

**GUIDELINES FOR PRACTICE**  
**UNDER THE**  
**NATIONAL VACCINE INJURY COMPENSATION PROGRAM**

**Revised April 24, 2020**

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These revised Guidelines represent an effort by the Office of Special Masters, with input from both the petitioners' bar and counsel for the respondent, to provide the bar and pro se petitioners with information that will assist in the prompt and efficient resolution of claims submitted under the National Childhood Vaccine Injury Act ("Vaccine Act"), as amended, 42 U.S.C. §§ 300aa-1 to -34.

Practitioners are cautioned that these Guidelines provide a practical explanation of how to proceed under the Program and are not intended to replace or supplement the Vaccine Act or the Vaccine Rules. The Guidelines do not mandate particular practices or procedures but instead inform practitioners of best practices in preparing and presenting their clients' cases before the Office of Special Masters.

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## SECTION I. INTRODUCTION

### Chapter 1. Purpose.

These Guidelines are intended to facilitate the prompt and efficient resolution of claims submitted under the National Childhood Vaccine Injury Act (“Vaccine Act”), as amended, 42 U.S.C. §§ 300aa-1 to-34, which established the National Vaccine Injury Compensation Program (“the Program”). The following explanation of the conduct of proceedings under the Program, with links to templates and sample documents located on the Vaccine Program section of the Court of Federal Claims website [www.uscfc.uscourts.gov](http://www.uscfc.uscourts.gov), should assist petitioners in presenting their claims and assist respondent in evaluating the merits of the petitions. Consequently, the special masters will be able to resolve the claims fairly and expeditiously.

Attorneys new to Vaccine Act litigation and *pro se* litigants should carefully review the sections and chapters that follow. These Guidelines were written to aid such attorneys and *pro se* litigants, but even attorneys experienced in Vaccine Act litigation may find this information useful in expediting the resolution of their cases.

The statute, court rules, and case precedent give special masters wide latitude in handling individual cases. Thus, where circumstances warrant, special masters may employ procedures different from those found in these Guidelines. Practitioners are also encouraged to suggest creative ways of resolving cases in the most efficient manner. Any such proposal must ensure fairness to each party and the creation of a complete and orderly record for decision.

These Guidelines are organized into sections dealing with major topics, including filing the petition, proving causation, exiting the Program, establishing damages, and filing for attorneys’ fees and costs. Most sections provide a brief overview, followed by chapters dealing with specific issues within the broad section topic. For example, Section VI, “Determining Entitlement,” contains chapters on expert reports and hearings.

### Chapter 2. Emergency Access.

Electronic access to the court (e.g., electronic filing, telephone, fax, and e-mail contact) may be disrupted by power outages, natural disasters, or other circumstances. In the event of a disruption of access, the court will use a variety of means to inform the public, including members of the bar, of the circumstances and any alternate means to obtain contact. The Court of Federal Claims website ([www.uscfc.uscourts.gov](http://www.uscfc.uscourts.gov)) should be checked for any announcements of court closure or temporary telephone or power disruptions. In the event the court’s website is unavailable, check the central telephone number for the Clerk of Court (202-357-6400). During periods when the court is officially closed, deadlines for filing are suspended until the court reopens.

### **Chapter 3. Overview of the Processing of a Vaccine Act Case.**

Vaccine Act litigation begins with the filing of a petition setting forth the pertinent facts, including what vaccine or vaccines are alleged to be causal, when and where they were administered, and the nature of the injury sustained.

Vaccine Act cases are bifurcated, with the initial phase devoted to determining entitlement to compensation, and the second phase focused on assessing damages. For this reason, petitioners should incur expenses associated with proving damages only after consulting with the special master assigned to the case. Expenses necessary for settlement negotiations are generally approved.

How the case progresses after the initial filings depends on the completeness of the medical records filed, whether the opinion of a medical expert is necessary to resolve any issues regarding causation, and how long obtaining such an opinion may require.

All Vaccine Act petitions are initially assigned to the Chief Special Master's docket to undergo a Pre-Assignment Review ("PAR"), intended to confirm that the filed record is substantially complete as required by Section 11(c) of the Vaccine Act.<sup>1</sup> The PAR process makes it more likely that cases are ready for resolution/analysis; in the past, cases were often filed despite the fact that records needed to substantiate the claim had not been identified, which negatively impacted the efficient processing of claims.

The initial PAR process results in either an Activation Order (if the medical records and other evidence are deemed to be substantially complete) or a PAR Scheduling Order. If a PAR Scheduling Order is issued, it will include a checklist of outstanding items required for completing of the PAR process.

After the petitioner files the required documentation, he or she must file a "Statement of Completion," which indicates that all medical records pertaining to causation have been filed. At this stage, the PAR process is complete and an Activation Order will be issued followed by an order reassigning the case to either a special master or the Special Processing Unit ("SPU"), discussed below.

In non-SPU cases, the respondent thereafter is ordered to file a "Rule 4 report" summarizing the evidence and addressing any legal issues the case presents. In some cases, the special master may defer ordering respondent to file the Rule 4 report until the petitioner files an expert report, in which case the Rule 4 report will typically include an expert report.

The case then progresses toward resolution of any contested issues, including that of causation. In this process, the special master will issue orders and conduct

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<sup>1</sup> Cases filed by *pro se* petitioners are promptly reassigned to a special master for review and do not go through the PAR process.

status conferences to monitor and guide the development of the evidentiary record. A special master may also provide substantive feedback to the parties on the relative merits of their evidence.

In some cases, petitioners may be unable to substantiate their vaccine injury claim or may decide to pursue their case in a state court or another federal court. Information about how to exit the Vaccine Program, while preserving the right to file suit in another court, is provided in Section IX below.

Alternatively to, or in conjunction with, preparing the case for a hearing, the parties may find it beneficial to engage in settlement negotiations, particularly in cases where either a Table injury (*i.e.*, injuries falling within the Vaccine Injury Table, 42 C.F.R. § 100.3(a)) is alleged or where other factors indicate a litigative risk, *i.e.* where a party's likelihood of prevailing on the merits is subject to reasonable uncertainty. More formal alternative dispute processes, including neutral evaluation or mediation by a special master, judge, or an outside mediator, are also available.

If the case is not settled, one or more evidentiary hearings may be scheduled. When facts surrounding the administration of the allegedly causal vaccination, the nature of the symptoms displayed, or their onset are in controversy, the special master may decide that a fact hearing is necessary. In appropriate cases, the special master may hear the testimony of health care providers who treated the vaccinee, particularly if the medical records are incomplete or inconsistent. Counsel should be careful to avoid interfering with the doctor-patient relationship if treatment is ongoing.

Causation hearings generally involve the testimony of the medical experts who opined in the case. Hearings may take place at the Office of Special Masters in Washington, DC, or in other courtrooms throughout the country. Generally, the most cost-efficient location is selected, but factors such as the ability of a petitioner to travel are also considered in selecting a hearing location. With the approval of the special master, telephonic or video conferencing equipment may allow a witness to testify or a petitioner to observe a hearing from another location.

In most cases, the special master will issue a written decision on the issue of whether the petitioner is entitled to an award. A ruling against the petitioner may be reviewed by a judge of the Court of Federal Claims on motion by the petitioner. A ruling in favor of the petitioner puts the case into the damages phase.

When damages are relatively straightforward, direct negotiations between counsel for the parties usually result in a stipulation regarding a damages award. In more complex cases, the services of "life care planners" may be necessary to substantiate the need for and cost of various medical services. The parties may each retain a life care planner if necessary, or a joint life care planner may be employed to prepare a single plan on behalf of both parties. Use of a joint life care planner usually results in a faster resolution of damages. Economists and other financial consultants

are sometimes employed, but the special master should be consulted prior to retaining one.

Once a decision awarding damages has been issued, the petitioner must decide whether to accept the award, seek review of the special master's decision, or leave the Program and pursue a civil action. Likewise, respondent may seek review of the special master's decision, including the initial ruling determining that the vaccinee was entitled to compensation. A petition for review must be filed with the Court of Federal Claims within the statutory period. No waivers of this requirement are permitted.

Finally, the issue of attorney fees and costs must be resolved. Careful and contemporaneous documentation of the hours spent on the case, broken down by individual tasks performed and an indication of who performed them, is required to establish that the fees and costs claimed are reasonable. Unlike the contingent fee system prevailing in most other tort litigation, petitioners' reasonable attorneys' fees and costs are paid by the Vaccine Program, including, in most cases, fees and costs for unsuccessful litigants. In order to obtain fees and costs when a petitioner is unsuccessful, the petitioner must establish that the petition for compensation was brought and maintained in good faith and on a reasonable basis.

## SECTION II. INITIAL FILINGS

This Program is based on the statutory requirement that the initial submissions—the petition and the supporting documents—will contain the petitioner’s case-in-chief. § 11(c).

The proper discharge of respondent’s obligation to provide a complete evaluation of the merits of the claim (see Section III) and, in turn, the special master’s responsibility to render a timely decision, are held to and dependent upon the completeness of the petition. To assist petitioners in meeting the statutory filing requirements and to limit the time a case remains in the PAR process, some practical observations are offered below.

### Chapter 1. Drafting the Petition.

#### A. General Considerations.

Vaccine Act litigation begins with the filing of a petition setting forth the pertinent facts. The petition’s required contents are set forth in Vaccine Rule 2(c)(1). Sample petitions for both “On-Table” and “Off-Table” claims may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>. The models are based on factual assumptions that may or may not apply to a particular case. The petitioner should adapt this model to the factual circumstances of the case.

The petition should provide the respondent and the special master with a clear and complete notice of the specific nature of petitioner’s claim. Unlike pleadings in many civil actions, the petition should not be a formalistic document that merely tracks the statutory language, designed to “preserve” all possible claims or arguments. For example, a petition should not allege all possible Table injuries, but only those for which reasonable supporting evidence exists. If the evidence unexpectedly turns out to support an alternative theory of proof, leave to file an amended petition is routinely granted.

The petitioner should be aware that the statute requires that the Secretary publish in the Federal Register notice that a petition has been filed. § 12(b). This notice discloses to the public that the named petitioner is seeking compensation through the Program so that anyone with information about the case is on notice of the petition’s filing. Although no information about the petition or the petitioner is published, it is the practice of the Secretary, consistent with the statutory requirement, to publish the name of the petitioner. However, when the special master issues a decision in the case, information about the petitioner, including details about the claim and the petitioner’s medical condition, will be publicly available. Information about redacting a special master’s decision is in Section VI below.

Petitioners should be mindful of the applicable statute of limitations. See § 16.



## B. Matters to be Included.

### 1. Style of the Case (Case Caption).

#### a. Cases Involving Living Adult Competent Vaccinees.

The heading of the petition should identify the petitioner by full name. A sample caption is available at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>. Because the Vaccine Act permits recovery only for the vaccine-injured person, a spouse should not be listed as a petitioner.

#### b. Cases Involving Minors or Disabled Persons.

Because the statute requires notice that a petition has been filed, the names of all petitioners are published in the Federal Register. See § 12(b). Petitions involving minors should be captioned with the initials of the minor to avoid public disclosure of the minor's name. Vaccine Rule 16(b). A sample caption for a case involving a minor is available at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>. If the vaccinee is a minor, the heading of the petition should include the full name of the person or persons bringing the petition on the minor vaccinee's behalf, and the representative capacity in which the case is brought (e.g., "parent," "legal representative," "guardian," or "next friend"). The minor vaccinee should be identified in the case heading only by initials. To aid in tracking cases, petitions involving a minor vaccinee should be captioned with the parent or guardian name listed first, followed by the minor's initials.

If the vaccinee is a non-competent adult, the heading should include the full name of the person bringing the petition, the full name of the vaccinee, and the representative capacity in which the suit is being brought.

#### c. Death Cases.

If the vaccinee is no longer living, the petition heading should include the full name of the person bringing the claim on behalf of the estate of the deceased vaccinee, followed by the full name of the vaccinee, and an indication of the representative capacity in which the case is being filed.

### 2. Preamble.

The initial paragraph of the petition should identify the petitioner and, if the case is being filed in a representative capacity, the vaccinee. Unlike the caption, the full name of the minor vaccinee should be included in this introductory paragraph. The preamble should identify the vaccine(s) alleged to be causal. The petitioner should consult the Vaccine Injury Table, 42 C.F.R. § 100.3(a), to ensure that the vaccine is one covered by the Vaccine Program.

The preamble should also identify the injury suffered and whether the petitioner is claiming an injury listed on the Vaccine Injury Table (a “Table” injury), alleging a cause-in-fact injury (an “off-Table” injury), or is pleading both in the alternative. The petition should not allege a Table injury if the facts clearly do not support one. To allege a Table injury, the exhibits must support the occurrence of an injury listed on the Vaccine Injury Table within the time frame specified for the vaccine received and under the conditions required by the “Qualifications and aids to interpretation” section of the Vaccine Injury Table, 42 C.F.R. §100.3(c).

The geographic location of the administration of the vaccine, not the anatomical location of the injection, should also be specified, as the Vaccine Act covers only vaccines administered in the United States. § 11(c)(1)(B)(i)(I). If one of the exceptions to the statutory requirement calling for the vaccine to have been administered in the United States is applicable, fulfillment of the conditions of § 11(c)(1)(B)(i)(II) or (III) must be alleged. One caveat to this requirement involves claims for injection site injuries. In such cases, the petitioner should specify the anatomical site of administration, in addition to identifying the geographic location.

### 3. Body of the Petition.

The body of the petition should be presented in numbered paragraphs. Ideally, the factual assertions made in each paragraph should be supported by a reference to exhibits.

Each numbered paragraph should include citations to the record and the following information:

- a. The vaccinee’s full name and date of birth.
- b. Type of vaccine(s) alleged to have caused the injury and the specific date(s) of administration.
- c. Exact injury claimed. § 11(c)(1)(C). If an injury within the Vaccine Injury Table is alleged, this must be stated. If alleging an off-Table injury caused by a vaccine, the reason for believing that a causal relationship exists must be stated. A petition may allege both a Table injury and an off-Table (causation-in-fact) injury.
- d. Date and, if appropriate, time of day of the first symptom or onset of injury or condition following the vaccine’s administration. See 42 C.F.R. § 100.3(a).
- e. Fact-specific description of the claimed injury and symptoms. See 42 C.F.R. § 100.3(c). Vague statements such as “neurological injury” or “an immune dysfunction” are not sufficient. The petition should set forth:

(1) In a death case, an allegation that the deceased died from the administration of the vaccine or as a consequence of a Table Injury. § 11(c)(1)(C).

(2) In an injury case,

(i) The extent and nature of the injury; and

(ii) A statement that the injured party has suffered residual effects or complications for more than 6 months or suffered an injury from the vaccine which resulted in inpatient hospitalization and surgical intervention. § 11(c)(1)(D).

(3) In a case alleging that the vaccine “significantly aggravated” a pre-existing condition, the nature of the pre-vaccination condition or impairment and how the condition was worsened by the vaccine.

f. A brief description of the injured party’s condition prior to the administration of the vaccine.

g. If filed on behalf of a deceased person, or if filed by someone other than the injured person or a parent of an injured minor, an explanation of the authority to file the petition in a representative capacity. § 11(b)(1)(A).

h. A statement requesting deferral of a compensation demand. Because most vaccine cases are bifurcated, with evidence concerning compensation not presented until causation is established or conceded, the petitioner should request to defer presentation of the relief requested. If a petitioner is found to be entitled to compensation, the special master will set a schedule for the submission of such information. § 11(e).

i. A statement regarding whether any civil action relating to the vaccination has ever been filed. If a civil action was previously filed, the petition should set forth the date of filing and the date of dismissal of the civil action. Copies of the original complaint and of the dismissal documents should be filed as one of petitioner’s exhibits. A Vaccine Act petition may not be filed while a civil action for damages is pending in any state or federal court. § 11(a)(5)(B).

j. A statement indicating that the petitioner and/or the vaccinee has not received any compensation in the form of an award or settlement for the alleged injuries.

