

NPDB PROVIDES NEW GUIDANCE

In October of 2018, the National Practitioner Data Bank ("NPDB") revised the NPDB Guidebook to provide additional guidance on a number of issues. Some of the revisions will be welcomed by the health care industry, but others do not provide as much additional clarity on issues as might be desired. Following is a discussion of the most significant revisions.

The revised Guidebook contains a new Figure E-2 on page E-33, which is a flowchart regarding the steps involved in deciding whether a report to the NPDB is required for a professional review action. Unfortunately, the chart contains a couple of confusing statements. First, the chart refers to filing a report based on "a practitioner's surrender of, or failure to renew, privileges while under **or to avoid investigation.**" This language perpetuates a misstatement that has been in previous editions of the Guidebook. The Health Care Quality Improvement Act ("HCQIA") provides that a report is required if a hospital "accepts the surrender of clinical privileges of a physician" either "while the physician is under an investigation ... relating to possible incompetence or improper professional conduct," 42 USC § 11133(a)(1)(B)(i) or "**in return for not conducting** such an investigation or proceeding." 42 USC § 11133(a)(1)(B)(ii). There is no requirement to report someone who resigns their privileges to avoid an investigation as long as there is no agreement that an investigation will not be conducted "in return for" the surrender of privileges.

The flowchart also gives the confusing instructions that a report should be submitted "within 30 days of when the action was taken." This differs from the language used in the Regulations implementing HCQIA reporting requirements, which provide that reports must be submitted "within 30 days following **the action to be reported...**" (45 CFR § 60.5)(emphasis added). The "action to be reported" regarding suspensions occurs when the suspension has been in place for more than 30 days. So, the 30-day time period for reporting does not begin to run when "the action was taken" (e.g., the suspension was imposed) but rather when the suspension has been in place for more than 30 days. This interpretation is confirmed elsewhere in the Guidebook. (See "Time Frame for Reporting, p. E-2). The different phraseology creates a significant practical difference. Specifically, the phraseology within Figure E-2 can decrease the reporting deadline from 60 days following the beginning of a suspension to just 30 days.

A major focus of revisions to the Guidebook involves an attempt by the NPDB to overcome the confusion caused by the U.S. District Court decision in *Walker v. Memorial Health System of East Texas* in which the court ruled that a report to the NPDB was not required if a suspension of indefinite duration was imposed and did not necessarily require it to last longer than 30 days. (231 F.Supp 3d 210, 216 (E.D. Tex 2017)). The revisions to the Guidebook indicate that the NPDB intends that only suspensions **actually** lasting longer than 30 days "must" be reported, but suspensions that might last more than 30 days "may" be reported. However, the Guidebook still states that "a summary suspension **must** be reported if it is "in effect "or imposed for" more than 30 days," which can lead to confusion. (See Summary Suspensions, p. E-38).

The section on summary suspensions in the Guidebook now addresses "indefinite" suspensions by adding the language in **bold italics** below:

In addition, summary suspensions ***imposed for an indefinite length*** that have not lasted more than 30 days but are expected to last more than 30 days, and are otherwise reportable, may be reported to the NPDB. If the summary suspension ultimately does not last more than 30 days, the report must be voided.

Based on these changes, the Guidebook seems to be giving health care entities the following options regarding suspension or restriction of privileges that are professional review actions:

- Suspensions that will, based on the terms of the suspension, definitely last more than 30 days must be reported within 30 days after the imposition of the suspension.
- Suspensions that could last more than 30 days, but will not necessarily do so (e.g., suspension/restriction for a specific number of cases), may be reported within 30 days after the imposition of the suspension if the expectation is that the suspension will last more than 30 days and must be reported within 30 days after the suspension has actually been in effect for more than 30 days.

- If a suspension is reported before it has actually been in place for 30 days but is then terminated before it has been in place for 30 days, the initial report is to be voided.

It should be noted that the new guidance makes a distinction between when a report must be filed for summary suspensions versus other forms of restrictions on privileges, such as requiring a proctor to be present and observe the practitioner. While a report may be filed if it is uncertain a suspension will last more than 30 days, the new instructions are that the reportability of restrictions other than summary suspensions, such as proctoring, "hinges on whether the restriction, in fact, is in effect for a period longer than 30 days." (E-41). The guidance that proctoring is considered a reportable restriction on privileges only if it requires proctor approval to exercise privileges, or that the proctor must be present and watching the practitioner, remains unchanged.

A new section relating to residents and interns has been added (p. E-40) making it clear that residents and interns should not be the subject of adverse action reports unless the adverse action relates to events occurring outside of the formal training process, e.g., while moonlighting in an ICU or ED.

A new section entitled "Payments for Sole Shareholder Corporations" has also been added to provide guidance regarding when payments for medical malpractice claims made against a sole shareholder corporation ("SSC") are reportable. Unfortunately, the advice is somewhat equivocal in stating that a payment "may" be reportable if an individual owner or employee of the SSC is "sufficiently" described or identified in the body of the claim "and" in the settlement or final adjudication. A claim may also be reportable if a practitioner (owner or employee) is "named, identified, or otherwise described" in the complaint and is dismissed from the suit as a condition of settlement. No examples are given of what would constitute sufficient description or identification of a practitioner. These new provisions are similar to the guidance in earlier editions of the Guidebook in the section entitled "Identifying Practitioners."

