



Office of the Inspector General
Internal Audit

Report No. 13-06
February 2014

**Adverse Incident Report Process
Division of Health Quality Assurance
Florida Center for Health Information and Policy
Analysis**

All exempt and/or confidential information has been removed from the public version of this report. Exempt information is only available to individuals appropriate to the activity reviewed.

EXECUTIVE SUMMARY

As part of the Agency for Health Care Administration's (Agency) fiscal year 2012-2013 annual audit plan, we conducted an audit of the adverse incident reporting process within the Florida Center for Health Information and Policy Analysis (Florida Center) in the Division of Health Quality Assurance (HQA). The focus of this audit was to determine if the Agency was in compliance with applicable state laws and rules, if proper internal controls were in place to govern the reporting process and if the reporting process utilized was efficient and effective.

Overall, the Agency needs to address the following areas:

- Monitoring for timeliness of report submission from facilities for non-compliance with statutory deadlines is not adequate.
- Facilities are not fined for late reports.
- **(Removed)**
- The report referral process from the Florida Center to the Complaint Administration Unit (CAU) is not adequately documented.
- Adverse Incident reports were not reported timely or securely to the Department of Health (DOH).
- The receipt and review of litigation notices by Florida Center's Risk Management and Patient Safety office (RMPS) is not properly administered.
- Although required by current law, the receipt and review of annual reports from facilities does not appear to be a cost effective use of agency resources.
- Some Agency rules, policies and forms regarding adverse incidents are outdated and conflict with statutes and each other.

SCOPE, OBJECTIVES AND METHODOLOGY

The scope of this engagement covered the adverse incident reporting process. The audit period was the calendar year ending December 31, 2012. Our objectives were to determine if the Agency complied with applicable state laws and rules, if the proper internal controls were in place to govern the reporting process and if the process utilized was efficient and effective. To accomplish our objectives, we reviewed pertinent laws, rules, policies, procedures and a Memorandum of Understanding (MOU) between the Agency and DOH; interviewed key personnel; reviewed records; and analyzed data from the Adverse Incident Data Collection System as well as the Nursing Homes Reporting System.

BACKGROUND

Health care facilities are required to report adverse incidents to the Agency within timeframes specified by Florida law (see Table 1). Hospitals, ambulatory surgical centers (ASCs), health maintenance organizations (HMOs), assisted living facilities (ALFs), and nursing homes (NHs) are required to report adverse incidents.¹

RMPS compiles statistical information from adverse incident reports and publishes these statistics on its web page to show trends for risk management purposes. They also review these reports for completeness. Additionally, critical incident ² reports are referred to the CAU for review and potential investigation. Reports are referred to DOH for potential investigation, if the incident involved conduct by a health care professional.

Table 1: Facility Adverse Incident Report Time Requirements

Facility Type	Authority	Deadline to Report to the Agency
Hospitals and Ambulatory Surgical Centers	Section 395.0197(7), F.S.	Within 15 calendar days after the incident occurred.
Assisted Living Facilities	Section 429.23(3), F.S. Section 429.23(4), F.S.	Within one business day after the occurrence, the facility must provide a preliminary report. Within 15 days to provide a full report.
Nursing Homes	Section 400.147(7), F.S.	Within 15 calendar days after the incident occurred.
HMO's	Section 641.55(6), F.S.	Within three working days after the incidence occurred. Within ten days after the first report to file a more detailed follow-up report.

¹ The definition of an adverse incident and the deadlines for submittal differ by facility type. Appendix A outlines the different definitions of adverse incidents.

² A critical incident is defined in Finding 3. The RMPS administrator, hired in September 2012, stated that most incident reports are now referred to CAU.

FINDINGS AND RECOMMENDATIONS

Finding 1: RMPS Did Not Monitor for Timeliness of Report Submission Nor Did They Fine Facilities for Non-compliance with Statutory Deadlines

Some facilities did not submit reports within the statutory timeframes (see Table 2).