#### 4. Signature.

The petition must be signed by the petitioner, if appearing *pro se*, or if the petitioner is represented by counsel, by one attorney who is admitted to the Bar of the Court of Federal Claims<sup>2</sup> at the time the petition is filed.<sup>3</sup> That attorney will be designated “counsel of record” for petitioner(s), and his or her signature must appear on all subsequent filings. Only one counsel of record is permitted, but the rules permit another attorney to sign documents on behalf of the attorney of record. See Vaccine Rule 14(b)(3).

### Chapter 2. Filing the Petition.

#### A. Method of Filing the Petition.

##### 1. Paper Form.

*Pro se* petitioners **must** file the petition in paper form. Represented petitioners **may** file the petition in paper form. Once the petition is filed, all cases except those filed *pro se* will be automatically converted to electronic filing.

##### 2. Electronic Form

Represented petitioners may file the petition electronically in compliance with the Supplement to the Vaccine Rules.

#### B. Accompanying Documents.

##### 1. *Pro Se* Petitioners.

A *pro se* petitioner should file, along with the petition, two copies of the documents discussed in Chapter 3 of this section and a certificate of service, paying careful attention to the exhibit numbering and page numbering requirements. An exhibit list (effectively, a table of contents) should also be filed, listing each exhibit by number and identifying the documents contained in the filing. A sample exhibit list and certificate of service may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>. An updated exhibit list should accompany any future filed exhibits.

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<sup>2</sup> To obtain admission to the Court of Federal Claims Bar, see Rules of the United States Court of Federal Claims (“RCFC”), Appendix of Forms, Form 1 (“Admission Instructions” and the accompanying admission form). The RCFC may be accessed through the court’s website at [www.uscfc.uscourts.gov](http://www.uscfc.uscourts.gov).

<sup>3</sup> A petition filed by an attorney who has not yet been admitted to the court’s bar will be processed as if it is filed *pro se*. The time and costs associated with obtaining bar membership are not compensable as part of attorneys’ fees and costs. See *infra* Section X.

## 2. Represented Petitioners.

Counsel should not file exhibits in paper form. If the petition is electronically filed, the documents discussed in Chapter 3 of this section should be electronically filed, accompanied by an exhibit list, concurrently with the petition. If the petition is filed in paper form, the documents discussed in Chapter 3 of this section should be electronically filed, accompanied by an exhibit list, immediately after the case is converted to electronic filing. An updated exhibit list should accompany any future filed exhibits. A sample exhibit list may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

### C. Cover Sheet.

All petitions filed in the Court of Federal Claims must be accompanied by a Court of Federal Claims “Cover Sheet.” The Cover Sheet may be found on the Court’s website ([www.uscfc.uscourts.gov](http://www.uscfc.uscourts.gov)), attached to the Rules of the United States Court of Federal Claims (“RCFC”) at Appendix of Forms, Form 2. The Cover Sheet is used to input data into the court’s computer. Experienced practitioners are reminded that this form is periodically updated and the latest version of the form should be used.

The form is self-explanatory, but following are some tips. The “Agency Identification Code,” is “HHS.” The “Amount Claimed,” is “to be determined.” The appropriate three-digit “Nature-of-Suit Code,” depends on whether petitioner’s case involves a death or an injury and the type of vaccination involved, and should be selected from the accompanying codes for vaccine cases.

### D. PAR Questionnaire form.

Petitioners must also file a PAR questionnaire form, signed by the petitioner, along with the petition. The PAR questionnaire form can be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

## **Chapter 3. Filing Supporting Documents.**

### A. Obtaining Records.

Counsel should identify all pertinent medical care providers and obtain a current address for each provider before the petition is filed. It is the petitioner’s obligation to preserve and present all pertinent medical records and other evidence.

Although some petitioners’ counsel have filed copies of medical records they received from their clients, experience has demonstrated that such copies are often incomplete and must be supplemented later, causing delays. Counsel must obtain

certified copies of all records for filing directly from health care providers. Complete (unedited and unaltered) and certified records, regardless of content, must be filed. A sample certification statement for medical records may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>. Records filed without certification may lead to delays in the PAR process.

Some providers may be uncooperative or unresponsive. Subpoenas may aid in efforts to obtain records, but subpoena authority must be formally sought from the special master. In such cases, counsel should note at the time of filing that additional records are outstanding. Subpoena authority should be sought promptly to obtain these records. A sample motion for subpoena authority may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>. Delays in obtaining records have resulted in lost records because state statutes regarding retention of medical records vary. Tornados, floods, and fires have also resulted in lost records. Counsel should make every effort to obtain a complete list of health care providers at the earliest opportunity, and make prompt efforts to obtain records.

## B. Records Required.

The statute and the Vaccine Rules require that the petition must be supported by all medical and related records potentially relevant to the issue of whether petitioner is entitled to an award. Such records should be filed along with the petition if filed *pro se*. If the petition is filed electronically by an attorney on petitioner's behalf, the records should be filed electronically as described in Section D (Special Provisions Regarding Electronic Filing) of this chapter. If the petition is filed in paper form by an attorney on petitioner's behalf, the supporting records should be filed electronically within three days of the date of conversion to electronic filing. This early filing of evidence is necessary to process the case expeditiously. Accordingly, it is important that petitioner's counsel assemble the records before filing the petition.

The statute at § 11(c) explicitly sets forth the required documents, as does Vaccine Rule 2(c). The scope of the requirements is intentionally very broad. Counsel should include all medically related records that might possibly shed light on the question of causation, including all records pertaining to the vaccination itself and post-vaccination medical examination and treatment records.

Medical records must be in English and must be legible. If medical records were recorded in a language other than English, petitioners must arrange for professional translation as soon as practicable. If the records are illegible due to poor copying, petitioners should arrange to photocopy the original records. If handwritten records, particularly those surrounding the initial vaccination and treatment, are illegible, the health care provider should be requested to supply a transcription of them.

Some health care providers keep telephone logs separate from their records. These telephone logs may help to substantiate contemporaneous reporting of

symptoms, reactions, or problems, and requests for records should include a request for any telephone logs from physicians' offices or after-hours call services.

Petitioners should file the following records and documentation:

1. Records of Treatment Prior to Vaccination.

In the case of an infant or child under the age of three at the time the vaccine was administered, the documents supporting the petition should include all medical records, including laboratory and genetic testing records, relating to the pregnancy and birth, and all records pertaining to the infant prior to the vaccination, including those of "well baby" visits.

If the vaccinee is an older child or an adult, the filed records should include all records from all primary care providers for three years prior to the administration of the vaccine(s) alleged to be causal. The filing of earlier medical records may be required by the special master in some cases.

2. Emergency Records.

If the vaccinee required emergency attention in the form of ambulance service or emergency squad treatment, all records relating to such incidents should be obtained and filed, including records of the ambulance service, emergency medical technicians, police and fire departments, and "911" telephone records – in short, any records of any organization that was contacted or responded to the emergency situation.

3. Vaccination Records.

Complete vaccination records must be submitted in cases involving injuries to children. For cases involving adults, records for the vaccination claimed to be causal must be submitted. The filing of other vaccination records may be required by the special master.

4. Records of Post-Vaccination Treatment.

Complete records of all post-vaccination treatment, including all laboratory and genetic testing; speech, physical, and occupational therapy records; rehabilitation services; and specialty care records, should be submitted in the initial filing of supporting documents. Supplementation of these records will likely be required as the case progresses.

5. Day Care and School Records.

School records, including individual educational plans and developmental testing, may be required, especially in cases where records may indicate the student's state of

health or progress. For example, school records may provide useful corroboration of the onset of an illness or its severity.

## 6. Affidavits.

Under the statute, an affidavit must accompany the petition. § 11(c)(1). Vaccine Rule 2(c)(2)(B) clarifies this statutory requirement, stating that when a “petitioner’s claim does not rely on medical records alone but is based in any part on the observations or testimony of any person, the petitioner should include the substance of each person’s proposed testimony in a detailed affidavit(s) supporting all elements of the allegations made in the petition.” For example, the petitioner’s affidavit must support the fact, location, and type of vaccination, the disposition of any prior civil action, and the representative capacity if the petition is not brought by the injured person in his or her own capacity. Affidavits are sworn statements signed by the affiant and signed before a notary public, *i.e.*, notarized. Affidavits are to be filed as numbered exhibits.

The testimony of any other factual witnesses should be set forth in an affidavit. If an expert witness will be relying on symptoms of the injured party described by the parents or others, the petition must be supported by affidavits of such witnesses, setting forth fully the substance of what each witness observed. Memories of events are more accurate the closer in time to the events described, and thus affidavits of facts filed later in a case are often of lesser evidentiary value, particularly if the evidence was available at the time the petition was filed.

## 7. Medical Evidence not Available in Paper Form.

In some cases, autopsy slides, X-ray films, MRIs, CT scans, and similar items of medical evidence not in paper form will be relevant. Such evidence, if not available in digital form, may be impossible or highly expensive to copy. In such cases, these items need not be submitted with the other medical records. However, the existence of such items should be clearly communicated within the petition or by other written notice when petitioner or counsel becomes aware of them.

In these circumstances, the respondent should determine as quickly as possible whether it will need such items in evaluating petitioner’s claim, and if the evidence is deemed necessary, respondent’s counsel should advise petitioner’s counsel as soon as possible of the specific records needed. Petitioner’s counsel should provide the items forthwith (directly to respondent, not the court), so as not to delay the proceedings. Such items are presumed to be relevant, absent an extraordinary reason, and should be forwarded without the necessity of a special master’s order to do so. Respondent is charged with taking due care of the items while the items are in respondent’s possession. If necessary, special provisions may be made for supplying such items to the special master.



## 8. Death Certificates.

A death certificate must be filed in any case alleging a vaccine-caused death. Should a petitioner die before the case is resolved, a copy of the death certificate must be filed promptly with the court.

## 9. Records of Other Disability Claims.

If the petitioner has filed for or has obtained disability compensation under a state or federal program (e.g., workers' compensation or Social Security) or under a private disability policy, records pertaining to the filing and adjudication of the claim should be filed.

## 10. Video Records and Social Media Files.

Videos made prior to and after the administration of the vaccine(s) in question may be relevant to a vaccine injury claim. Likewise, entries in various social media or e-mail messages made at or near the time of the injury claimed may provide information relevant to establishing onset or severity of an injury. Such videos and files should be located and preserved, and their existence reported to the court and opposing counsel.

## 11. Additional Documentation.

All allegations made in the petition must be supported by documentary evidence. Therefore, the following should be included with the petition:

- a. If the petition is brought in a representative capacity by someone other than the parents of a minor, evidence supportive of that capacity.
- b. If a related civil action was previously filed, copies of court records regarding the filing and final disposition of that case.

## 12. Expert Reports (see *also infra* Section VI, Chapter 4) and Medical Literature.

The inclusion of an expert report with the initial filings accompanying the petition may expedite the resolution of the case. Whether it is necessary to include the opinion of a medical expert in the filings accompanying the petition will depend on the nature of the case. Many cases are resolved without the need for an expert report, either because the respondent concedes causation in the Vaccine Rule 4 report or because the parties settle the claim on a litigative risk basis, thus saving petitioners and their counsel the up-front costs of obtaining an expert report.

In the absence of medical records attributing the vaccinee's injuries to a vaccine covered by the Program and/or in cases presenting a novel theory of causation, the report of an expert supporting vaccine causation is required. The more novel the theory

of causation advanced, the greater the need for an expert report. Filing such a report shortly after the petition is filed will expedite resolution of the case.

In contrast, in cases involving vaccines and injuries that are frequently compensated, whether on a litigative risk basis or otherwise, filing an expert report along with the petition may be unnecessary. A review of the unpublished decisions of the special masters (available on the Vaccine Program section of the Court of Federal Claims website — [www.uscfc.uscourts.gov](http://www.uscfc.uscourts.gov) ) may be helpful in determining if compensation has been awarded previously or frequently. If the need for an expert report is in doubt, the matter should be addressed in the initial status conference held shortly after counsel for respondent enters an appearance in the case. Experts should not be retained in cases assigned to the Special Processing Unit (described in Section V, Chapter 3) without first conferring with the court.

The necessary content of expert reports and the qualifications of experts are addressed in more detail in Section VI, Chapter 5, below. If medical literature accompanies the expert report, each article should be filed as a separate exhibit. The expert should identify pertinent sections of medical journal articles by highlighting or underlining.

#### 13. Unavailable Documents.

If, after diligent efforts, required records are unobtainable because the records were lost, destroyed, or otherwise not available, their absence and the reason they are unobtainable must be explained by affidavit. § 11(c)(3).

#### 14. Statement of Completion.

When petitioner believes that all relevant medical records have been filed, petitioner should file a separate document titled “Statement of Completion.” A Statement of Completion is simply a statement that all medical and other records relevant to the petition have been filed. If additional medical records or other documents are necessary to complete the record, petitioner should delay filing the Statement of Completion until all necessary and relevant records have been filed. A sample Statement of Completion may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

### C. Organization and Filing of Exhibits.

The following requirements pertaining to the preparation and filing of exhibits concern both parties and apply whether exhibits are filed in paper or electronic form. Petitioners will use Arabic numbers to designate their exhibits. Respondent will use letters.

## 1. Exhibit Lists.

A table of contents listing all exhibits must accompany the petition. The exhibit list must be descriptive particularly clarifying which exhibits contain petitioner's primary care records (e.g., "Ex. 1, Birth Certificate"; "Ex. 2, Vaccination Records"; "Ex. 3, Prenatal records, Smith Obstetrics"). The exhibit list should also include the date range each exhibit contains (e.g., "Ex. 4, Jones Primary Care 2/2015-4/2018"). Respondent, likewise, must file an exhibit list for any submitted evidence.

Thereafter, any additional exhibits should be filed as attachments to a notice of filing and include an updated exhibit list. Including an updated exhibit list avoids the inadvertent or careless mislabeling of exhibits, resulting in duplicate use or omission of an exhibit number or letter. All evidentiary filings, including affidavits, expert reports, curriculum vitae, and medical literature, must be assigned an exhibit number or letter. Samples of both the notice of filing and exhibit list may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

## 2. Organizing and Labeling Exhibits.

The documents submitted with each petition must be organized into separately numbered exhibits. Exhibits from different medical care providers should be assigned separate exhibit numbers. When filing electronically, each exhibit should be filed as a separate PDF file attached to the petition or a notice of filing. A sample notice of filing may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

Each exhibit of more than one page must be separately paginated (e.g., Ex. 1's twenty pages are numbered 1 through 20; Ex. 2's five pages are numbered 1 through 5). Bates stamps may be used but should be reset at each separate exhibit. Hand numbering is acceptable, if legible. Computer generated numbering systems are encouraged, as are systems that identify both the exhibit number and the page number on each page of the exhibit.

Care should also be taken to ensure that documents are photocopied in legible form. Petitioner bears the burden of proving the case and illegible photocopies add nothing of probative value to the evidentiary record. Care should also be taken to ensure that the binding or hole-punching of paper exhibits does not obscure any portion of the medical records or other documents.

## 3. Filing Additional Exhibits.

Additional exhibits, such as updated medical records, records that were not available at the time the petition was filed, expert reports, medical literature, curriculum vitae, and supplemental affidavits, should be prepared and filed as indicated above. An updated exhibit list must be prepared and filed each time a new exhibit is filed.

Supplemental exhibits and updated exhibit lists should be filed as attachments to a simple “Notice of Filing Exhibit \_\_\_” and a “Certificate of Service,” examples of which may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>. Electronically filed supplemental exhibits do not require a Certificate of Service.

