



February 29, 2016

CONFIDENTIAL

Elizabeth Dudek, Secretary Agency for Health Care Administration 2727 Mahan Drive Tallahassee, Florida 32308

Dear Secretary Dudek:

In accordance with Internal Auditing Standards, attached is the 24-month status report from the Florida Center for Health Information and Policy Analysis, Division of Health Quality Assurance in response to Report #13-06, Adverse Incident Report Process published on February 28, 2014. This status report contains information 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.

To date, management has implemented eight of our 27 recommendations and is progressing on the remaining 19. The implementation for most of the 19 recommendations is contingent on available funding. A detailed description of all issues, recommendations, and management's responses are in the attached table. This is our final report on the efforts taken by the Florida Center for Health Information and Policy Analysis to correct all open issues.

If you have any questions regarding this status report, please let me know.

Sincerely,

Eric W. Miller Inspector General

EWM/kv Enclosure

cc: Molly McKinstry, Deputy Secretary, Health Quality Assurance Nikole Helvey, Director, Florida Center for Health Information and Policy Analysis Polly Weaver, Assistant Deputy Secretary, Health Quality Assurance Michelle Hart, Complaint Administration Unit Supervisor



Report Title: 24 Month Status Report on Adverse Incident Reporting Process

No.	Finding	Recommendation	Previous Management Response	24-Month Status Update	Anticipated Completion Date and Contact Name
1	RMPS did not monitor for timeliness of report submission nor did they fine facilities for non-compliance with statutory deadlines.	We recommend Risk Management Patient Safety (RMPS) develop policies and procedures to monitor the timely submission of reports.	RMPS was tasked with developing and implementing a fining process for untimely/late submissions of Adverse Incident (AI) Reports to the Agency for each facility type. The process will be implemented in phases. The following schedule will be used for identifying and determining which facilities meet the definition of a late AI report per the Florida Statutes for each facility type: ALF AI Reports will be identified and processed weekly because of the potential larger volume. NH AI Reports will be identified and processed monthly. HOSPITAL and ASC AI Reports will be identified and processed monthly. HMO AI Reports will be identified and processed monthly. It was anticipated to have all phases implemented by August 31, 2015.	A detailed process for imposing fines for late reports was developed and implementation is in process. Implementation was delayed partially due to reduced staff capacity in the RMPS unit for several months. The vacancy was filled and the new staff member began work in the unit on February 15, 2016. The RMPS manager has also worked extensively with the Agency's legal counsel to develop a set of appropriate notices for each facility type and differing circumstances. These include violation notifications, plan of correction letters and notices of intent to fine. Each requires a different set of circumstances and condition; separate processes were mapped for each. The letter templates were submitted to the Systems Management Unit for upload into the appropriate software systems. The following enforcement template letters were sent to Systems Management Unit on 10/26/15 to be added into the VR system: **NOI TO FINE** **ALF - 1 DAY PRELIMINARY* **ALF - 15 DAY FULL* **ASC - 15 DAY**	Phase I: NH 15 Day, "fining process" was complete as of 6/30/15 Phase II: ALF No 15 Day, and HMO No 10 Day, "violation notification process" anticipated completion date is 6/30/16 Phase III: ALF 1 and ALF 15 Day, "fining process" anticipated completion date is 6/30/16 Phase IV: Hospital 15 Day, and ASC 15 Day, "plan of correction process" anticipated completion date is 8/31/16 Phase V: Hospital 15 Day, ASC 15 Day, and HMO 3 and HMO 10 Day, "fining process" anticipated completion date is 8/31/16 RMPS and the Florida Center will provide implementation status updates to the HQA Deputy Secretary at least monthly; and will notify of any further delays immediately as they occur.

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		We recommend RMPS 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.	Completed – It was determined that the Agency does have enforcement authority; and RMPS will implement an administrative process to impose fines for late reporting of Adverse Incidents to the Agency.	 HMO - 3 DAY PRELIMINARY HMO - 10 DAY FULL HOSPITAL - 15 DAY NH - 15 DAY POC LETTER ASC - 15 DAY HOSPITAL - 15 DAY VIOLATION LETTER ALF - NO_15 DAY FULL HMO - NO_10 DAY FULL N/A 	N/A
2	Removed				