Table 2: Compliance Rates Among Facility Types

Facility Report Type	Number of Reports	Percent in Compliance	Percent Late	Percent More than 10 days late	Average Number of Days from Incident to Submission to RMPS
Hospital/ASC 15-day	46	72%	28%	17%	25 days ³
ALF 1-day	76	45%	55%	11%	5 days
ALF 15-day	54	57%	43%	13%	22 days
NH 15-day	73	84%	16%	1%	11 days

Note: Our sample consisted of all hospital/ASC, and ALF reports filed in July 2012 and all NH reports of incidents in December 2012. There were no HMO reports filed in our selected time period.

For hospital and ASC reports, 72% were submitted in compliance with Chapter 395, F.S which includes five facilities that requested extensions⁴ while 28% were filed after the required deadline of 15 days. RMPS did not take any action against the facilities that filed late.

ALFs had a lower compliance rate than the hospitals. Forty-five percent of the preliminary reports were filed within the one day deadline; 57% of their final reports were submitted within 15 days. Unlike hospital and ASC reports, the law does not allow ALFs or NHs to request an extension.

NHs had the highest compliance rate of all facility types. Eighty-four percent of NH reports were in compliance with the statutory deadline of 15 days or less while the remaining 16% were filed after 15 days.

RMPS staff did not monitor hospital and ASC reports to determine whether the reports were filed timely. Even though staff monitored ALF report submissions to determine if a 15-day report followed a 1-day report, they did not monitor whether a 1-day report was filed within one day after the incident or if a 15-day report was filed within 15 days after the filing of the 1-day report.

When a reported incident meets certain critical criteria, RMPS refers it to CAU. CAU reviews the report and determines if a complaint should be initiated and investigated. When a facility submits a report after the deadline, this delays the Agency's investigation of serious incidents as well as hinders timely referral to

³ This average excludes the reports with requested and approved extensions.

⁴ Section 395.0197(7), F.S. states "The agency may grant extensions to this reporting requirement for more than 15 days upon justification submitted in writing by the facility administrator to the agency."

DOH, if required. Timely investigation determines if the facility has taken prompt, adequate corrective action. In a sample of 38 reports referred to CAU, 16 were filed late. Ten of these reports resulted in complaints and were investigated by the HQA field office staff.⁵ The range of days from incident to receipt by RMPS for these ten reports was one day to 86 days. If these reports had been filed on time, investigations would have been initiated earlier and existing conditions that did not meet standards corrected sooner.

RMPS does not have a policy that addresses monitoring for timely submission of reports by the facilities. Although Section 395.0197(12), F.S. and Section 408.08(2), F.S. appears to authorize the Agency to fine for noncompliance with reporting requirements, RMPS did not impose fines on facilities for submitting late reports.

Recommendations

We recommend that RMPS:

1. Develop policies and procedures to monitor the timely submission of reports; and
2. Consult with the Office of the General Counsel (OGC) to determine if the Agency has statutory authority to fine facilities for submitting their adverse incident reports after the statutory deadlines and if it does have such authority, fine facilities for late report submission.

Management Response

1. RMPS has drafted two policies to address monitoring of report timeliness. Policies will be finalized by March 31, 2014.
Anticipated date of completion: No sooner than March 31, 2014
2. Facilities may be fined by surveyors for being out of compliance with reporting requirements. In such cases the RMPS unit will issue a Request for Sanction (RFS) if they fail to receive a report in a timely manner. The surveyors will cite the facility for failing to file a report for a substantiated incident that should have been reported but was not.
Anticipated date of completion: Completed

Finding #2 has been classified as exempt from public records release and/or confidential in accordance with Section 282.318(4)(f), Florida Statutes and thus is not available for public distribution.

Finding 3: RMPS Does Not Adequately Document and Track Report Referrals to CAU

RMPS written policy requires RMPS to refer a critical adverse incident report to the CAU the same day as reviewed. CAU nurse consultants then review the report and determine if it should be investigated by HQA field office staff as a complaint.