Each notice of filing must include on the signature page the date on which it is signed. Vaccine Rule 17(c). (Note: For all paper documents filed after the petition, if the total document is more than 50 pages in length, only an original and one copy, not two copies, need be filed with the court. See Vaccine Rule 17(d).)

#### D. Special Provisions Regarding Electronic Filing.

##### 1. General Provisions.

*Pro se* litigants may not file documents electronically. However, such litigants may file documents on CDs, provided that the documents comply with the rules pertaining to such filings as set forth below. A sample notice of intent to file on CD may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

To file documents electronically, counsel must have an individual PACER account and must be granted access to file documents electronically in the court’s ECF system. Applications for access to file documents electronically are submitted through PACER at [www.PACER.gov](http://www.PACER.gov) and will be granted to an attorney who is admitted to the bar of this court. The court will notify counsel when access to CM/ECF has been granted.

Counsel may not permit his or her log-in and password to be used by anyone other than an authorized agent of the “Filing User.” It is the Filing User’s responsibility to protect the user name and password.

##### 2. Filing and Viewing Documents Electronically.

When a document is electronically filed, the ECF system automatically generates a “Notice of Electronic Filing” (NEF), which is forwarded to all of the case participants via the email address(es) associated with the participant’s CM/ECF account.

The transmission of the Notice of Electronic Filing satisfies the service requirement of RCFC 5 and proof of service for RCFC 5.3. All electronic filings made in CM/ECF constitute both a filing under RCFC 5 and a docket entry pursuant to RCFC 58 and 79. The official court record is the electronic recording (or docket entry) as stored by the court, and the filing party is bound by the document as filed. A document submitted through this method is deemed “filed” on the date stated in the Notice of Electronic Filing, and filings made prior to midnight Eastern Time will be considered filed by that date.

When an electronic filing is made, counsel of record will receive a NEF at their designated email address. Counsel may add additional/secondary email addresses to their accounts, which can also receive NEFs on a case-by-case basis or for all cases in which the attorney is the attorney of record. NEFs contain hyperlinks to the electronically filed documents in the ECF system, the hyperlink is the document number on the court's docket. When the recipient clicks on the hyperlink, the PACER login screen will appear if the recipient is not already logged in to PACER. Recipients should enter their PACER login credentials. The document should open in a PDF file and should be saved to avoid future PACER charges. The attorney of record is afforded one free look at the document but for any future access, PACER fees may be incurred.

To query a case or view documents, the user must login to the court's CM/ECF system using his or her PACER credentials. Case dockets are accessed by selecting the Query option located on the blue menu bar at the top of the CM/ECF main screen. Any electronically filed document in a case may be accessed as long as the user is the attorney of record for one of the parties.

### 3. Other Filing Considerations.

Questions regarding proper document preparation, labeling, and filing may be directed to the Clerk's Office at (202) 357-6400. Some commonly encountered problems are addressed below.

a. Motions, objections, replies, or other pleadings are referred to in CM/ECF as the "Main Document." Exhibits to such filings should be attached to the main document and assigned the next sequential exhibit number in the case. Each exhibit must be a separate attachment. See Supplement to Appendix B Electronic Case Filing Procedure in Vaccine Act Cases ("Vaccine ECF Rules"), Section IV, Filing Requirements, numbered paragraph 10(a).

b. When preparing PDF files, whether for upload via CM/ECF or for filing on CD, the documents should be reviewed to determine that all files have been paginated. If printed on both sides, care must be taken to ensure that both sides of the document are scanned. Unless electronic page numbering is available on the scanner, the documents should be paginated before scanning. Exhibits should be divided into independent PDF files.

c. Care should be taken to ensure that uploaded PDF files do not exceed the CM/ECF file size limit. See Vaccine ECF Rules, Section IV, Filing Requirements, numbered paragraph 9. For file size and attachment limitations, please visit the Court's website at [www.uscfc.uscourts.gov](http://www.uscfc.uscourts.gov) or call the Clerk's Office at (202) 357-6406 for current file size/attachment rules. Because the file size limit has increased over time and accessing these larger files on a slower network connection can sometimes take an excessive amount of time, attorneys should avoid scanned files whenever practicable and should always utilize PDF optimization methods to keep files as small as possible. Optimization methods vary depending on the PDF software used but can often reduce

file size by 50 to 90 percent. Before attempting to upload PDF files, attorneys should also remove any imbedded security protections that could prevent upload, including passwords, encryption, and write protection.

d. Exhibits should be separately paginated. See Vaccine ECF Rules, Section IV, Filing Requirements, numbered paragraph 10(a). Each attached exhibit should be consecutively numbered or lettered, labeled according to its source or subject matter, and include a brief written description of its contents (e.g., Petitioner’s Exhibit 1 \_\_Prenatal Records, Dr. Smith). See Vaccine ECF Rules, Section IV, Filing Requirements, numbered paragraph 10(b). PDF files of exhibits that exceed the size limitation may be split into separate PDF files and labeled by part (e.g. “Exhibit 1 part 1,” “Exhibit 1 part 2,” etc.).

e. Each electronic filing (the main document when exhibits are attached) must be signed by the attorney of record or by a member of the bar authorized to sign on behalf of the attorney of record. See RCFC 11(a); Vaccine ECF Rules, Section VI, Signatures and Related Matters, numbered paragraph 19.

f. The case caption, docket number, and special master’s name should be carefully checked before the document is filed. See Vaccine Rule 16.

g. The filer should exercise care in selecting from the event menu. A common error is identifying a “motion” as a “notice.” By way of definition, if a party is requesting the special master to take some action, then the party is filing a “motion,” not a “notice.”

h. When possible, medical journal articles should be converted by optical character recognition (“OCR”) or other text recognizable format before filing, allowing the journal article to be searched electronically for specific terms relevant to the case.

#### 4. Filing Documents on CD.

As an alternative to uploading very large files or a large number of smaller files through CM/ECF or for filings that exceed the maximum file size set by the court, parties may file material on CD.

Filing on CD is accomplished by first entering a “Notice of Intent to File on Compact Disc” through CM/ECF (or, in the case of *pro se* petitioners, filing a written notice to that effect). This document should be styled in the same manner as any other filing, including the case caption, case number, and special master’s name. The document must contain an exhibit list for the material filed on the CD and a certification that the CD was scanned using up-to-date antivirus software, and must also include a Certificate of Service. A sample of a Notice of Intent to File on Compact Disc is available at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

Two copies of the CD, along with a printed copy of the Notice of Intent to File on Compact Disc are due within five days of the filing date of the Notice. A copy of the CD must also be served on opposing counsel. The CD will be deemed “filed” on receipt by the Clerk of Court, not on the date the Notice was filed. If the CD is not received within five days, the Notice of Intent to File on Compact Disc may be stricken from the record.

Files on the CD must be in PDF, paginated, and designated by exhibit number (for petitioner) or by letter (for respondent). Each exhibit will comprise a separate PDF file. The file name should contain a brief description of the content of the exhibit (example: Ex. 3\_University Hospital\_pp. 52-100.). All discs must be “closed” and “finalized” prior to filing so that additional information cannot be written to the CD. Scanning with antivirus software should be performed after the CD is closed.

#### 5. Formats for Electronic Submissions Made Outside the CM/ECF System.

Electronic submissions made outside the CM/ECF system, including CDs, DVDs, or other storage systems, must be submitted on media that are readily accessible on a Windows compatible computer. Counsel should contact chambers for guidance prior to submitting any electronic files in a format not accessible with standard office software.

## SECTION III. RESPONDENT'S REVIEW AND REPORT

### Chapter 1. Respondent's Initial Review.

Pursuant to Vaccine Rule 4(a), within 30 days of the filing of a petition, respondent must review the petition and accompanying documents, e.g., medical records and affidavits. This review is necessary to determine whether all information needed to permit respondent to evaluate the merits of the claim has been filed.<sup>4</sup> If respondent identifies deficiencies in the petition and accompanying documents, such as pertinent medical records yet to be filed, respondent should contact petitioner's counsel immediately and provide petitioner's counsel with a list of missing records. Petitioner should obtain and file the requested records as soon as possible.

In general, any questions regarding the relevancy of records and the need for their production will be resolved in favor of production. If petitioner has doubts about the relevance of requested records, petitioner should keep in mind that the standard used for determining relevance is a liberal one, *i.e.*, whether the requested records might shed light on any issues relating to petitioner's claim. Such an approach is consistent with the statute governing the Program, which provides for less-adversarial, expeditious, and informal proceedings as well as flexible and informal standards for the admissibility of evidence. See *generally* § 12(d). On a practical level, it may be quicker and more efficient simply to provide the requested records rather than delay the case while the special master resolves a relevancy dispute even if the petitioner believes that the requested records are of dubious relevancy. In the rare case when the parties cannot resolve a relevancy dispute on their own, they should contact the special master.

If additional documentation is requested by respondent or by the court, petitioner shall file a "Statement of Completion" when all the additional documents are filed, regardless of whether one was filed earlier in the case.

### Chapter 2. Respondent's "Rule 4 Report."

#### A. Overview.

Once the pertinent records are filed, respondent reviews the records and provides an assessment of the claim pursuant to Vaccine Rule 4. Known as a "Rule 4 report," this report, consistent with the flexible and informal process envisioned for Vaccine Act proceedings, is filed in lieu of an answer.

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<sup>4</sup> In some instances, e.g., where the statute of limitations is soon to run, it may be necessary to file a petition without all the relevant records. A meaningful evaluation of the documents submitted with the petition cannot occur until most of the pertinent records have been filed. When the petition is filed with few or no medical records, respondent's review may be deferred until sufficient records are filed.



## B. Timing.

Pursuant to Vaccine Rule 4, respondent's report is due within 90 days of the filing of a petition. This deadline is frequently extended because the records accompanying the petition are not complete, because the special master determines that petitioner needs to file an expert report before a Rule 4 report is filed, because the parties agree to discuss settlement, or because respondent requires additional time to review the records and evaluate the case. If the petition is accompanied by an expert report or if petitioner files an expert report prior to the Rule 4 report deadline, respondent's Rule 4 report must include at least one expert report, unless respondent does not contest entitlement or the special master grants respondent's request to suspend the filing of an expert report.

## C. Content.

### 1. Analysis.

Respondent's report is not intended to be a formalistic legal document designed to preserve defenses or arguments. Rather, the report should be a straightforward statement of respondent's evaluation of the medical and legal basis for petitioner's claim. As such, the focus of the report should not be on a recitation of the cases governing adjudications. Instead, the report should give both petitioner and the special master full notice of and an opportunity to evaluate the details of respondent's position regarding an award of compensation. As is the case with petitions, there is no need for a formalistic pleading because in the event that the evidence develops in an unanticipated direction, supplemental reports may be filed to clarify or modify respondent's position. Pro forma objections, such as those indicating that a petitioner has failed to supply an expert report before one has been ordered, do little to advance resolution of the case and, thus, if included, should constitute only a small part of the analysis in the Rule 4 report.

### 2. Legal and Factual Issues.

The report should identify any legal or factual impediments to petitioner's claim. For instance, if there is a dispute as to whether a vaccine was received, this is a factual issue that must be resolved prior to further proceedings and thus should be identified in the Rule 4 report. When warranted by the pleadings and evidence filed to date, respondent should file appropriate motions, such as a motion for summary judgment or a motion to dismiss, with the Rule 4 report. The failure to file such motions along with the Rule 4 report does not preclude respondent from raising such issues later in the proceedings, but raising such issues early in the proceedings will save time and effort and avoid needless expenditure of Program funds on cases that are time-barred or present factual issues that should be resolved before obtaining expert reports.

### 3. Medical Conclusions.

If petitioner has filed an expert report in support of the claim, respondent shall file a medical expert report along with the Rule 4 report. If respondent believes an expert's report is not warranted, respondent must so inform petitioner and, prior to the Rule 4 report due date, bring the issue to the special master's attention.

When there are no legal, factual, or threshold impediments to petitioner's claim, the Rule 4 report may consist entirely of respondent's medical analysis of petitioner's claim. In addition to a summary and assessment of the completeness of the medical records, the Rule 4 report should address respondent's position as to the adequacy of petitioner's claim in light of petitioner's burden of proof and what alternative cause, if any, respondent believes is responsible for petitioner's medical condition.

In addition to setting forth respondent's view of the case and the evidence on which respondent relies, the Rule 4 report should address petitioner's evidence and the causation theory or theories advanced by petitioner. Where petitioner has included affidavit testimony, respondent's report should review and address whether it is consistent with statements in the medical records. If appropriate, respondent's report should note whether the affidavit testimony is implausible or inconsistent with the medical records.

Respondent's report should identify any inconsistencies between the injured party's symptoms as described in affidavits and those set forth in the medical records. It may be helpful for respondent's expert to give a hypothetical opinion assuming the affidavit testimony to be credible. This will **not** in any way constitute an admission by respondent as to the accuracy or relevancy of the affidavit testimony, but may be helpful if the special master should decide to accept the affidavit testimony as accurate.

Respondent, like petitioner, may wish to submit documents as evidence along with the report. Such documents may include articles from medical literature. The expert should identify pertinent sections of medical journal articles by highlighting or underlining.

The report should indicate clearly whether respondent agrees or disagrees that petitioner is entitled to compensation. Alternatively, the report may indicate that respondent takes no position, will not expend further resources with respect to the petition, and requests a ruling on the record.

## **SECTION IV. ROLE OF THE SPECIAL MASTER**

### **Chapter 1. General Matters.**

The special master's role differs slightly from that of an adjudicator in traditional litigation. The special master may be more actively involved in the early stages of proceedings than is usually the case with a judge in a traditional civil proceeding. The special master may confer frequently with the parties in informal status conferences. In these status conferences, the special master may identify information that is needed, and, where appropriate, may assist a party in obtaining it. A special master may make tentative findings, ask the parties to clarify their positions, and work actively with the parties to develop a streamlined method for resolving the case.

Further, in recognition of Congress's intent that the special masters be more "inquisitorial" than judges in typical litigation, the special masters may ask for more documents when such a need is determined, file medical articles that appear relevant, question witnesses where appropriate, and inform the parties concerning what additional evidence is necessary. In unusual instances, special masters may suggest the hiring of a neutral medical expert to render an opinion on a medical dispute, such as the appropriate diagnosis or prognosis. Special masters have ordered medical testing to be performed in order to clarify a diagnosis or to resolve conflicts in medical opinions, particularly when a medical expert opines that such testing would be relevant to the issue of causation or the quantum of damages.

The special masters' inquisitorial powers do not change the evidentiary burdens of the parties. The parties are responsible for the traditional litigative tasks of identifying and developing information supporting or opposing an award, securing and presenting fact witnesses and expert testimony, and meeting their respective burdens of proof.

### **Chapter 2. Orders and Status Conferences.**

In order to expedite the processing of Vaccine Act cases, special masters will conduct periodic status conferences and issue orders to the parties. Generally, status conferences will be conducted by telephone and will not be recorded. They may, however, in the discretion of the special master or at the request of a party, be digitally recorded.

Specific types of status conferences are used at certain stages of case processing. The frequency and content of other status conferences and orders vary considerably among special masters, with some preferring more frequent status conferences and others relying more heavily on written orders and status reports to move cases to resolution.

Parties may request a status conference at any time to resolve any matter that arises. Typically, a status conference is requested to resolve disputes, update the special master on matters of import, discuss problems with recent filings, and determine

the next steps in the case and set deadlines for those steps. Counsel are strongly encouraged to confer with each other prior to requesting a status conference.

#### A. Post – PAR Initial Order or Conference.

Once a petition is assigned to a special master, he or she will schedule an initial status conference, issue an initial order, or do both.