A new, frequently asked question ("FAQ") has been added to the section relating to reporting of medical malpractice payments advising that the requirement to report payments made as a result of a written claim is not limited to written claims made by patients. Payments in settlement or satisfaction of written claims made by anyone are reportable. (New FAQ 7. P. E-29).

The revisions to the Guidebook include seven new FAQs addressing the following situations relating to reporting actions affecting the exercise of privileges:

- An agreement not to exercise privileges is reportable as a restriction of privileges if otherwise reportable. It should be noted that the key term seems to be "agreement," which seems to mean that if there is no "agreement" between the practitioner and the hospital, but only a unilateral offer by the practitioner not to exercise privileges while an investigation takes place, there would be no reportable restriction. (New FAQ 22, p. E-50).
- Leaves of absence while under investigation are reportable if the practitioner's leave restricts a practitioner's ability to exercise privileges. The new guidance states that no report is required if a practitioner can take a leave of absence "without affecting his or her privileges, and his or her privileges remain intact during the leave." However, it is not clear what the NPDB has in mind since a practitioner on a leave of absence could never exercise privileges while on leave. (When asked, the NPDB could not identify any circumstances where a leave of absence would have no bearing on a practitioner's privileges, but they could not foreclose the possibility that could occur.) One can only surmise that no report will be required for a leave of absence as long as there is nothing about the leave that expressly provides that while on leave, the practitioner's privileges will be restricted or suspended in any way. Perhaps the best way to address this issue is to have a medical staff bylaw or rule/regulation that says something to the effect that the privileges of practitioners on leave will not be adversely affected and will remain intact unless otherwise stated in connection with the leave of absence. (New FAQ 23. P. E-50).
- Resignations while under consideration for reappointment will be reportable if the review of the application for reappointment is not considered to be routine. The new FAQ 24 (p. E-50-51) gives the example of a request by a credentials committee for additional information regarding pending medical malpractice cases. If such inquiry is something that is regularly done when an applicant reports pending medical malpractice cases, then the review is considered to be "routine" and not an "investigation" for purposes of reporting if the practitioner withdraws the application for reappointment while the review is ongoing. Unfortunately, the new guidance does not really help decide when an inquiry is more than just "routine," which would seem to give the hospital a great deal of latitude in deciding what is and is not "routine." Having a "credentialing procedures manual" that describes the circumstances under which additional

information is requested could be helpful in establishing that an inquiry is "routine."

- Whether resignation while under a "quality improvement plan" ("QIP") amounts to a resignation while under investigation depends on what the improvement plan involves (New FAQ 25, p. E-51). A new FAQ gives the examples of a quality improvement plan that involves limiting the number of patients a practitioner can have in the hospital at any one time or a requirement that surgical cases be discussed in advance with (but not approved by) a department chair. Unfortunately, the guidance does not specifically give guidance regarding how to handle the situations it identifies but only says that consideration should be given to various factors such as:
 - Is the QIP focused on one practitioner?
 - Do such QIPs typically lead to a professional review action?
 - Does the QIP describe disciplinary actions that may be taken if elements of the plan are not met?
 - What do bylaws or policies say about QIPs?

Since most QIPs are put in place in the hope that quality can be improved, and thereby a professional review action avoided, it would seem that the new guidance gives hospitals a great deal of discretion in determining that a QIP is not an investigation, thereby permitting the practitioner to resign while the QIP is in effect with no report to the NPDB being required.

- A requirement that a surgeon operate only with a qualified first assistant may or may not be a restriction on privileges requiring reporting if in effect for more than 30 days (New FAQ 31, p. E-53). If the requirement to have a first assistant is applied to all surgeons granted new privileges, then it is not a restriction that requires reporting. But, if the requirement is imposed on just one surgeon and constitutes a professional review action (i.e., based on competence or professional conduct), it would be reportable after it has been in effect for more than 30 days. This broad statement would seem to implicate almost all requirements to use a first assistant or assistant surgeon that are imposed on a specific surgeon.
- New guidance has been provided that a report is required when there has been a recommendation by a medical executive committee that a practitioner not be reappointed, but the practitioner's current two-year appointment ends before a hearing can be held and final action taken by the governing body (New FAQ 46, p. E-57). However, in providing the guidance, the NPDB seems to be creating a new reporting requirement that is not contained in the HCQIA or its implementing regulations. The answer to the new FAQ refers to "non-renewal while under investigation" being reportable to the NPDB. However, "non-renewal" while under investigation is not addressed in the HCQIA, only resignation while under investigation.
- If adverse action regarding a practitioner's clinical privileges is reported to the NPDB, but then subsequently modified by court action, the health care entity should submit a revision-to-action report (New FAQ 49, p. E-58). If the court overturns a health care entity's decision to take a professional action entirely, the health care entity should void the initial report.

While many will find much of the new guidance helpful in determining when reports should be filed with the NPDB, there are still many lingering gray areas for which the NPDB may simply not be able to provide more definitive guidance because of the statutory language of HCQIA. Hospitals and other reporting entities will need to carefully review the new guidance when determining whether a report to the NPDB is required. However, everyone should always keep in mind that the NPDB Guidebook is not a law or regulation and therefore does not have the force of law, even though courts may give deference to the position of the NPDB stated in the Guidebook on various matters.

If you have any questions or would like additional information on this topic, please contact:

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