A report that must be referred to CAU on the day of the RMPS review is an incident that:

⁵ Our sample consisted of 38 hospital, ASC, ALF, and NH reports that had selected serious outcomes. The hospital, ASC and 1-day ALF sample consisted of reports filed in July of 2012 while the NH reported incidents occurred in December 2012.

- Poses an immediate and/or serious threat or danger to a patient/resident and caused or is likely to cause serious injury, serious harm, impairment or death if not corrected immediately;
- Poses a threat to the safety and well-being of the patient/resident, and the facility’s corrective action plan needs observation by field office staff to determine if it is being implemented;
- Clearly reflects a statutory or rule violation;
- Involves the death of a resident/patient; or
- Involves surgery on the wrong site, surgery on the wrong patient, wrong procedure, surgery to correct injury not covered in the informed consent, or foreign body left/removed.

We identified two concerns with this process. First, RMPS does not document the date of review on the report or other written document; thus they cannot monitor compliance with the same day policy. Second, the current referral practice does not ensure that CAU receives the reports.

The policy requires RMPS to send an e-mail alert to CAU on the same day of RMPS review to notify them of the incident report for the incidents listed above. CAU receives the e-mails and accesses the reports in Versa or the Nursing Homes Reporting System. Neither management nor our audit team could determine RPMS’s compliance with the same day policy due to the following limitations:

- While the hospital, ASC and HMO report forms had fields for the date received and reviewed by RMPS, the date reviewed field was not completed by staff;
- The ALF report form did not have a field for the date reviewed by RMPS, only for the date received; and
- The NH report form did not have fields for either the date received or date reviewed by RMPS.

If the date of review is not documented on the report, management cannot determine if the reports are referred according to policy requirements. We selected a sample of 38 reports from hospital/ ASCs, ALFs and NHs with serious outcomes to determine the number of days between RMPS receiving the report and the day the e-mail notification was received by CAU. Twelve (32%) of the 38 reports were received within the same day. The remainder were received one or more days later. Table 5 shows the results of the review.

Table 5: Number of Days between Date Received and Date Received by CAU

Type of Facility	Number of Reports Received by CAU on Same Day as Received by RMPS	Number of Reports Received by CAU between 1 day and 5 days	More than 5 days	Not Received	Total
Hospital/ASC	7	11	5	3	26
ALF 1-day	5	3	0	1	9
NH	0	3	0	0	3
Total	12 (32%)	17 (45%)	5 (13%)	4 (11%)	38

Note: May exceed 100% due to rounding. Due to form limitations, we could not determine the number of days from review by RMPS staff to referral to CAU. We used the date received by RMPS staff and date received by CAU. Our sample consisted of: hospital and ASC reports filed with the Agency in July 2012 with the outcomes of death, fetal death, surgery on the wrong site or wrong surgical procedure

used; ALF reports filed in July 2012 with the outcome of death; and NH reports where the incident occurred in December 2012 with the outcome of death. One of the four NH report was withdrawn so our sample is based on 38 reports.

Of the 38 reports, CAU did not have a record of receiving four (11%) of the e-mails. Additionally, while RMPS stated that they record a comment on the report form if referred to CAU, 5 of 38 reports did not have such a comment. There is not an electronic notification and tracking function in either of the two systems to notify CAU that a report was referred to them. Rather, RMPS must send an e-mail notifying CAU that a specific report is in Versa or the Nursing Homes Reporting System for their review.

Historically, CAU staff used Outlook folders to track these e-mail referrals from RMPS; however, in October 2012, CAU developed a Microsoft Office Access database to track these referrals. The database contains the file number, incident number, facility name, allegation category, incident date and complaint number assigned, if applicable. The database did not include the date the reports were received by CAU, the date reviewed by CAU or the date the adverse incident became a complaint. This information would be useful to track length of time from receipt to action. It could also be used to reconcile records between RMPS and CAU to ensure that CAU receives the referrals.