##### 1. Initial Status Conference.

An initial status conference may be convened following the PAR Activation Order and reassignment to a special master. This status conference has many purposes, including: (1) assessing the completeness of the petition and any supporting documents (additional records and other evidence may be identified as necessary to resolve a case notwithstanding the PAR Activation Order); (2) developing a timeline for completing the development and resolution of the case; (3) advising the parties of any practices or procedures unique to the assigned special master; (4) discussing the Vaccine Act's requirements, including the need to document time and expenditures for fees and costs applications; (5) assessing the parties' desires as to settlement negotiations; and (6) answering any appropriate questions the parties may have about the procedures to be followed.

##### 2. Post – PAR Initial Order.

Some special masters issue a comprehensive initial order prior to any initial status conference. Others may simply issue an initial order, particularly if counsel are experienced in the Vaccine Program and an initial conference is not needed.

Most special masters who conduct an initial status conference will follow it with an order, providing deadlines to the parties for completion of case-specific tasks. If asked for input regarding these deadlines, the parties are expected to provide candid answers. For example, if an expert has not yet been consulted or retained, a petitioner is unlikely to be able to provide an expert report within 30-60 days, and therefore should provide a reasonable, but realistic, estimate of the time needed to obtain an expert report.

#### B. Periodic Status Conferences and Reports.

Periodic status conferences and/or status reports provide an opportunity to work collaboratively to position the case for resolution. These conferences provide the parties an opportunity to update the special master about case progress or problems. They provide the special master with an opportunity to advise the parties about his or her views of the issues in the case and how the special master views the case progress. They are intended to expedite case processing, not to burden the parties.

If an attorney associated with a petitioner's attorney of record is more familiar with the particulars of the case, that associate may represent the petitioner at a conference. Also, at such conferences, counsel for both parties will have the opportunity to propose procedures to process the case most efficiently. Counsel are encouraged to make use of these opportunities, and should feel free to suggest creative ways to expedite a case. Opposing counsel are also urged to consult with each other outside of status conferences, thus enabling them to make joint proposals about procedures or to stipulate to portions of the case.

Counsel are also invited to use status conferences to make the special master aware of developments in the case, or to ask questions about procedures in vaccine cases. Either party may request a status conference at any time by telephoning the special master's chambers.

### C. Other Orders.

#### 1. Scheduling Orders.

Scheduling orders are used to establish a timeline for case development. Counsel are expected to comply with the deadlines established therein. If a deadline cannot be met, extensions will ordinarily be granted, but counsel are expected to comply strictly with the procedures for requesting extensions found in Vaccine Rule 19, particularly the requirement to contact opposing counsel and to inform the special master of that counsel's position on the requested extension. If opposing counsel is unavailable, counsel seeking the extension is responsible for continuing efforts to contact opposing counsel and to update the special master when contact has been made.

#### 2. Show Cause Orders.

A failure to comply with one or more court orders may result in an order to show cause why the case should not be dismissed. A failure to respond in a timely fashion to an order to show cause will likely result in the dismissal of the petition.

Some special masters may issue a show cause order when a motion to dismiss, motion for a ruling on the record, or motion for summary judgment is filed. Others may simply grant the relief sought without issuing a show cause order. No motion will be granted before the expiration of the time period to respond for the party against whom the relief is sought, unless the party represents that the motion is unopposed or is filed with the opposing party's consent.

## **Chapter 3. Enforcing Deadlines.**

The deadlines found in the Vaccine Act, prescribed by the Vaccine Rules, and set forth in scheduling orders, must be followed so that petitions may be resolved in a timely fashion. Upon good cause shown, a special master or judge may grant

extensions of time to accomplish the required tasks, except with respect to any time period specified in the Act, Rules, or case law as not susceptible to extension (e.g., the 30-day period for filing a motion for review of a special master's decision).

A request for an extension of time should comply with Vaccine Rule 19 and be made prior to the expiration of the given time period. If compliance with Rule 19 is not possible, the court will entertain a motion to extend *nunc pro tunc*. However, counsel must explain both why an extension is necessary and why it was not requested before expiration of the deadline.

Vaccine Rule 19 requires that a party requesting an extension of time confer with opposing counsel and report opposing counsel's position on the requested extension in the request. If opposing counsel is unavailable at the time the request must be made, the attorney seeking the extension shall continue efforts to ascertain opposing counsel's position on the requested extension and promptly report that position to the special master. Opposing counsel should be contacted no less than 24 hours prior to the relevant deadline in order to allow a reasonable time to obtain a response.

In certain situations, a party may seek an extension of a deadline without filing a written motion. For example, if computer systems are down in the attorney's offices, filing a motion may be difficult. In such cases, counsel should contact chambers to determine how to proceed. Otherwise, requests for extensions of time must be made by written filing, unless the special master has indicated otherwise.

If counsel presents no explanation, or an insufficient one, for not meeting a deadline, the court may take the following discretionary actions or fashion others appropriate to the circumstances:

- Should respondent's counsel be in default, the court may make a written report to that attorney's supervisor;
- Should petitioner's counsel be in default, the number of hours requested in any subsequent application for fees and costs may be reduced.

#### **Chapter 4. The "Rule 5 Conference."**

Under the Program, claim resolution is more expeditious and less formal than in traditional litigation. To this end, Vaccine Rule 5 sets forth a procedure designed to expedite and simplify the decision-making process. After reviewing the petition, the evidence, and the expert reports, the special master may conduct an informal conference (usually by telephone) at which the special master may: (1) give each party an opportunity to address the other's position; (2) state the special master's tentative view as to the merits of the case; and (3) establish with the parties what issues remain to be addressed and the most efficient means for deciding those issues.

The extent of the “Rule 5 conference” may vary, depending on the special master’s review of the available evidence. It is beneficial if each party fully develops its case before filing the petition and supporting evidence or Rule 4 report, respectively, and sets forth fully and completely the substance of its case. Information may not be withheld only to be supplied at subsequent stages of the proceedings.

The benefits from this early, full discussion of the case’s substance include: (1) notice of any deficiencies in the case in time to rectify such deficiencies; (2) the special master’s view of the merits of the case, possibly fostering settlement; (3) if settlement is not possible, an opportunity to narrow the issues through stipulation; (4) a discussion of the nature and timing of further proceedings needed; and (5) in the rare case where appropriate, a final decision.

Any tentative conclusions noted by the special master at the Rule 5 conference are just that – tentative. The special master’s comments will not have any official status and cannot be relied on in any formal sense. The special master may make candid assessments of the strengths and weaknesses in the case, but the special master’s comments should not be viewed as a final ruling. Occasionally, the Rule 5 conference may result in the filing of supplemental expert reports or other evidence. Additional evidence, argument, or further consideration by the special master may change the special master’s view of the case.

## **Chapter 5. Obtaining Evidence and Discovery.**

There is no discovery as a matter of right in a vaccine proceeding. Because the petition and respondent’s report are expected to disclose fully the substance of each party’s case, there is much less need for discovery than in traditional litigation. Moreover, when one party perceives a need for further information, such information should be disclosed quickly and informally without the need for formal discovery procedures.

If a party finds informal discovery insufficient, that party may seek formal discovery, either through a written motion or at a status conference. Such requests should be made at the earliest possible point in the proceeding. The moving party must demonstrate why informal discovery was not sufficient and why the matters sought are necessary to a fair decision. In response to such a request, the special master may, in the exercise of his or her discretion, order some form of discovery, *e.g.*, that documents be made available. Depositions and written interrogatories are rare but may be permitted in some circumstances.

Should a subpoena prove necessary, the moving party will precisely identify the records sought, the custodian, and the location of the records. A sample motion for subpoena authority may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>. The special master will issue an order specifying the allowed scope of discovery, and the movant should then utilize the sample subpoena form found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

The moving party should attach the special master's order to the subpoena before service to show that it has been authorized by the court. If petitioner is proceeding *pro se*, the special master may order respondent to prepare and serve the subpoena, based on the information supplied by petitioner.

Any ordered discovery will be closely supervised by the special master in accordance with the exercise of the special master's discretion. In extreme cases, special masters have ordered depositions of recalcitrant health care providers who were unresponsive to subpoena. On occasion, discovery from non-parties is sought, but such discovery has occurred only in rare and exceptional cases.



## **SECTION V. SETTLEMENTS AND ALTERNATIVE DISPUTE RESOLUTION (“ADR”)**

### **Chapter 1. Trends in Settlement in the Vaccine Program.**

A significant number of Vaccine Act cases are resolved by settlement, although the facts and circumstances of some cases may make settlement unlikely. Settlements are an expeditious and efficient method for resolving appropriate cases. Settlements generally occur (1) within the first 12-18 months after the petition is filed; (2) after the Rule 5 status conference; or (3) after a decision on entitlement. Settlements prior to a decision on entitlement generally represent so-called “litigative risk” settlements, in which a party’s likelihood of prevailing on the merits modifies the valuation of potential damages. In litigative risk settlements, the respondent does not concede that vaccines are responsible for petitioner’s injuries, or that petitioner has satisfied the criteria for compensation, but is willing, without formally conceding entitlement, to pay some compensation.

### **Chapter 2. Settlements.**

#### **A. Reasons to Engage in Settlement.**

Settlements significantly reduce the time period between filing of the petition and ultimate receipt of compensation. Both counsel are encouraged to consult with their respective clients soon after the petition is filed regarding settlement. A petitioner should feel free to initiate settlement discussions with respondent’s counsel at any point after a petition is filed.

Even with expeditious processing, however, a well-documented but contested off-Table injury case is unlikely to reach a ruling on entitlement in less than 24 months. If entitlement to compensation is found, additional time is required for the damages phase before compensation can be awarded. Many cases take much longer than 24 months to reach a causation decision. Updating and filing records, obtaining expert reviews and opinions, scheduling and conducting hearings, filing briefs, and issuing an entitlement decision take considerable time and effort and may ultimately result in a decision adverse to petitioners.

If a party proposes settlement, that fact will not be considered by the presiding special master should settlement negotiations fail to result in resolution of the case.

#### **B. Initiating Settlement.**

Some special masters encourage settlement discussions between the parties soon after the case is filed. Others expect the parties to indicate whether settlement discussions are desired. When the parties engage in early settlement negotiations, special masters are generally willing to assist the process by extending deadlines for filing documents and reports to avoid an unnecessary expenditure of resources, or to refer the matter to another special master or an outside professional for mediation

purposes. Parties are encouraged to contact the assigned special master whenever they enter into good faith settlement discussions or desire the guidance or assistance of the special master regarding potential negotiations or settlement. Either party should feel free to initiate settlement discussions at any point after a petition is filed.

To initiate participation in ADR, the parties should contact the presiding special master to request suspension of existing deadlines and the assignment of a mediator. Chapter 4 below contains more information about ADR in general and the types of ADR available.

### C. Obtaining Information to Facilitate Settlement.

Often, respondent will need additional documentation from petitioner unrelated to entitlement to enter into any meaningful discussions and to make a reasonable response to a settlement request. Such documentation may include health insurance plans, information regarding Medicaid payments, income tax returns or Social Security account statements (documenting past earnings), and out-of-pocket health care costs. If a petitioner's counsel anticipates making a settlement request, early efforts to obtain these documents from a client are necessary so that meaningful discussions can occur.

Information about prior settlements in cases involving the same vaccines and injuries can be found in decisions posted to the Court of Federal Claims website ([www.uscfc.uscourts.gov](http://www.uscfc.uscourts.gov)), under the Opinions/Orders tab. However, decisions approving voluntary settlements generally do not include information about the extent of the claimed injury or the economic loss suffered.

## **Chapter 3. The Special Processing Unit.**

### A. Purpose of the Special Processing Unit.

The Special Processing Unit ("SPU") is designed to increase the Vaccine Program's ability to provide for the expedited and informal resolution of claims that appear reasonably likely to settle at the outset of the matter's filing. Although all SPU cases are ultimately decided by the Chief Special Master, an OSM staff attorney conducts the day-to-day management of the case -- including providing support to the parties and informing the Chief Special Master of the parties' progress. If the parties cannot settle the action, the Chief Special Master thereafter resolves the case -- whether by deciding it or removing it from the SPU process, reassigning the case to another special master for disposition.

### B. Assignment to the SPU.

Once a petition is filed, it is reviewed during the PAR process to determine if it is a candidate for early resolution. If a case appears appropriate for expedited settlement or, less commonly, likely subject to dismissal, the case is assigned to the Chief Special Master as part of the SPU following the PAR Activation Order. Cases appropriate for

expedited settlement are those without substantial complicating factors that historically have been conceded or settled. Cases involving Table injuries, for example, may be appropriate for referral to the SPU. Cases subject to dismissal through SPU are those involving a substantial defect obvious from the allegations contained in the petition, such as a case involving a vaccine not covered by the Vaccine Program.

It is important for petitioners to accurately describe the facts and allegations on which their claims are based in their petitions, so that the appropriate identification can be made. Information regarding the proper contents of a petition can be found at Section II, Chapter 1.

### C. Processing of SPU Cases.

Like all vaccine cases, SPU cases are processed in accordance with the statute and Vaccine Rules. After a case is assigned to the SPU, an initial order is filed which:

1. Indicates the case has been placed in the SPU;
2. Suspends the deadline for respondent's Rule 4 report;
3. Reminds the parties to confer with each other, and with the court, before engaging the services of an expert;
4. Provides instructions regarding attorneys' fees;
5. Sets a time frame in which the initial status conference will be conducted; and
6. Provides the contact information for the staff attorney assigned to manage the case.

Suspension of the deadline for respondent's Rule 4 report allows the parties the opportunity to informally settle the case in an expedited manner. Respondent may, however, request to file a Rule 4 report.

All available relevant medical records should be filed with the petition. Petitioners must file the records required by the statute and Vaccine Rules in all vaccine cases. See § 11(c)(2) and (3); Vaccine Rule 2(c).

OSM's recently-adopted PAR process should result in SPU-identified cases having most if not all records necessary for review already filed. However, if additional time is needed to file records not identified in the PAR process but which the parties deem relevant to resolution of the matter, petitioners should file a motion for an extension of time pursuant to Vaccine Rule 19. If more time is allowed, the deadline for holding the initial status conference may be similarly extended.

The parties should not retain a medical expert, life care planner, or other expert without first consulting with each other and the Chief Special Master. The Chief Special Master may order an expert report or allow for the retention of a life care planner or other expert, but the parties should wait for instructions from the Chief Special Master before retaining an expert. If counsel retains an expert without such consultation, reimbursement of those costs may be affected.

In SPU cases, conference calls are held: (1) to allow the parties an opportunity to discuss the completeness of the petition and supporting medical records and documents; (2) to inform the parties of the practices and procedures implemented by the Chief Special Master in SPU cases; (3) to set the schedule going forward; (4) to determine if respondent has formulated a position regarding the merits of petitioner's case and if the parties are open to discussing settlement; and (5) to inquire if the parties have any questions or concerns for the Chief Special Master.

As soon as HHS has had the opportunity to review the claim (subject to the claim's age), respondent's counsel will report whether respondent agrees that the case meets the requirements for entitlement to compensation under the Act, or, alternatively, is amenable to pursuing an informal resolution of the case through a litigative risk settlement. If respondent finds that the requirements for entitlement to compensation have been met, this will be communicated through a Rule 4 report. Respondent will, however, otherwise communicate directly with petitioner and the court as early as possible if it is appropriate for petitioner to begin to work on damages. If the parties are considering an informal resolution, this may be communicated during a status conference, by email communication with the court, or in a status report.

If respondent contests entitlement and is not amenable to informal resolution, and if petitioner elects to proceed with litigation, the petitioner may be ordered to file an expert report supporting the claim. The Chief Special Master, however, will tailor instructions to the parties depending on the specific circumstances of the case. Because of the time necessary to obtain and file an expert report, such reports will not be favored for the majority of SPU cases unless the parties and/or the Chief Special Master believe an expert opinion is substantially likely to resolve the matter.