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3	RMPS does not adequately document and track report referrals to CAU	We recommend that RMPS and CAU periodically reconcile report referrals to ensure that all incidents referred by RMPS are actually received.	Completed	N/A	N/A
		We recommend that RMPS document the date reviewed on the hospital form.	Please refer to the status update for Finding #2.	Please refer to the status update for finding # 2. The new system will automatically date stamp reports.	December 31, 2016 Patricia Vidal
		We recommend that RMPS request that the ALF form be modified to include a date of review.	Please refer to the status update for Finding #2.	Please refer to the status update for finding # 2. The new system will automatically date stamp reports.	December 31, 2016 Patricia Vidal
		We recommend that RMPS request that the NH form include a date of receipt and date of review.	Please refer to the status update for Finding #2.	Please refer to the status update for finding # 2. The new system will automatically date stamp reports.	December 31, 2016 Patricia Vidal
		We recommend that RMPS request a field for date of referral to CAU rather than rely on staff to post this information in the comments' section for all three forms.	Please refer to the status update for Finding #2.	Please refer to the status update for finding # 2. The new system will automatically date stamp reports.	December 31, 2016 Patricia Vidal
		We recommend that RMPS update the policy outlining the criteria for referring	Completed	N/A	N/A

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		reports to CAU.			
		We recommend that RMPS consider an automated method to notify CAU that there is a report for review.	Please refer to the status update for Finding #2.	Please refer to the status update for finding # 2. The new system will generate an email notification to the CAU when a new report is available for review.	December 31, 2016 Patricia Vidal
		We recommend that CAU 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.	Completed	N/A	N/A
4	Adverse incident reports were not referred to DOH timely or securely	We recommend that the Agency work with DOH to update the MOU to address the security, method, and frequency of report transfer to DOH.	The new MOU is complete and was sent to DOH on 5/26/15 for review and signature. As of 7/6/15, the new MOU is being reviewed by DOH's legal department.	Agency legal counsel and Chief of Staff are working with DOH legal counsel to rectify any concerns in the updated MOU and to execute the agreement.	June 30, 2016 Patricia Vidal
		We recommend that 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.	Completed	N/A	N/A

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5	The referral of litigation notices to RMPS does not appear to serve a useful purpose	We recommend that the Florida Center consult with OGC, CAU, and HQA Field Office management to determine the purpose and intended results of reviewing these documents.	RMPS will perform a second review of the Florida Statutes related to the referral of litigation notices to the Agency prior to the upcoming 2016 session to ensure the previously submitted legislative proposal recommendations are complete.	RMPS met with OGC and CAU to review the intent and purpose of reviewing the litigation notices, and agreed there is still interest across the Agency in reviewing these and reconciling them against the complaints and adverse incident databases to look for linkages.	July 1, 2016 Patricia Vidal
		Further, if it is determined that RMPS should continue to receive and review the documents, we recommend that the Florida Center 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.	As of 6/30/15, IT is working to resolve an issue with the e-file system and awaiting available resources to begin working on PSR 598. The e-File system project completion timeframe is still contingent upon available resources for this IT project.	The RMPS manager, Florida Center Bureau Chief, and HQA Deputy Secretary met with Agency legal staff to finalize an alternative plan for the sharing and tracking of these documents. A plan has been developed that will ensure adequate documentation of the source and date of receipt of the document, to whom it has been referred and when, and any action taken by RMPS.	July 1, 2016 Patricia Vidal
6	The receipt and review of annual reports from facilities does not appear to be a cost effective use of	We recommend that Agency 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	RMPS will perform a second review of the Florida Statutes requiring the submission of annual reports to the Agency prior to the upcoming 2016 session to ensure the previously submitted legislative proposal recommendations are complete.	A legislative proposal was developed for the 2016 legislative session, but it was determined that it would be better to wait a year for multiple reasons. The RMPS manager and Florida Center Bureau Chief will continue to work with Agency leadership to update the proposed changes for future consideration. HQA will begin development for the	July 1, 2016 Patricia Vidal

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	agency resources	revisited.		2017 session in April 2016.	
		We recommend that RMPS publish the required malpractice claims statistics for hospitals and ASCs as required by law.	Completed	N/A	N/A
7	Some agency rules, policies and forms regarding adverse incidents are outdated	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.	The process of updating and aligning rules, policies, and forms with current statutory provisions regarding adverse incidents to ensure congruence among these documents is still ongoing and will be reviewed annually. The current Core Rule was recently withdrawn to add an effective date of 1/1/16. It should begin routing again by 8/1/15. New forms have been developed and will be routed with the new version of the Core Rule for approval. They will be incorporated by reference in the Core Rule along with language related to electronic submission.	The process of aligning and updating the statutes and rules is ongoing and will continued to be actively managed, with updates to the HQA Deputy Secretary at least quarterly. The Core Rule is currently being amended to include additional language related to licensure renewal requirements; publication of the notice of proposed rule is expected to occur in early March.	December 31, 2016 Patricia Vidal