During our audit period, RMPS stated that they referred all hospital, ASC and HMO reports to CAU regardless of incident type. However, only serious incident reports from ALFs and NHs were referred to CAU. Currently, RMPS now refers all reports from facilities to CAU. The RMPS policies have not been updated to reflect this practice.

Recommendations

We recommend RMPS and CAU jointly:

1. Periodically reconcile report referrals to ensure that all incidents referred by RMPS are actually received.

We recommend RMPS:

2. Document the date reviewed on the hospital form.
3. Request that the ALF form be modified to include a date of review.
4. Request that the NH form include a date of receipt and date of review.
5. For all three forms, request a field for date of referral to CAU rather than rely on staff to post this information in the comments' section.
6. Update the policy outlining the criteria for referring reports to CAU.
7. Consider an automated method to notify CAU that there is a report for review.

We recommend CAU:

8. Add fields to their complaint tracking database to include the date the report was received by CAU, the date the report was reviewed by CAU and date the report became a complaint, if applicable.

Management Response

1. The CAU will coordinate monthly meetings with RMPS for the purpose of reconciling referrals from RMPS.
Anticipated date of completion: March 3, 2014
2. Staff have been instructed to note the date of review in the comment section. The review date field is not accessible to RMPS staff at this time. RMPS plans to submit or modify an existing PSR to correct this issue.
Anticipated date of completion: No sooner than June 30, 2014
3. A PSR has been submitted and is being managed by HQA IT team. The final project completion date is to be determined based on Agency-wide IT programming priorities and was addressed at the APG meeting on February 13, 2014.
Anticipated date of completion: No sooner than June 30, 2014
4. A PSR has been submitted and is being managed by HQA IT team. The final project completion date is to be determined based on Agency-wide IT programming priorities and was addressed at the APG meeting on February 13, 2014.
Anticipated date of completion: No sooner than June 30, 2014
5. A PSR has been submitted and is being managed by HQA IT team. The final project completion date is to be determined based on Agency-wide IT programming priorities and was addressed at the APG meeting on February 13, 2014.
Anticipated date of completion: No sooner than June 30, 2014
6. Completed as per policy 11-18. This policy has been adopted by RMPS and shared with CAU staff.
Anticipated date of completion: Completed
7. Consideration is being given to the feasibility of including this requirement in existing PSRs.
Anticipated date of completion: No sooner than June 30, 2014
8. CAU has considered the recommendations of the auditor and added the appropriate fields in the adverse incident database.
Anticipated date of completion: Completed

Finding 4: Adverse Incident Reports Were Not Referred to DOH Timely or Securely

RMPS's referral process to DOH for adverse incident reports was fragmented and does not ensure timely receipt of the reports. The laws governing this process are:

- Section 395.0197(6)(b), F.S. requires the Agency to review each adverse incident report and refer it to DOH if the incident involved conduct by a health care professional licensed under Chapters 458, 459, 461, or 466, F.S., that occurs in hospitals and ASCs.⁶

⁶Chapters 458, 459, 461, and 466, F.S. refer to the regulated professions of Medical Practice, Osteopathic Medicine, Podiatric Medicine, and Dentistry, respectively.

- Section 641.55(6), F.S. requires the agency to immediately send reports that contain references to providers licensed under Chapters 458, 459, 461 and 466, F.S. to the appropriate regulatory board.
- Section 429.23(7), F.S. requires the Agency to refer all incidents to DOH that occur at ALFs that involved conduct by a health care professional licensed under Chapters 458, 459, 461, 464, or 465, F.S.⁷
- Section 400.147(7), F.S., requires the Agency to review each NH report and determine whether it potentially involved conduct by a health care professional who is subject to disciplinary action and refer it to DOH.