If the parties are able to agree on entitlement, damages, or a litigative risk settlement, then orders, rulings, and decisions will be issued as appropriate. At any time, the parties may request ADR and may be so referred to under the procedures set forth in Chapter 4 of this section.

#### D. Removal from the SPU.

In certain circumstances, the Chief Special Master may remove the case from the SPU and reassign it to another special master for the conduct of further proceedings, including, but not limited to, a hearing. Removal from SPU will not preclude further settlement discussions while the case proceeds.

## E. Limitations on Staff Attorney's Role in the SPU Process

OSM staff attorneys are the primary contact for litigants in SPU cases. However, staff attorneys do not decide SPU cases, and are not delegated any authority by any special master. In any and all disputed issues that arise in an SPU case, it will be the Chief Special Master who determines the outcome. The Chief Special Master is solely responsible for requiring the submission of evidence and other information, requiring testimony and production of documents, and conducting hearings. Parties should not ask the staff attorney associated with a given SPU case to "decide" any issues arising within it.

## **Chapter 4. Alternative Dispute Resolution Options.**

### A. ADR in General.

ADR is a term widely used to describe methods and techniques of facilitating settlement of disputes without resort to formal court proceedings. Generally, ADR methods assist the parties in understanding the strengths of both sides of the case, in assessing their chances of prevailing in formal litigation, and in viewing their case objectively from different perspectives. The success of any ADR technique depends to a great extent on the parties themselves. ADR techniques rely on collaborative discussion rather than adversarial proceedings. When ADR is successful, a voluntary settlement is reached quickly and efficiently. Even if a settlement is not achieved, the parties' understanding of the case is greatly enhanced, resulting in a more focused presentation to the special master and ultimately a quicker resolution.

The ADR techniques available in vaccine cases and the role of the special masters in facilitating the process are discussed below. The parties themselves, subject to the special master's approval, may choose the ADR procedure they believe most appropriate in their case. If one option is unsuccessful, the mediator may suggest another option, or a blending of options, to break a logjam. The parties are not limited to the options listed below and should feel free to suggest others.

### B. Preparation for ADR.

The success of any ADR proceeding depends to a great extent on the parties themselves and their preparation for and desire to enter into collaborative discussions. To maximize the potential for success, prior to a negotiation session, the mediator may hold a preliminary conference with counsel for both sides, either separately or together, or both. The mediator may ask the parties to be prepared to discuss certain issues, and may require the submission of a mediation statement or other information. Prior to the initial session with the mediator, the parties should review the file and become familiar with the factual and procedural history of the case, negotiations to date, any key factual or legal disputes, areas of agreement, possible areas of compromise or settlement, and any nonnegotiable areas or items.

## C. Types of ADR Options Available.

### 1. Mediation.

Mediation involves a third party working with respondent and petitioner to facilitate settlement negotiations. The mediator attempts to help the parties improve their communication with one another, identify the key interests of each side, and determine areas of each party's position in which there is enough flexibility to allow for compromise. The mediator usually has an initial meeting with both parties together, including the petitioners themselves, followed by meetings with each side separately in what has sometimes been called "shuttle diplomacy." Mediation may consist of a single session lasting from a couple of hours to a full day, or may consist of more than one session with time periods in between the sessions.

Prior to beginning mediation, the mediator may require the submission of a mediation statement. Even if no mediation statement is required, the parties should review the file and become familiar with and be prepared to discuss the history of the claim and response, the negotiations to date, any key factual or legal disputes, areas of agreement, possible areas of settlement, and any nonnegotiable areas or items.

### 2. Neutral Evaluation.

In neutral evaluation, a third party evaluates the substance of the case and the parties' respective positions, and then gives each side a frank assessment of the strengths and weaknesses of that party's case. Neutral evaluation can often break a logjam in settlement negotiations, particularly when a client or client agency has an overly optimistic assessment of the strength of the case or of the defense.

### 3. Early Neutral Evaluation.

Early neutral evaluation involves the evaluation of the case by a special master other than the one to whom the case is assigned. Early neutral evaluation occurs as soon as possible after the petition is filed, once sufficient medical records are filed so that a special master may assess the strength of petitioner's case. After meeting with the parties together (telephonically or in person) to hear their respective assessments of the case, the early neutral evaluation special master then meets separately with each party, and provides a candid assessment of the likelihood of prevailing on the merits and the probable range of any damages award, should the petitioner prevail.

The advantage of early neutral evaluation is that each party has an opportunity to hear how the other side assesses its own case, but the evaluation by the neutral special master is heard in private. Although additional negotiations are often necessary to reach a settlement of the case, the parties enter into mediation armed with information about how an experienced special master would evaluate the case.

#### 4. Mini-trials.

In a mini-trial, the parties present an abbreviated form of their case with an agreed-on time limit for case presentation. This procedure may be particularly useful when the record as it stands does not yet contain enough information for either side to appreciate fully the strengths of its case. The mini-trial can be conducted as informally as the parties prefer. The parties may choose the person to preside at the mini-trial—*i.e.*, the presiding special master, another special master, or someone else—and to what extent (if any) they wish the presiding official to offer an evaluation of the evidence after the presentation. The basic theory of the mini-trial is that it will give the parties in a short period of time a great deal of insight as to the strengths of each side's case, thus facilitating settlement. Typically, the parties retain their right to put on their entire case before the presiding special master at a later date if settlement fails.

#### D. Mediator or Evaluator.

Most ADR efforts within the Vaccine Program have involved the use of a special master other than the one to whom the case is assigned. This “settlement master” may engage in mediation, neutral evaluation, or a combination of the two, as dictated by the preferences of the parties, to help the parties reach a settlement. However, the assigned special master may also assist the parties in reaching settlement. The Rule 5 status conference, discussed in Section IV, Chapter 4, above, is, in effect, a neutral evaluation of the case and is often responsible for settlement thereafter. However, the parties may elect to request that a judge of the Court of Federal Claims serve as a mediator or neutral evaluator, or may opt to hire an outside professional mediator. Each option has advantages and disadvantages, as discussed below.

##### 1. Use of a “Settlement Master.”

Use of a “settlement master” has the benefit that if the ADR process fails to produce a full settlement, the settlement master will not be the one to decide the case. Therefore, the settlement master is free to give the parties a candid assessment of their respective cases, and the parties may be more amenable to the special master engaging in separate meetings with each party. Moreover, use of a settlement master may have advantages over ADR proceedings conducted by a professional mediator who is not familiar with Vaccine Act cases. As a judicial officer extensively experienced in hearing and deciding Vaccine Act cases, the settlement master is extremely well qualified to give each party an experienced assessment of the strengths and weaknesses of that party's case. For example, if the dispute concerns the proper amount of compensation, the settlement master will likely have a thorough working knowledge of what amounts special masters have awarded in similar cases—information that could greatly help the parties reach a compromise.

Of course, if ADR by the settlement master fails to produce a settlement, the case will return to the presiding special master for hearing and decision.

## 2. Use of a Professional Mediator.

Courts nationwide are now using private, professional neutrals in court-sponsored ADR programs with a high rate of success. The chief advantage of this form of ADR is that professional neutrals with practices devoted solely to mediation often have excellent specialized skills in resolving difficult conflicts. They have skills in building trust by remaining neutral at all times and in improving the communications among the parties and counsel.

Professional mediators are often particularly skilled in dealing with emotionally charged cases and in reaching out to the parties. While counsel usually drive legal negotiations, professional neutrals are trained to encourage the clients' direct involvement in settlement discussions to meet the needs and interests of the parties. Further, a professional mediator may bring "a fresh face and look" to a dispute as someone without preconceived notions about the case.

## 3. Use of the Presiding Special Master.

Using the special master who is already assigned to the case has worked in a number of Program cases. The primary advantage of this option is that the presiding special master already knows much about the substance of the case and can prepare very quickly for the ADR session. Further, to the extent that the special master gives the parties an evaluation of the case, the evaluation will be of considerable weight, since that same special master would be the one to decide the case if settlement efforts fail.

On the other hand, the parties may not wish to discuss their settlement negotiations with the same special master who would decide the case if settlement is not reached. With the presiding special master's approval, the parties could proceed to ADR with the presiding special master, with the agreement that if settlement is not achieved, then the case will be formally transferred to another special master for decision. This option would combine the key feature of the settlement master option (*i.e.*, mediation by a master who will not decide the case if a settlement is not reached) with the advantage of having mediation by a master who is already familiar with the case.

## 4. Use of a Court of Federal Claims Judge.

The Court of Federal Claims itself has a robust ADR program with judges experienced in conducting ADR. Because the court's judges hear motions for review in Vaccine Act cases, they have some degree of familiarity with the Act's causation and damages provisions and the cases interpreting them. If the parties are interested in a judge of the Court of Federal Claims conducting the mediation, they should so indicate to the presiding special master.



## E. Confidentiality.

Consistent with general principles governing settlement negotiations, written and oral communications made in connection with or during any mediation session are confidential. As such, the mediator, all counsel, the parties, and any other person attending or participating in the mediation are prohibited from disclosing information and materials used in the mediation. Information acquired through mediation must not be used for any purpose, including impeachment, in any pending or future proceeding in this or any other forum. However, information obtained (or obtainable) through the usual processing of the case does not become confidential by virtue of its use during the mediation.

Nothing prohibits the disclosure of information to persons not directly participating in a mediation, e.g., government officials, supervising attorneys, brokers, and life care planners, whose possession of such information is necessary to further the progress of the ADR proceeding. Individuals given information on this basis are bound by the confidentiality requirements above.

The mediator may not reveal to the presiding special master or others the nature of the discussions or specific offers made during the ADR process. The mediator is not prohibited, however, from providing the presiding special master with a brief general report on the progress of the negotiations and whether a settlement is likely, without disclosing the substance of the negotiations or the positions of the parties.

The parties ordinarily agree that if the ADR proceedings fail to result in settlement, the parties, and any other participants in the proceedings, will be bound by this rule of confidentiality.

In the “shuttle diplomacy” process, the mediator/evaluator will often be required to convey the substance of one party’s position or offer to the other party. If any additional information is to be conveyed, the party should explicitly inform the mediator/evaluator of that information and grant permission to disclose it.

## F. Procedures

At any point in the litigation the parties may notify the assigned special master of their desire to pursue ADR. There is no single format for ADR. Any procedures agreed to by the parties and adopted by the settlement special master, judge or third-party neutral may be used. Certain basic ground rules will be observed, however, as follows:

(1) ADR is generally voluntary. A party’s good faith determination that ADR is not appropriate in a particular case should be respected by other parties and by the court. However, in certain cases, the assigned special master may require the parties to participate in a settlement conference.

(2) If the parties and the assigned special master agree that ADR would be

beneficial, the assigned special master will issue an order directing the clerk of court as follows: (1) to refer the case to an ADR special master or ADR judge who serves on the court's ADR Committee upon the agreement of the parties and both special masters or both the assigned special master and ADR judge; or (2) to refer the case to a third-party neutral upon whom the parties have agreed.

(3) All scheduling orders issued by the settlement special master or judge and a notice of each conference or hearing conducted within the scope of the ADR proceeding will be entered on the case docket. There will be no transcript of any ADR proceeding. All ADR proceedings, including documents generated solely for a proceeding and communications within the scope of a proceeding, are confidential and will not be filed or entered on the case docket, provided to a special master, judge, counsel, or party not a part of the proceeding. However, documents and information, such as medical records, that are routinely requested in vaccine cases may be requested by the settlement special master or judge and filed by the parties.

(4) The parties must agree to and sign a confidentiality agreement prior to ADR. In the event a party or counsel fails to maintain the confidentiality of any documents generated solely for the ADR proceeding or any communications made within the scope of the proceeding, the assigned special master may issue an order for sanctions pursuant to RCFC 16(f)(2). Documents and information that are otherwise discoverable or admissible do not lose that characteristic merely because of their use in the ADR proceedings.

(5) Participation in ADR constitutes agreement by the parties not to subpoena or seek in any way the testimony of the settlement special master, judge or third-party neutral in any subsequent proceeding of any kind.

(6) During the ADR process, the matter will remain on the docket of the assigned special master and the assigned special master may require the parties to file periodic reports with the assigned special master indicating the status of the ADR proceeding.

(7) At the conclusion of the ADR process, the settlement special master or judge will issue an order concluding the ADR proceeding and indicating whether a proposed settlement has been reached in whole or in part. The details of the ADR proceeding will remain confidential between the parties and the settlement special master, judge or third party neutral.

(8) Within 14 days after the entry of judgment following an ADR settlement, the clerk may request the parties to respond to a confidential survey designed to elicit quantitative data to assist the court with its statistical reporting requirements on the use of ADR in the court.

## **Chapter 5. Post-Settlement Processing.**

### **A. Approval Process Time Constraints.**

Once a case is tentatively settled, there is a period of time before the settlement is approved and payment can be made. Because both the client agency (Health and Human Services) and the Department of Justice are required to review any tentative settlement reached by the parties, these agencies must obtain final approval from the authorized agency personnel. The time frames vary, depending on whether entitlement has been determined prior to settlement. If entitlement has been determined prior to the tentative settlement, a proffer is often used, resulting in faster processing. If entitlement has not been determined, the special master will issue a “15-Week Order,” setting deadlines for finalizing and filing an executed settlement agreement.

### **B. Issues Regarding the Purchase of Annuities.**

The parties may negotiate that the annuity pay a stream of benefits, usually expressed as annual payments of certain amounts for a specific number of years or for the life of the payee. Alternatively, on some occasions, the parties negotiate a sum certain to be used to purchase an annuity. In such instances, the agreed on settlement amount is the sum used to purchase the annuity. The distinction between these two approaches is significant because fluctuations in market conditions between the time of negotiation and the time the annuity is purchased may affect the annuity’s value. If a stream of benefits has been negotiated, then the amount paid to petitioner is certain and any fluctuation will affect the amount the respondent pays for that annuity, increasing or decreasing the cost. If a sum certain has been negotiated, the cost of the annuity is set, and any fluctuation will affect the stream of benefits, increasing or decreasing the amount paid to petitioner.

## **SECTION VI. DETERMINING ENTITLEMENT**

### **Chapter 1. Matters Generally Applicable.**

Unless a case is settled, conceded, or withdrawn, the assigned special master will decide whether the petitioner is entitled to compensation. Petitioner has the burden of proof and must produce preponderant evidence of each required element.

§ 13(a)(1)(A). Precisely what must be proven depends on whether the case involves a Table injury or an off-Table (causation-in-fact) claim.

The typical timeline involves completing the evidentiary record, filing respondent's Rule 4 report, obtaining expert reports (if not done prior to filing the Rule 4 report), holding a Rule 5 conference, setting a hearing date, filing a pre-hearing order, filing pre-hearing briefs, holding an evidentiary hearing, filing post-hearing briefs, and issuing a written decision. Although bench rulings may be issued, they are rare.

None of these steps is mandatory. The Vaccine Act provides that rules of evidence do not apply and specifically indicates that hearings are not required in all cases. There is no right to file briefs, although the special master may order briefs to be filed. In keeping with the Vaccine Act's provisions regarding "conducting a proceeding on a petition," the presiding special master may dispense with any or all of the steps listed in the preceding paragraph in making an entitlement determination. § 12(d)(3)(B).

In determining entitlement, special masters are not bound by formal rules of evidence, and the procedures employed to reach entitlement decisions may vary based on the circumstances of a given case. Counsel are encouraged to take the initiative in suggesting ways in which the record can be constructed quickly and with minimal expense, while ensuring fairness to both parties and creating a complete and orderly record.

Extensive evidence may be presented without the need for an evidentiary hearing. Documents will ordinarily not be subject to formal authentication procedures, unless there is some particular reason to doubt their authenticity. Factual testimony, and even opinion testimony, may be presented in affidavit or sworn declaration form. In addition, a party may present videotaped testimony if so desired.

