted that might advance needed improvements, or if other actions are needed to protect beneficiaries in the event that the facility fails to achieve substantial compliance.

OIG Recommendation

CMS should address late referral of nursing home enforcement cases by States to ensure that mandatory remedies are imposed as required.

CMS Response

We regard the issue of untimely DPNA as the more serious of the two issues, since a DPNA at the 3-month mark can constitute an effective “heads-up” that effectively helps a facility appreciate the seriousness of the quality issues and the prospect of termination (at 6 months) if the quality problems are not resolved.

Multiple actions, including a separate notice to the facility, are usually involved when a DPNA is applied. The more steps involved, the greater the likelihood of breakdown and the greater the work burden that exacerbates CMS staff and funding shortages. For this reason we will conduct a test of a simplified communication protocol, as described below. The reason for testing the method is to identify whether there are any undesirable and unintended consequences before adopting the procedure nationally.

CMS Action: We will test an approach in which the initial notice of survey findings of deficiency includes a notice that mandatory DPNA will be instituted at 3 months of noncompliance if any issues are not resolved by that time. By guaranteeing proper advance notice in the initial conveyance of survey findings, we will avoid the need for a separate notice on the DPNA. This will assist in the timely imposition of a DPNA in cases where the facility has not come into substantial compliance within 3 months, as required by law.

² See Survey & Certification Letter S&C-05-13

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Enforcement and the timely remedy of identified problems in nursing homes are extremely important. CMS action in this area is yielding further improvement. The OIG report provides an excellent baseline to measure such improvements and suggests additional actions we can take.

► A C K N O W L E D G M E N T S

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