To comply with these laws, RMPS referred or submitted the reports to DOH using three different methods:

1. For hospital, ASC, and HMO 15-day reports, staff made copies of reports and periodically notified DOH staff to pick them up from the Agency. DOH staff do not have the capability to view these reports using their access to Versa.
2. For 15-day ALF reports, staff generated reports from the Adverse Incident Reporting System that listed 15-day ALF reports received by report number. Each day, the list was e-mailed to DOH staff who reviewed the ALF reports in Versa.
3. In October 2012, NHs began to submit their reports using the Nursing Homes Reporting System. Since DOH staff did not have access to this system to view these reports, RMPS staff e-mailed copies of the reports to DOH staff. Prior to October 2012, staff referred the NH reports in the same manner as the ALFs.

The current method of referring hospital, ASC, and HMO reports to DOH is not efficient and delays notification of the incidents to DOH. In a sample of 26 hospital and ASC reports, no documentation was available that seven (27%) of these reports were sent to DOH. In addition, DOH staff stated they did not receive these reports. Of the remainder, the average number of days from date of receipt by RMPS staff to receipt by DOH staff was 57 days.⁸

In a sample of ten ALF reports, we could not find documentation that three were sent to or received by DOH; the report numbers for the other seven were sent to and received by DOH the same day through e-mail. Of the 15 NH reports in our sample, the actual report copies were sent to DOH within two days of RMPS receipt however they were e-mailed unencrypted. The e-mailing of NH reports unencrypted to DOH is not in accordance with the Agency's *HIPAA and HITECH Policies and Procedures Manual* since health information and other protected information are contained in the reports. DOH staff stated that they started receiving NH reports encrypted through e-mail as of June 13, 2013.

Reasons for the inefficient methods of transfer to DOH are:

- The MOU between the two agencies is outdated and refers to systems that are obsolete such as FRAES.

⁷ Chapter 464, F.S. refers to Nursing. Chapter 465, F.S. refers to Pharmacy.

⁸ Samples consisted of 26 hospital and ASC reports filed with the Agency in July 2012; ten 15-day ALF reports filed in July 2012 and 15 NH reports where the incident occurred in December 2012.

- The MOU addresses referrals of ALF and NH reports, not hospital, ASC and HMO reports.
- The MOU refers to a statutory citation, Section 400.423, F.S., that has been repealed.
- RMPS lacks written procedures for the method and frequency that reports are to be transferred from the Agency to DOH.
- DOH lacks the capability to review hospital, ASC and HMO reports in their version of Versa. Thus, RMPS staffs make actual copies of these reports.
- DOH also does not have access to the Nursing Homes Reporting System.

Recommendations

We recommend:

1. The Agency work with DOH to update the MOU to address the security, method and frequency of report transfer to DOH.
2. The Agency work with DOH technical staff to address the Versa System issues that impede DOH staff from reviewing hospital, ASC and HMO reports as well as examine the feasibility of access to the Nursing Homes Reporting System.

Management Response

1. Staff have already discussed this with Agency Privacy Office. We will be moving forward using new “model” MOU language. This will ensure that MOU language best meets unit and Agency needs.
Anticipated date of completion: March 31, 2014
2. A PSR has been submitted and is being managed by HQA IT team. The final project completion date is to be determined based on Agency-wide IT programming priorities and was addressed at the APG meeting on February 13, 2014.
Anticipated date of completion: No sooner than June 30, 2014

Finding 5: The Referral of Litigation Notices to RMPS Does Not Appear to Serve a Useful Purpose

The Agency receives legal notices from claimants regarding claims filed against facilities and practitioners. Chapter 766, F.S., instructs the Agency to review a medical malpractice complaint and determine whether it involved conduct of a licensee that is potentially subject to disciplinary action. The law also requires a claimant for Florida Birth-Related Neurological Injury Compensation to submit their petition to the Division of Administrative Hearings. The Division is responsible for furnishing a copy to the Agency to determine if a violation of Chapter 395, F.S., occurred.

As part of the Agency’s process, the RMPS administrator stated that the unit receives copies of these notices from civil litigants for review. A draft RMPS policy states that the information is to be researched to see if the incident was reported as an adverse incident at the time of occurrence. In cases where the event happened less than a year prior, RMPS would forward the adverse incident report to CAU for referral to HQA field office staff.