If an evidentiary hearing is necessary, several options are available. Witnesses may testify in person at a hearing held in Washington, DC, or elsewhere at the special master's discretion. If multiple witnesses reside at a single location, the special master may hold the hearing at or near that location to minimize Program costs. The site for a hearing will be chosen with a view to the maximum convenience for all involved and the minimum overall cost to the Program. Alternatively, oral testimony may be taken via telephone conference, by video-conferencing, or by DVD. (It is also possible to combine these procedures – e.g., for some witnesses to appear in person and others to appear by telephone.)

The special master will ordinarily accept a party's evidence in the form desired by the party. A caveat is in order, however, with respect to the weight to be given different types of evidence. Both factual testimony and opinion testimony will in most circumstances be more valuable and entitled to greater weight if the declarant is available for questioning. For example, if the diagnosis of a Table injury is dependent solely on eyewitness accounts regarding symptoms displayed by the vaccine recipient, the credibility of such testimony becomes paramount, and thus in order to make a persuasive case, a petitioner should make every effort to present the oral testimony of such witnesses. Ordinarily, non-party fact witnesses will be excluded from the hearing until called to testify. Although parties to the litigation have a right to be present throughout the hearing, if a petitioner intends to testify, he or she should do so prior to the testimony of other fact witnesses.

## **Chapter 2. Table Cases.**

Most Table cases are assigned to the Special Processing Unit ("SPU") and resolved expeditiously, in keeping with congressional intent that vaccine injured persons be compensated quickly, easily, and with generosity. A Table case will, in most instances, be processed substantially faster than an off-Table (causation-in-fact) case, provided that the *pro se* petitioner or petitioner's counsel takes some care in drafting and supporting the petition alleging a Table injury.

Section 14 of the Vaccine Act established the original Vaccine Injury Table, but its provisions do not govern Table injuries today. A petition should be drafted based on the most recent amendments to the Vaccine Injury Table, which may be found at 42 C.F.R. §100.3(a).

### **A. Table Cases Defined.**

A Table case is one in which the injury sustained is listed in the Vaccine Injury Table for the vaccine alleged to be causal. The injury must manifest within the time frame specified on the Table for that vaccine and injury, and the nature of the injury must track the description, if any, listed in the "Qualifications and aids to interpretation" section of the Vaccine Injury Table, 42 CFR § 100.3(c). If these conditions are met, vaccine causation is presumed. This presumption is rebuttable. Furthermore, petitioners still have the burden to demonstrate the other prerequisites to entitlement to compensation, including satisfaction of the six-month requirement or the surgical exception thereto.<sup>5</sup>

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<sup>5</sup> To be compensable, the vaccine injury alleged must either persist for more than six months or require inpatient hospitalization and surgical intervention. § 11(c)(1)(D)(i).

## B. Pleading and Proving a Table Case.

### 1. The Petition.

If the vaccinee experienced a Table injury, care in drafting the petition to allege each of the requirements will expedite the processing of the case. The petition not only should allege that a Table injury was experienced, but should clearly specify the time and date of the vaccination and the time and date when the injury manifested.

Significant care should be taken in describing the symptoms that establish the Table injury, paying careful attention to the “Qualifications and aids to interpretation.” Of note, a diagnosis of “encephalopathy” is generally insufficient, in and of itself, to establish the Table injury of encephalopathy. Specific symptoms indicative of an acute and chronic encephalopathy are required by the “Qualifications and aids to interpretation” section before a special master can find the existence of a “Table encephalopathy.”

Petitioners may consider alternatively pleading an off-Table (causation-in-fact) case if there is any issue concerning whether all the Table injury requirements are present. This is particularly important if the medical records available do not clearly support the existence of all the “Qualifications and aids to interpretation requirements.”

### 2. Expert Opinion.

In most Table injury cases, filing an expert report with the petition is unnecessary if the medical records are sufficient to establish vaccination, diagnosis, and timing. If an expert opinion proves necessary, one will be ordered after respondent’s Rule 4 report is filed. In most cases in which an expert opinion is necessary, one is required to establish the medical predicate (*i.e.*, the presence of an encephalopathy that meets the Table definition) for finding a Table injury.

### 3. Hearings in Table Cases.

To establish the predicate for a Table injury, a fact hearing is sometimes necessary. Because the Vaccine Act prohibits a special master or court from making “a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion” (§ 13(a)(1)), careful attention should be given to supporting any assertions made by petitioner concerning the factual predicates for a Table injury with as much circumstantial evidence as may be available.

If respondent does not concede the existence of a Table injury in the Rule 4 report, and in particular, if respondent alleges the existence of an alternative cause, the processing of the case will likely follow the stages for an off-Table (causation-in-fact) case.

If the petitioner is proceeding on both a Table injury claim and an off-Table (causation-in-fact) claim, the special master will determine how the evidence is to be presented. Ordinarily, factual witnesses will be heard first (or in a first hearing), followed, as needed, by expert testimony.

### **Chapter 3. Off-Table (Causation-In-Fact) Cases.**

To demonstrate entitlement in off-Table (causation-in-fact) cases, petitioners must prove by preponderant evidence that a covered vaccine caused their injuries. Such proof generally will include the opinion of a qualified expert. While a treating physician's statements or conclusions regarding causation are entitled to careful consideration, such statements often do not address all the *Althen* factors necessary to establish causation. See *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Treating physicians often focus on the "Did it cause?" question, without addressing the medical theory or biological mechanism by which causation probably occurred and the issue of appropriate timing.

### **Chapter 4. Presenting Expert Reports and Testimony.**

In virtually any off-Table case in which respondent does not concede causation, petitioner's case succeeds or fails based on the strength of the expert reports. Care in selecting an expert appropriate to the medical issues is paramount. Experts should be advised of the legal requirements for proof in the Vaccine Program so that their initial reports specifically address all the *Althen* factors. See *Althen*, 418 F.3d at 1278. The parties should keep in mind that an expert opinion alone may not be sufficient to establish causation as the special master is not bound to accept any such diagnosis, conclusion, judgment, test result, report, or summary. § 13(b)(1).

#### **A. Considerations in Selecting Experts.**

Witnesses may be accepted as experts in certain disciplines based on their experience or education, as detailed in their curriculum vitae. The parties should carefully evaluate the medical evidence presented in the case before deciding on the medical specialty in which an expert will be sought. When the theory presented by the expert initially consulted involves matters outside that expert's field, it may be advisable to seek the opinion of a second expert. While there is no requirement that an expert be a medical doctor, the testimony of witnesses with a PhD or other advanced degrees who are not physicians may receive less weight when their testimony concerns a medical diagnosis. Occasionally, a party may file an expert report from a witness with a PhD who provides the scientific basis for the theory of causation, as well as a report from a physician who explains why the theory is applicable to the petitioner's case.

The parties should carefully examine the curriculum vitae of their experts. Deficiencies in experience, credentials, and professional integrity may adversely impact the weight accorded to an expert's testimony.

Clinicians who routinely diagnose and treat particular conditions may offer relevant and insightful opinions on matters related to the diagnostic criteria for a condition and its expected course and treatment. Such expertise may be most helpful when issues concerning the precise nature of a petitioner's injury are presented. The scope and duration of a clinician's diagnostic and treatment experience with a particular condition merits consideration during the expert selection process.

The special masters are well aware that experts do not provide reports *pro bono*. However, in evaluating an expert's report, the special master may properly consider whether the expert derives substantial portions of his or her income from testifying, as opposed to the full-time practice of medicine. The testimony of specialists, researchers, teachers, or clinicians will likely prove more persuasive and is more likely to assist special masters or the court in better understanding the scientific or medical community's view about particular biological processes and mechanisms.

Knowledgeable witnesses who can communicate well and explain concepts clearly are favored. Witnesses who have maintained a current understanding of the relevant medical and scientific issues presented in a case and who are able to discuss easily current developments and trends in the field or in the pertinent peer-reviewed literature serve best. An expert who requires substantial time and effort to research the issues presented in the case is not, generally speaking, likely to be the most persuasive expert. Ideally, an expert should have current experience with the condition at issue and some research or treatment expertise in the relevant field.

Treating physicians may serve as experts, but in most cases their testimony is primarily relevant in addressing the second *Althen* prong — providing the logical connection between the vaccination and the injury alleged. See *Althen*, 418 F.3d at 1278. This is not a hard and fast rule.

## B. Matters to Include in Expert Reports.

### 1. The Expert Report.

In most cases, petitioners rely on the diagnosis of an expert medical witness as part of their proof. This diagnosis should be set forth in a report which includes the basis for the expert's reasoning. The expert opinion should address the facts and circumstances surrounding the vaccinee's individual case and reference, by exhibit and page number, the medical records on which the expert relies in reaching his or her medical opinion. If the expert's diagnostic impression differs from that of the vaccinee's treating doctors, the expert should explain why he or she reaches a different conclusion. If the expert's report is premised on facts not set forth in the record, the expert should identify the specific facts on which he or she relies.

### 2. Supporting Medical Literature.

While supporting medical literature is not a requirement for obtaining compensation, statements or assertions in an expert report should be accompanied by citations to medical or scientific literature supporting the position advanced, if such



literature exists. Statements supported only by the *ipse dixit* of the expert may be given little or no weight. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). When an expert report cites to a medical textbook, journal article, or other publication, copies of the references should be filed as exhibits. If not filed with the expert report, they should be filed within 30 days of the filing of the expert report. The special master may specify a different period.

New or novel theories of causation, particularly those involving new vaccines or rare conditions, may lack any support in current medical literature. This does not preclude presenting such causation theories in Vaccine Act cases. However, if an expert is relying on a new theory of causation or a new condition associated with an old theory of causation, he or she should carefully explain the theory, why the theory should apply in the case, and why the timing between the vaccination and the medical condition is appropriate. If the available epidemiological evidence suggests that the alleged injury is not one causally connected to a vaccine, the expert should address why such studies, pre- or post-licensure for the vaccine in question, should not be relied upon in the case.

### C. Expert Testimony.

Expert testimony is often extremely helpful in resolving a case, as it provides an opportunity to clarify ambiguities in the expert reports. When the experts draw contrasting conclusions from the same facts, the weight accorded to an expert's opinion may depend on the ability of the expert to explain and answer questions concerning that expert's opinion.

However, expert testimony is not required in all cases. A well-prepared and documented expert report that clearly addresses all the *Althen* factors (418 F.3d at 1278) may suffice, particularly if the only dispute between the opposing experts involves the diagnosis or the facts on which the opinion is based.

Two other points concerning oral testimony by experts are worthy of note. First, while a witness testifying orally will always be subject to questioning by the special master, questioning of a witness by opposing counsel will not be a matter of right, but will be within the special master's discretion. Some cross-examination is usually permitted, but the special master will prohibit abusive, irrelevant, or repetitive examination. All questions must be germane to the merits of the case and further the development of the record.

Issues concerning the qualification of an expert witness to testify should be addressed before the hearing, if possible. The curriculum vitae of an expert should be filed contemporaneously with the expert's report, and a challenge to an expert's qualifications to opine should be raised in a pre-hearing filing. Other issues regarding an expert's qualifications may also be appropriate for pre-hearing resolution.

#### D. Compensating Experts.

Experts' fees, like those of attorneys, are computed using a lodestar analysis. The reasonable hourly rate is multiplied by the reasonable number of hours to arrive at the amount of compensation to be paid.

The specialty, if any, of the expert is an important factor in determining compensation. Evidence concerning what the witness or a similarly qualified expert has been paid in other cases is relevant to, but not dispositive of, the hourly rate to be awarded. The nature of the work required by the case is also an important factor in determining the hourly rate. A highly qualified pediatric neurologist who spends hours summarizing medical records will not be paid the same rate for this task as he or she might be paid for testifying as to causation of a seizure disorder. The nature of the expert's current practice is also a factor; a busy clinician who must forgo seeing paying patients in order to testify may warrant a higher hourly rate than a retired physician no longer involved in clinical practice, research, or teaching.

When retained, experts should be informed of the Program requirement for careful and contemporaneous documentation of time and activity devoted to the case. An expert's invoice should identify the nature of the services provided, the date they were performed, and the hourly rate requested. An expert who bills for large blocks of time for research into the nature of the injury and its causes likely does not possess the requisite qualifications to opine in the first place. Special masters are unlikely to compensate for original research conducted in anticipation of litigation.

Additional information concerning reimbursement of attorneys' fees and costs (including expert fees) is contained in Section X below.

### **Chapter 5. Hearings and Decisions.**

#### A. Fact Hearings.

Fact hearings may be conducted to resolve conflicts in the evidence, and may be particularly useful when the matters resolved can lead to concession, settlement, or dismissal of the case. Otherwise, factual disputes and matters concerning the vaccinee's prior and current conditions may be resolved at the same hearing in which expert testimony is presented.

Fact hearings may involve the testimony of petitioners, treating physicians, or other witnesses with relevant information concerning conflicts in the evidence. The testimony of treating physicians regarding gaps in records, the absence of records reflecting telephone calls, or explanations or interpretations of notations in medical records may be unnecessary if the treating physician files an affidavit. A transcription or explanation of illegible or ambiguous record entries may preclude the need for a hearing at all, particularly if the opposing counsel is provided an opportunity to pose questions to the physician informally or through written questions.

Fact hearings are often conducted in person and, if necessary to accommodate a petitioner's circumstances, may be held in courtrooms near the petitioner's location. In exceptional circumstances, such as in the case of a bed-ridden or paralyzed petitioner or other essential witness, fact hearings may be conducted at places other than a courtroom. Video conferencing is also an option for presenting the testimony of a witness.

Although formal rules of evidence do not apply to Vaccine Act proceedings, most special masters prefer that testimony about events in controversy be presented outside the presence of other fact witnesses.

## B. Entitlement Hearings.

### 1. Primary Focus.

The primary focus of most hearings involves the presentation of expert testimony. When no prior fact hearing has taken place, hearings may begin with testimony from petitioners and/or other witnesses concerning the vaccinee's condition prior to the vaccination(s) in question, the development of the injury alleged, and the impact of the injury on the vaccinee's life. This not only assists the special master in placing the injury into perspective, but may also obviate the need for similar testimony on damages if entitlement to compensation is found. Petitioner's experts ordinarily testify first.

### 2. Transcripts.

The court obtains the services of a court reporter from whom the parties may obtain transcripts.

### 3. Presenting Expert Qualifications.

In most cases, curriculum vitae have been filed for each testifying expert. Thus, questions regarding the expert's qualifications should be abbreviated, involving relevant undergraduate or graduate degrees, medical school, medical training, board certifications, and a brief summary of relevant experience and publications. The expert's past or current treatment of similar conditions and current employment may also be relevant.

Likewise, any voir dire of an opposing party's expert should be short and to the point, and may be conducted as part of any permitted cross-examination. The opportunity to raise disqualifications of a witness prior to a hearing does not preclude cross-examination of an expert witness during a hearing about such matters as disciplinary actions, résumé misstatements, lack of clinical experience, or other issues that go to the weight of the expert's testimony, rather than to the requisite qualifications to opine.

It is unnecessary to tender the witness as an expert, but it may be helpful to identify the disciplines or specialties about which the expert will testify.

#### 4. Presenting Expert Testimony.

An expert's testimony should be presented with the understanding that the special master has read the expert report and those portions of the medical literature provided that are relevant to the opinions and theories presented. Thus, focusing the expert's presentation toward concerns expressed by the special master during the pre-hearing conferences and those matters contested by the opposing party will provide the most valuable assistance to the special master. The hearing should be focused on educating the special master about the vaccinee's medical condition, issues raised by the medical records or fact finding, why the medical theory presented is or is not reliable and probable, and why the theory is implicated in the case at bar. The issue of whether the interval between vaccine and injury is medically and scientifically appropriate is also highly important.