RMPS's review is limited for the following reasons:

- The legal notices often involve incidents that are older than one year; thus the date of the incident is older than the one year limit specified in the draft policy.
- The notices may not contain enough information for RMPS to determine if the incident was an adverse incident and therefore should have been reported.

During our audit, we couldn't determine if review of the documents occurred due to a lack of adequate documentation. For example, RMPS did not keep a log noting the entity that routed them the document, the date received by RMPS, the RMPS date of review, or the action taken by RMPS such as referral to CAU. Also, there was no evidence of review on the documents. Currently, OGC is establishing procedures for routing, review and storage of the documents.

Recommendations

We recommend:

1. The Florida Center consult with OGC, CAU, and HQA Field Office management to determine the purpose and intended results of reviewing these documents.
2. If it is determined that RMPS should continue to receive and review the documents, the Florida Center should finalize a policy that includes how staff should record, at a minimum, from whom they received the document, the date received by RMPS, the date of review by RMPS, and the action taken by RMPS such as a referral.

Management Response

1. The review is mandated by statute. The Agency will include removal of review requirement in the 2015 Agency legislative proposal.
Anticipated date of completion: September 30, 2014
2. The review is mandated by statute. The Agency will include removal of review requirement in the 2015 Agency legislative proposal.
Anticipated date of completion: September 30, 2014

Finding 6: The Receipt and Review of Annual Reports from Facilities Does Not Appear To Be a Cost Effective Use of Agency Resources

Hospitals, ASCs, and HMOs are required by Chapters 395 and 641, F.S., to submit an annual report to the Agency every year that includes:

- The number of adverse incidents for the calendar year;
- A listing by category of the injuries and the number of incidents in each category;
- A code number for the health care practitioners and other individuals directly involved, including the number of incidents for each individual involved; and

- A description of all malpractice claims filed against the licensed facility.

Section 395.0197(8), F.S., requires the Agency to publish on the agency's website an annual summary and trend analysis of all adverse incident reports and malpractice claims information provided by hospital and ASC facilities in their annual reports. The stated purpose of the publication of summary and trend analysis is to promote the rapid dissemination of information relating to adverse incidents and malpractice claims to assist in avoidance of similar incidents and reduce morbidity and mortality.

We identified the following concerns:

- For the 2011 calendar year reports, 63 of the 717 facilities submitted their reports late (after April 1, 2012). Also, 31 active facilities did not submit an annual report.
- Staff did not monitor reports to ensure that facilities submitted annual reports on time or at all.
- Staff did not fine facilities that submitted reports late or facilities that did not submit reports.⁹
- Staff told us the information from the annual reports is not used by the Florida Center. The Florida Center currently compiles Agency website statistics from the individual adverse incident reports, not the annual reports. Additionally, the Florida Center did not compile and publish a summary of hospital and ASC malpractice claims information provided in the annual reports for calendar years 2011 and 2012 until we identified this issue. Florida Center administrators stated that this event was an oversight and they corrected it in November 2013.

We also noted that in fiscal year 2010, Florida Center management drafted legislation to amend Chapter 395, F.S. to eliminate the requirement for annual report submission. This legislation was not passed by the Legislature.

RMPS estimated that reviewing and storing the 2012 reports took approximately 290 hours which amounted to \$5,426.¹⁰ This time could be used for performing more beneficial functions such as tracking incident trends and monitoring adverse incident report deadlines. The costs to facilities to submit and review these reports should also be considered. Facility risk managers spend time preparing these reports and submitting them.

Recommendations

We recommend:

1. Management determine the benefit of requiring facilities to submit annual reports. If Agency management determines that the annual report requirement is not useful or cost beneficial to either the Agency or facilities, we recommend that the law be revisited.
2. RMPS publish the required malpractice claims statistics for hospitals and ASCs as required by law.

⁹ According to Chapter 395, F.S., the agency may impose an administrative fine, not to exceed \$5,000 for any violation of the reporting requirements of this section or part II of Chapter 408, F.S.

¹⁰ Estimate based on staff hours and salary amounts.

Management Response

1. The Agency has determined that the annual reports serve little useful purpose. However, annual reports are required by statute. The Agency unsuccessfully pursued removal of the requirement in 2009 and 2010 legislative sessions. The Agency will include removal of review requirement in 2015 Agency legislative proposal.

Anticipated date of completion: September 30, 2014

2. The 2012 reports have recently been added; the 2013 reports will not arrive until April and will be posted by the end of May.

Anticipated date of completion: September 30, 2014

Finding 7: Some Agency Rules, Policies and Forms Regarding Adverse Incidents are Outdated

During our review to determine compliance with statutory laws, rules, and policies, we identified several provisions that should be updated. The following issues exist:

- Section 59A-4.123, Florida Administrative Code (F.A.C.)¹¹ Risk Management and Quality Assurance, refers to filing a 1-day NH report and 15-day NH report. This rule has not been updated to reflect changes to Section 400.147(7), F.S. which only requires the facility to submit a 15-day report as of July 1, 2012. Staff stated that this rule is currently being amended to reflect the change to Section 400.147(7), F.S. The notice of rule development was published on October 31, 2013 and the Agency anticipates publishing a notice of proposed rule by February 28, 2014.
- Section 59A-12.012(5), F.A.C., Internal Risk Management Program, requires HMOs to report an adverse incident within 15 calendar days of its occurrence and use HRS¹² Form 1654. This rule conflicts with Section 641.55, F.S. that requires an HMO to report certain adverse incidents within 3 working days followed by a more detailed follow-up report within 10 days of the first report. Additionally, the rule refers to an obsolete HRS form; the Agency uses AHCA Form 3140-5001. Staff told us this rule is currently under development and the Agency anticipates publishing a notice of rule development by March 31, 2014.
- Section 429.23, F.S. was amended July 1, 2009, to exclude abuse, neglect and exploitation from the definition of adverse incident; the law requires ALFs to report abuse, neglect or exploitation to the Department of Children and Family Services. The current ALF electronic adverse incident report form still lists abuse, neglect and exploitation as a type of adverse incident to be reported to the Agency. Additionally, RMPS Policy #11-03 addressing abuse, neglect and exploitation reporting should be revisited after the ALF form is modified. Staff told us the Agency has been working with the Department of Elder Affairs on rule promulgation to address necessary changes. Language has been proposed to remove the form and a rule development hearing was held on December 19, 2013 addressing these issues.
- Some rules regarding adverse incident report submission conflict with other rules. Section 59A-35.110, F.A.C. discusses electronic submission of NH and ALF reports. However, Section 59A-4.123, F.A.C. Risk Management and Quality Assurance, still requires Nursing Homes to submit paper report forms and does not address electronic submission of reports. These facilities now use

¹¹ Florida Administrative Code

¹² Former Florida Department of Health and Rehabilitative Services

an electronic system to submit their reports to the Agency with few exceptions. Staff stated this rule is currently being amended to reflect the change to Section 400.147(7), F.S. The notice of rule development was published on October 31, 2013 and the Agency anticipates publishing a notice of proposed rule by February 28, 2014.

Recommendations

We recommend the Florida Center continue to update and align the rules, policies and forms with current statutory provisions regarding adverse incidents and ensure congruence among these documents.

Management Response

This activity is ongoing but requires coordination with IT and OGC because the forms are or will be automated and must go through the rulemaking process to be activated once they have been developed. However, RMPS has submitted PSRs to modify existing forms for HMOs, ALFs, ASCs, and hospitals. *Anticipated date of completion: No sooner than June 30, 2014*

FINAL COMMENTS

The Office of the Inspector General, Internal Audit would like to thank the Division of Health Quality Assurance management and staff for their assistance and cooperation extended to us during this engagement.