Expert witnesses who appear to be partisan advocates for the party employing them are often less persuasive or credible than witnesses who candidly acknowledge problems with their own position, while recognizing the relative strength of the evidence that supports opposing positions. Witnesses who refuse to concede well-established medical facts, beliefs, or theories must be prepared to explain why they do not accept them. Witnesses who interrupt opposing counsel's or a special master's questions do little to advance the case of the party presenting their testimony.

Although cross-examination is not a matter of right in the Vaccine Program, most special masters permit cross-examination, followed by questions from the special master. A special master may question witnesses at any point during a party's direct or cross-examination in order to clarify a point or to ask follow up questions. In some cases, the special master may have opposing expert witnesses engage in limited dialogue in order to clarify areas of agreement or disagreement.

#### 5. Using Medical Literature Effectively.

##### a. Medical Literature in General.

The presentation of supportive medical literature is not a condition precedent to recovery under the Vaccine Act. In most cases, however, some medical literature is cited by the experts in their reports and filed by both parties. The parties should not file medical literature not cited or relied on by their experts.

The most persuasive forms of medical literature include well-conducted case control or similar studies. In most Vaccine Act cases, such studies are not available, particularly in cases involving new vaccines or novel claims of vaccine causation. Single case reports are rarely persuasive because the association reported may be

based on chance alone. Similarly, a mere temporal relationship is, of itself, insufficient to establish vaccine causation. Other types of medical literature fall in between case control studies and case reports in persuasiveness and reliability. Factors involved in evaluation of such literature include publication and the quality of the medical journal in which the studies appear (sometimes referred to as the “impact factor”), whether the paper was peer reviewed, the nature of the paper (e.g., based on a study, a literature review, or meta-analysis), the existence of supporting or contradictory studies, and whether the studies were human- or animal-based or were conducted *in vitro* or *in vivo*.

Medical literature can provide powerful support for a party’s position on causation, if used effectively. Effective use of medical literature involves limiting the literature filed to articles or textbook excerpts relevant to the issues addressed. If a point is widely accepted by the medical community, literature may not be needed to support that point. If, however, the opposing side’s experts challenge the “widely accepted” assertion, support should be filed in lieu of or along with a supplemental expert report. Identifying the portions of medical journal articles that are relied on is extremely helpful, particularly if a long and complex article is filed in support of a position but only a small portion of the article is relevant.

Over years of service, special masters often develop expertise in areas of science commonly referenced in the Vaccine Program. Nevertheless, it is incumbent on the parties to provide some basic information regarding their theory and the disease, disorder, or syndrome allegedly caused by the specific vaccine in question. The expert report and its accompanying medical literature are the appropriate places to define terms and explain basic concepts so that the hearing can focus on more complex issues.

b. Identifying and Filing.

Medical literature to be relied on at a hearing must be submitted no later than 30 days prior to the hearing. Counsel should consult with their experts, in person if necessary, at least 45 days prior to the hearing to determine what, if any, additional medical literature must be filed before the hearing. Pre-hearing submissions should include a complete listing of the specific medical literature on which the party intends to rely. If the submission indicates reliance on more than 10 journal articles, textbook chapters, or similar matters, the parties must include with the literature a concise statement of the points in the experts’ testimony supported by each individual article, textbook, or similar filing.

c. Untimely Filed Medical Literature.

Failure to timely file medical literature may result in its exclusion. An aggrieved party may request other sanctions to include delaying the hearing, excluding testimony based on the literature, and/or limiting testimony to literature identified in a timely fashion.

### C. Post-Hearing Process.

The post-hearing process varies depending on the nature of the case and how the hearing was conducted. The parties should not assume that filing post-hearing briefs, supplemental reports, or additional evidence will be permitted. The special master may limit matters to be filed, specify simultaneous filings, or make post-hearing filings optional. If the pre-hearing filings identify the issues or matters in controversy and explain the parties' positions on those matters, then post-hearing filings are often unnecessary.

### D. Entitlement Decisions.

Although bench rulings are occasionally issued, in most cases a special master will issue a written decision summarizing the law and relevant evidence, the issues presented, and the positions of the parties on those issues. The special master will decide any remaining factual disputes, and will apply the law to the evidence. In many cases, the special master's decision comes down to a determination of which expert or experts the special master found most persuasive and why.

The length of time necessary to produce such a decision is highly variable. To the extent the parties can agree on some or all of the relevant facts beforehand, the decision drafting time may be shortened. Special masters endeavor to produce written decisions within six months of the filing of the transcript or the last filing by a party post-hearing. However, caseloads may impact the ability of a special master to issue written decisions within this time period. In specific cases where the issues are complex and the records are voluminous, a decision may take much longer to prepare.

## **Chapter 6. Publication and Redaction of Decisions.**

All decisions, and other rulings, issued by special masters and judges in vaccine cases are made available to the public unless either party files, within 14 days, an objection to the disclosure of any material in the decision "which is trade secret or commercial or financial information which is privileged and confidential" or "which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." § 12(d)(4)(B); Vaccine Rule 18(b).

Public disclosure includes releasing each decision or ruling online by posting it on the court's website ([www.uscfc.uscourts.gov](http://www.uscfc.uscourts.gov)) pursuant to the statutory requirement and the requirements of the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). This means the decision, or ruling, will be available on the internet. The decision, or ruling, must be made publicly available even if it is designated as "Unpublished" or "Not to be Published."

If petitioners have concerns about such disclosure, guidance should be sought from counsel. In all events, petitioners' counsel should endeavor to ensure petitioners

are aware of and understand the time-limited opportunity to seek redaction in accordance with § 12(d)(4)(B) and Vaccine Rule 18(b).

To request redaction, the party requesting redaction must file a written motion within 14 days of the issuance of the decision or ruling. The 14-day redaction deadline is strictly enforced because, once posted, the decisions and rulings are virtually impossible to recall.

Requests for redactions should focus on the statutory provisions that exempt specific information from public disclosure, such as trade secrets or commercial or financial information which is privileged and confidential, or medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy. § 12(d)(4)(B); Vaccine Rule 18(b).

There are few cases interpreting these provisions. Special masters do not ordinarily grant motions to redact a petitioner's medical condition from a decision or ruling, as such redactions render the decision or ruling uninformative and deprive the public of the opportunity to understand the action taken by the special master.

## **SECTION VII. DETERMINING DAMAGES**

Because proceedings in Vaccine Act cases are bifurcated, documentation concerning damages generally is not submitted with the petition. See § 11(e). Instead, issues pertaining to damages are usually deferred until entitlement to compensation has been determined, or when the parties are pursuing settlement. (Cases assigned to SPU, however, may appropriately involve damages determinations far sooner in a case's life, given the expedited nature of SPU and the types of claims it seeks to resolve).

Once entitlement has been found, the special master sets a schedule for the submission of information on the issue of the amount of compensation – often referred to as the “damages” phase or stage. The special masters have each devised a detailed damages order to guide the parties in resolving the damages issue. The damages order discusses the proof required, the methods for resolving damages, and a schedule for filing the required documentation.

Strict adherence to damages orders will speed case resolution and, ultimately, payment to the petitioner. As with other procedural issues, the parties should request a status conference with the assigned special master to address any questions.

Most damages cases are resolved without the need for an evidentiary hearing. However, considerable work is required before the parties agree on the amount and terms of a damages award. As discussed in Section V above, various forms of third-party neutral assistance are available to assist the parties in settlement.

### **Chapter 1. Damages Available.**

#### **A. Death Cases.**

When the vaccinee is deceased, the statute sets the compensation for the death at \$250,000. § 15(a)(2).

However, cases interpreting the statute indicate that compensation for injuries incurred prior to a vaccine-related death may be awarded in some circumstances. The circumstances under which damages other than the death benefit may be awarded are evolving, and future decisions may provide guidance on this issue.

#### **B. Injury Cases.**

The statute sets forth the categories of damages available. Damages fall generally into four categories (each of which is discussed in more detail below): (1) pain and suffering (which is statutorily capped at \$250,000 (§ 15(a)(4))); (2) lost actual and future earnings/wages (§ 15(a)(3)); (3) past out-of-pocket medical expenses (those not reimbursable by insurance) (§ 15(a)(1)(B)); and (4) actual future medical needs (those not reimbursable by any other source) (§ 15(a)(1)(A)). Future medical needs are often



compensated through an annuity. See § 15(f). Attorneys' fees and costs (including expert fees) are addressed in Section X below.

## **Chapter 2. Supporting Evidence.**

### **A. General Guidance.**

The facts and circumstances of each case will dictate the amount and type of evidence required to substantiate damages. It is imperative, however, that petitioners contemplate damages issues at the outset of a case, proactively engage in discussions with respondent to determine the documentary evidence necessary to support damages, and expeditiously act to procure the necessary documentation. Proactive discussions by both parties allow disagreements to be addressed at an early stage of the litigation. A hands-on approach to discussing damages at the beginning of a case, coupled with cooperation between the parties, will significantly expedite case resolution.

### **B. Uncomplicated Damages Cases.**

Some damages cases are relatively uncomplicated and can be settled without the necessity for life care plans, which can be expensive and time consuming to produce. Cases involving transient injuries, scarring, or focal injuries are often limited in the scope of damages and thus do not require life care plans. However, when the vaccinee requires extensive care and treatment, such as in the case of a neurologically-injured child or a paralyzed adult, the determination of needs and the amount of the award becomes more complicated. These cases may require the services of a professional life care planner and other relevant experts to support the claim.

In the uncomplicated damages cases, where no life care plan is needed, there are many ways of presenting evidence in support of damages. In general, some documentation and evidence of how the claimed damages were calculated will be required, *e.g.*, doctors' bills, prescription receipts, wage slips or W-2 forms, or other evidence showing an incurred cost for the vaccine-related injury and future needs. However, the facts and circumstances will dictate how much evidence is required.

### **C. Complicated Damages Cases.**

Based on the collective experience of special masters presiding over complex damages cases, the most commonly disputed damages categories are (1) the precise amount to be awarded to a petitioner for pain and suffering; (2) the determination of the appropriateness and the calculation of lost actual and future earnings/wages; and (3) the reasonable future medical costs to be awarded, an inquiry that often requires preparation of a life care plan. A variety of factors (discussed in more detail below) are relevant to each of these damages sub-categories and must be substantiated by evidence just as in non-complex cases. Both parties should understand, however, that the ultimate overall damages award inquiry is based on a fact-intensive analysis of the individual circumstances of each case, and will be informed by many subjective factors.

As with less complex damages cases, the parties are encouraged to exchange information and attempt to address damages issues on their own. However, although the special masters are fully supportive of the parties' efforts to informally resolve cases, the parties must keep the special masters informed of problems of proof or other disagreements that may delay resolution. The special masters retain the right to resolve formally issues that the parties are unable to efficiently resolve.

The special masters understand that resolving disputed damages issues in complex cases can be a prolonged, time-intensive process. Accordingly, special masters will generally allow the parties a reasonable period of time (depending on the nature of the damages components to be calculated) to informally resolve damages issues. The special masters may, however, assume a more involved role in resolving outstanding damages issues expeditiously if too much time passes in a case without evident progress toward resolution. Such involvement is consistent with the ultimate interest of the petitioner.

### **Chapter 3. Life Care Plans.**

#### **A. General Points**

In complex damages cases, a petitioner will usually rely on a central piece of evidence, a "life care plan." Such a plan is a professionally prepared report detailing what treatment and care the injured party will need for the rest of his or her life and the estimated cost, after offsets, of the individually projected items of care. But while the services of a "life care planner" may be necessary in complex cases, the testimony of an economist or similar expert to determine the amount of money necessary to fund any given life care plan will in most cases be unnecessary. See Chapter 3 of this section, "Funding of Life Care Plans."

A great deal of information is available regarding life care planners and the minimal requirements for a life care plan. The assigned special master and the damages order are essential sources. In addition, the Vaccine Litigation Group of the Torts Branch of the Department of Justice has prepared a publication titled "*Steps to Streamlining Damages Under the Vaccine Program*." While this publication represents the views of only one party to the vaccine compensation process and does not necessarily reflect the views of the special masters, it may be helpful to petitioners' counsel as an overview of the damages phase of proceedings from respondent's perspective. A copy may be obtained by contacting the Department of Justice attorney assigned to the case.

#### **B. Selecting a Life Care Planner.**

Once it appears that a case may move to damages or settlement and that the future medical needs of the vaccinee will be long term or substantial, consideration should be given to selecting a life care planner. When petitioner's counsel believes a life care plan may be necessary, respondent's counsel should be informed. When a

joint life care planner is not used, much time and duplication of effort can be avoided by having the life care planners work together to coordinate interviews and site visits.

Care should be taken to select a knowledgeable professional experienced in preparing comprehensive life care plans. The treating physician is usually not qualified to prepare a comprehensive plan (although such physician's prognosis may be a crucial starting point for the life care planner). An effective life care planner must have broad knowledge of available services, the cost of those services, and the effect of applicable insurance on those costs. The planner must be able to support in writing and through testimony each recommended item of care.

Occasionally, the parties have agreed to engage a joint life care planner. Selecting a joint life care planner can often cut months from the time period between an entitlement determination and the award of damages. With a joint life care planner, the damages process moves more quickly and with less contention.

### C. Supporting Evidence for Preparation of a Life Care Plan.

Affidavits, reports, or interviews may provide evidence of need for the services requested in a life care plan. If interviews are planned and each party has a life care planner, both planners should be present at each interview in order to minimize the inconvenience to health care providers and conflicts based on what a provider said. Supporting evidence is commonly obtained from:

1. At least one parent (preferably the primary caregiver) as to the immediate past needs of the child – *e.g.*, information on prescriptions, types of therapy, a description of a typical day in the vaccinee's life, and any information that would aid the special master in determining the future needs of the injured;

2. The treating physician as to the necessity of the care, treatment, or other expenses called for in the life care plan;

3. Treating doctors or therapists regarding future care and therapy needs, including attendant care and long-term living arrangements. For example, as part of a life care plan for an individual with a major disability, the cost of long-term, in-home care often represents a sizable portion of the requested compensation. If a petitioner seeks compensation for the services of a skilled individual – *e.g.*, a licensed practical nurse – rather than an unskilled companion, the petitioner must demonstrate why the services of such a skilled person are necessary. General requests will not be accepted as reasonably necessary. For example, if the injured party will need a particular type of therapy, the basis for the request must be documented, along with the number of hours needed per month or week, the expected cost, and the number of years for which such therapy will be needed;

4. School systems, including such information as individual educational plans and other services available;

5. Medical insurance policies, payments, offsets, and liens;

6. A video recording depicting a typical day in the life of the vaccinee. An amateur quality video recording is sufficient for this purpose;

7. A video recording showing the interior and exterior of the vaccinee's home if structural changes to the residence are requested. Typically, a report from an appropriate architect or builder will also accompany such a request.

A complete list of potentially compensable items is found at § 15(a)(1)(A). The special master's damages order will also provide guidance regarding the life care plan.

The life care plan typically presents cost in present value. The life care plan does not inflate these values even though the costs are projected to rise. Through experience, special masters have recognized 4% as an annual growth rate for medical expenses. If this default rate is acceptable, the parties do not need to retain an economist to opine about how inflation may affect the costs of the services proposed in the life care plan. If petitioners do not accept the special master's assumed rate of inflation, petitioners should notify the special master before retaining an economist.

#### D. Funding of Life Care Plans.

##### 1. Use of Annuities.

The statute gives the special master authority to order all or part of a compensation award to be made in the form of an annuity rather than a lump sum. See § 15(f)(4)(A) and (B). Some of the obvious benefits of an annuity are that it: (1) ensures benefits for the lifetime of the recipient, even if the vaccinee lives longer than estimated; (2) eliminates the need to determine a "life expectancy" or "rated age"; and (3) eliminates the burden and uncertainty of investing a large lump sum. In cases of minors or mentally disabled persons, the special master is likely to award compensation for life care items in the form of an annuity, and may do so as well in other portions of a damages award. If there are compelling reasons to do otherwise, petitioners should fully document those reasons. If an annuity is requested for only a portion of the award, the damages request should clearly identify the funds requested for an award outside the annuity.