Appendix A - Adverse Incident Definitions

Facility Type	Florida Statute	Deadline to Submit	Adverse Incident Definition
Hospitals and Ambulatory Surgical Centers	Section 395.0197(5)	Within 15 calendar days after incident occurrence	<p>...an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred, and which:</p> <p>(a) results in one of the following injuries:</p> <ol style="list-style-type: none"> 1. Death; 2. Brain or spinal damage; 3. Permanent disfigurement; 4. Fracture or dislocation of bones or joints; 5. A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility; 6. Any condition that required specialized medical attention or surgical intervention resulting from nonemergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or 7. Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident; <p>(b) Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;</p> <p>(c) Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or</p> <p>(d) Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.</p>
Assisted Living Facilities	Section 429.23(2)	One business day after the occurrence must provide preliminary report/ 15 days must provide full report	<p>(a) An event over which facility personnel could exercise control rather than as a result of the resident's condition and results in:</p> <ol style="list-style-type: none"> 1. Death; 2. Brain or spinal damage; 3. Permanent disfigurement; 4. Fracture or dislocation of bones or joints; 5. Any condition that required medical attention to which the resident has not given his or her consent, including failure to honor advanced directives; 6. Any condition that requires the transfer of the resident from the facility to a unit providing more acute care due to the incident rather than the resident's condition before the incident; or

Facility Type	Florida Statute	Deadline to Submit	Adverse Incident Definition
			7. An event that is reported to law enforcement or its personnel for investigation; or (b) Resident elopement, if the elopement places the resident at risk of harm or injury.
Nursing Homes	Section 400.147(5)	Within 15 calendar days after the incident occurred	<p>(a) An event over which facility personnel could exercise control and which is associated in whole or in part with the facility's intervention, rather than the condition for which such intervention occurred, and which results in one of the following:</p> <ol style="list-style-type: none"> 1. Death; 2. Brain or spinal damage; 3. Permanent disfigurement; 4. Fracture or dislocation of bones or joints; 5. A limitation of neurological, physical, or sensory function; 6. Any condition that required medical attention to which the resident has not given his or her informed consent, including failure to honor advanced directives; 7. Any condition that required the transfer of the resident, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the resident's condition prior to the adverse incident; or 8. An event that is reported to law enforcement or its personnel for investigation; or (b) Resident elopement, if the elopement places the resident at risk of harm or injury.
Health Maintenance Organizations	Section 641.55(6)	Three working days and a more detailed report within 10 days after first report	<p>If an adverse or untoward incident, whether occurring in the facilities of the organization or arising from health care prior to enrollment by the organization or admission to the facilities of the organization or in a facility of one of its providers, results in:</p> <ol style="list-style-type: none"> (a) The death of a patient; (b) Severe brain or spinal damage to a patient; (c) A surgical procedure being performed on the wrong patient; or (d) A surgical procedure unrelated to the patient's diagnosis or medical needs being performed on any patient.



The Agency for Health Care Administration’s mission is Better Health Care for All Floridians. The Inspector General’s Office conducts audits and reviews of Agency programs to assist the Secretary and other agency management and staff in fulfilling this mission.

This review was conducted pursuant to Section 20.055, Florida Statutes and in accordance with the *International Standards for the Professional Practice of Internal Auditing* as established by the Institute of Internal Auditors. The review was conducted by Kathryn Voigt, MPA, CFE, CIGA and Cathe Ferguson under the supervision of Mary Beth Sheffield, Audit Director, CPA, CIA, CFE, CIG. Please address inquiries regarding this report to the AHCA Audit Director by telephone at (850) 412-3978.

Copies of final reports may be viewed and downloaded via the internet at:
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Copies may also be obtained by telephone (850) 412-3990, by FAX (850) 487-4108, in person, or by mail at Agency for Health Care Administration, Fort Knox Center, 2727 Mahan Drive, Mail Stop #5, Tallahassee, FL 32308.