Section V, Chapter 5, above discusses how interest rate changes may affect settlements that involve annuities. In a case in which the petitioner is entitled to compensation, respondent bears the risk of any interest rate changes.

##### 2. Constraints on Use of Economic Experts Regarding Annuities.

Most awards funding life care plans are paid with a government-purchased and government-owned lifetime annuity. A large body of case law has been developed in

this area, and each special master is well aware of the advantages and disadvantages of lump sums versus annuities and the attendant considerations, such as future inflation rates, growth rates, and discount rates. Accordingly, petitioners' counsel are advised not to expend funds on such an expert without first consulting with the special master at a status conference.

#### **Chapter 4. Lost Wages – Actual and Future**

Section 15(a)(3) provides for recovery of lost actual and future wages if the vaccinee's earning capacity is impaired. Lost wages for an adult are based on the evidence (e.g., the injured party's employment, the period of time the individual was out of work, or the circumstances under which he or she was out of work).

Calculation of lost future/anticipated wages or earnings can present a more complex question. If the vaccinee is injured prior to the age of 18, the calculation of lost wages is governed by a formula provided in the Act, on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy. Such circumstances seldom present an issue as to the correct calculation of the formula. However, the Act provides that no award is made if the claimant can reasonably be expected to earn the wages of the prototypical worker described in the statute. As a result, in some cases respondent may contest the minor's future ability to earn a sum up to, or in excess of, the formula calculation. In such cases, opinions from vocational experts may be needed to evaluate the injured minor's future capacity to work and at what compensation levels. The opinion of a credentialed vocational expert is useful to this inquiry.

By contrast, if the vaccinee was over the age of 18 at the time of the injury, the lost earnings are calculated pursuant to generally recognized actuarial principles. Evidence to support a claim may include the statement of a treating doctor and/or reports and testimony of a vocational expert. Specific categories of evidence offered to support a lost wages claim for an adult include information regarding past earnings, as supported by income tax returns, Social Security benefits statements, or any other sources of income that are affected by the vaccine injury. Proposed lost wages or earnings cannot be based on speculation.

#### **Chapter 5. Pain and Suffering**

There is no formula for assigning a monetary value to the pain and suffering associated with an injury. Because case law articulates the way in which the cap on pain and suffering awards is applied in the Program, petitioners and their counsel should familiarize themselves with relevant decisions.

The following factors are often considered by special masters in awarding compensation for pain and suffering and emotional distress: (1) the individual's awareness of the injury, (2) the severity of the injury, and (3) the duration of the suffering. Petitioner bears the burden of proof with respect to demonstrating the extent of pain and

suffering and emotional distress. Typically, medical records will be considered the most reliable evidence regarding petitioner's condition. A special master may also look to awards in prior cases to help assess the appropriate amount of compensation for pain and suffering and emotional distress – although pain and suffering awards must ultimately be based on the record evidence, rather than any continuum of severity among different types of injuries.

Awards of compensation for pain and suffering and emotional distress may include compensation for both past (or “actual”) damages as well as future (or “projected”) damages. As noted above, such awards are capped at \$250,000.00 by §15(a)(4) of the Vaccine Act. When a petitioner is awarded compensation for projected pain and suffering, the amount of the award must be reduced to net present value. When the total award of compensation for actual and projected pain and suffering and emotional distress exceeds \$250,000.00, the statutory cap must be applied before any reduction to net present value is calculated.

### **Chapter 6. Reimbursed Expenses and Offsets.**

Practitioners should keep in mind that the Program is intended to be a secondary payor for expenses arising out of vaccine injuries. See § 15(g). Compensation will not be awarded for any expense for which the petitioner or injured party has been reimbursed or compensated, or can reasonably be expected to be reimbursed or compensated, by a health insurance policy, an entity providing health benefits on a prepaid basis (e.g., a Health Maintenance Organization), or any state agency benefits program. Future benefits under Title XIX of the Social Security Act (Medicaid) will not be considered an expected source of benefits. All health and disability insurance policies must be provided.

Consequently, petitioners' counsel must address and provide, with particularity, accurate information on the questions of what health insurance benefits have been and will likely be available to petitioner, what school system services (e.g., speech therapy) have been and will be available, and what state and federal program benefits (e.g., state “crippled children's funds,” federal Medicare, or similar benefits programs) have been and will be available. The Federal Circuit has ruled that Supplemental Security Disability Income (SSDI) awarded as a result of a vaccine injury is not an offset to any lost wages request pursuant to this provision.

### **Chapter 7. Guardianships and Estates.**

Under the laws of many states, the person who receives payments on behalf of a minor, incapacitated person, or a deceased individual must be appointed as guardian or conservator of the injured person or as the executor or administrator of the estate of a deceased person. Petitioner's counsel must investigate the legal requirements in the relevant state and take the necessary steps to comply with the state law. The appointment of a legal representative is a condition precedent to receiving an award.

If a guardianship, conservatorship, or appointment as the representative of an estate is required to receive any Program award, the expenses associated with the creation of the guardianship in state court are frequently requested as part of the fees and costs incurred by petitioners. The law regarding reimbursement of these expenses is unsettled, but most, if not all, special masters have awarded reimbursement for such costs when the guardianship or conservatorship is required as a condition of payment of a settlement or award. Special masters examining these issues as part of awarding reasonable attorneys' fees and costs have determined that the appropriate test by which to analyze reimbursement of such costs is a "but for" test. § 15(e)(1) (allowing reimbursement for attorneys' fees and costs that are "incurred in any proceeding on such petition"). Respondent has contested the award of fees and costs for these services, but the issue has not yet been addressed by the Federal Circuit.

If a guardianship or conservatorship is required to receive a Program award in a case, the absence of such guardianship or conservatorship will delay payment of the award, but it will not delay the special master's decision awarding compensation. Bills for legal services incurred for any local court actions, other than those required by the court or by the Secretary before payment of compensation awarded, will not be considered work done "during the pendency of a petition."

## **Chapter 8. Other Damages Categories/Issues**

### **A. Past Unreimbursable Expenses.**

Section 15(a)(1)(B) provides for payment of actual unreimbursable expenses incurred on behalf of the vaccinee prior to judgment. This area is seldom a point of contention between the parties. Petitioners should organize receipts, insurance information, or other billing records that show funds expended on behalf of the vaccinee for the items listed in § 15(a)(1)(B)(iii). This information should be organized by petitioners or their counsel before submission. Simply providing respondent with a box of receipts or bills will serve only to delay a damages award.

### **B. Medicaid Liens.**

Medicaid must be reimbursed for past payments made on behalf of the vaccinee for vaccine-related expenses. See § 15(g). It is incumbent on petitioner to alert the special master and respondent's counsel as soon as possible to any past Medicaid payments so that the appropriate portion of the damages award may be made to the state Medicaid agency. Since obtaining sufficient information from state Medicaid agencies may take some time, such inquiries should be made early. Either petitioner or respondent may engage in negotiations with the state agency regarding the amount to be reimbursed. Following these steps will eliminate a lien for past Medicaid payments being placed on an award.

## **Chapter 9. Decisions Determining Damages.**

Regardless of how the amount of compensation is determined (*e.g.*, proffer, stipulation, or resolution of disputed issues by the special master), the special master will issue a written decision awarding compensation. When a particular damages component is contested, the special master often will hold a hearing on the matter before deciding the issue. The provisions for publication and redaction of decisions are explained in Section VI, Chapter 6, above.



## SECTION VIII. OBTAINING PAYMENT

All awards of damages are obtained through decisions by the court, even if damages are resolved by settlement or by proffer. If a settlement agreement is filed by the parties or a proffer is filed by respondent, it must be formally approved by a decision of the special master. If the parties do not settle damages, the special master will determine the appropriate damages and issue a decision awarding damages.

After the decision is filed, either party may file a motion for review within 30 days. If the parties do not intend to file a motion for review, such as in a settled case, the parties may expedite the entry of judgment by each party filing a notice (or both parties filing a joint notice) renouncing the right to seek review of the special master's decision by a Court of Federal Claims judge. See Vaccine Rule 11(a). A form for such a notice is available at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

Pursuant to the statute and Vaccine Rule 12, after a judgment on the merits is entered, the petitioner must file an election in writing either to: (1) accept the judgment or (2) file a civil action for damages for the alleged injury or death. On failure to file an election within the 90 days prescribed, a petitioner will be deemed to have filed an election to accept the judgment. Sample election forms are found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

Thus, at the conclusion of the case, in order to speed the receipt of the award, counsel should be ready to file an election immediately on entry of judgment, but not before judgment has issued. Since the election is a statutory requirement, respondent cannot process an award until the election is filed or deemed filed at the close of 90 days, even if the judgment results from a settlement with respondent.

Finally, under Vaccine Rule 33, if an appeal is taken from a U.S. Court of Federal Claims judge's ruling to the Federal Circuit by either party (*see infra* Section XIII), the election whether or not to accept judgment is not due until 90 days after the mandate of the Federal Circuit, or after a subsequent Court of Federal Claims judgment if the appellate court should order a remand. If a petitioner files an election to accept the judgment, and the respondent subsequently files a notice of appeal, the petitioner's election becomes moot. The petitioner will have to file a superseding election once the appeal is resolved and the judgment becomes final.

The processing of the award after the election to accept judgment until a check is mailed typically takes approximately 30 days. The government pays judgments with a paper check, not via an electronic system. Initial questions regarding non-receipt of a check should be directed to the Department of Justice attorney representing respondent, as the court is not involved in the issuing or mailing of checks.

## **SECTION IX. EXITING THE VACCINE PROGRAM AND FILING A SUBSEQUENT CIVIL ACTION**

Subsequent to filing a petition in the Vaccine Program, petitioners may decide against proceeding further on the merits, or may decide to pursue other civil remedies. There are multiple ways that petitioners may exit the Vaccine Program and conclude their case.

### **Chapter 1. Motion for a Dismissal Decision.**

If petitioners do not believe the available evidence can prove entitlement to compensation and wish to conclude the case, petitioners may file a motion for a dismissal decision. After petitioners file a motion for a dismissal decision, the special master will file a short decision, if appropriate and pursuant to § 12(d)(3)(A), dismissing the case without discussing the evidence submitted, such as medical records or reports, in detail. Judgment will enter following the issuance of this decision. A template for a motion for a dismissal decision is available at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

### **Chapter 2. Motion for a Ruling on the Record.**

If petitioners do not wish to submit additional evidence or request an evidentiary hearing, petitioners may file a motion for a ruling on the record. The special master will rule on the merits of the claim based on the evidence filed. Judgment will enter following the issuance of this decision.

In their motion, petitioners should specifically identify the evidence in the record on which petitioners are relying with reference to the exhibit numbers and specific page numbers, including any specific statements, diagnoses, and conclusions made by medical professionals that support their claim. References must specify the exhibit and page numbers (simply referring to exhibits generally is insufficient). A template for a motion for a ruling on the record is available at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

### **Chapter 3. Election to File a Civil Action.**

Within 90 days subsequent to the entry of judgment on the special master's decision, petitioners may file either an election to file a civil action or an election to accept judgment. § 21(a). An election to file a civil action rejects the Program judgment and must be filed to preserve whatever right petitioners may have to file a civil action in another court. Templates for an election to file a civil action and an election to accept judgment are available at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

## **Chapter 4. Voluntary Dismissals.**

### **A. Voluntary Dismissal before Respondent's Rule 4 Report.**

If petitioners wish to dismiss their case voluntarily and withdraw from the Vaccine Program, and the respondent's Rule 4 Report has not yet been filed, petitioners may file a notice of voluntary dismissal. See Vaccine Rule 21(a)(1)(A). A template for a notice of voluntary dismissal is available at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

### **B. Stipulation of Dismissal after Respondent's Rule 4 Report.**

If petitioners wish to dismiss their case voluntarily and withdraw from the Vaccine Program after respondent's Rule 4 Report, petitioners must seek respondent's consent. Petitioners must sign a joint stipulation of dismissal and forward it to respondent's counsel at the Department of Justice for review and co-signature. See Vaccine Rule 21(a)(1)(B). Once signed by all parties the stipulation is filed with the court. A template stipulation of dismissal is available at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

### **C. Effect of Voluntary Dismissal.**

A dismissal pursuant to a notice of dismissal or a joint stipulation of dismissal is typically without prejudice. However, the special master may, in his or her discretion, deem the notice or stipulation to operate as a final adjudication on the merits if petitioner has previously dismissed the same claim. See Vaccine Rule 21(a)(2). Subsequent to the filing of the notice or joint stipulation of dismissal, the special master will file an order concluding proceedings to close petitioner's case, but no decision is issued and no judgment is entered. See Vaccine Rule 21(a)(3). Thus, counsel should be aware that a notice of voluntary withdrawal or a joint stipulation of dismissal may not suffice to permit petitioners to pursue a traditional tort remedy in another court.

## **Chapter 5. Withdrawal in the Absence of a Timely Decision.**

When the statutory time period for the special master's submission of a decision expires without the filing of a decision by the special master, petitioners may elect to withdraw from Program proceedings and pursue a traditional tort remedy. See § 21(b)(1). The statute provides the special master with 240 days, measured from the date of the filing of the petition, exclusive of any periods of suspension, in which to file the decision. See § 12(g); § 12(d)(3)(C); Vaccine Rule 10(b).

If the special master fails to issue a decision within the statutory time period, the special master will ordinarily issue a formal notice informing petitioners of this fact. See § 12(g); Vaccine Rule 10(d)(1). Petitioners should, within 30 days, file a notice indicating an intent either to continue in the Program or to withdraw. See § 21(b); Vaccine Rule 10(d)(2). If petitioners elect to withdraw from the Vaccine Program, the

special master will issue an order concluding proceedings. Vaccine Rule 10(d)(3). Templates for these notices may be found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>. If within 30 days of the formal notice, the petitioners fail to file a notice of intent to withdraw, an intent to remain in the Program is presumed. A notice of intent to withdraw filed more than 30 days after the formal notice is filed may not be effective in preserving whatever rights petitioners may have to file a subsequent civil action.

Petitioners and counsel should note that if the option to withdraw is selected, petitioners may be precluded from reentering the Program to seek compensation for damages resulting from the vaccination specified in their petition.

If the special master's decision is timely, but after a motion for review of that decision is filed, the Court of Federal Claims fails to enter judgment on the claim within the statutory time period (see § 21(b)(2) for computation of this period), a petitioner has an identical option to withdraw or continue in the Program. See § 21(b)(2); § 12(g)(2); Vaccine Rule 29.

## SECTION X. ATTORNEYS' FEES AND COSTS

### Chapter 1. Availability of Attorneys' Fees and Costs.

#### A. Entitlement to Fees and Costs.

To ensure that vaccine claimants have readily available a competent bar to prosecute their claims, Congress provided for the award of attorneys' fees and costs. The Vaccine Act provides for an award of fees in a majority of cases, regardless of whether the petitioner prevails, and thus counsel may neither pursue nor accept funds from petitioner in addition to or in lieu of the fees and costs awarded under the Vaccine Program.

To obtain an award of fees and costs, counsel must present contemporaneous records of actual time spent on a case, by whom, their status and usual billing rates, as well as a breakdown of expenses. Absent this information, the special master cannot award fees. Therefore, it is incumbent on counsel to keep contemporaneous and detailed records of time expended, and costs incurred.

When a petitioner receives vaccine injury compensation, an award of reasonable attorneys' fees and costs is assured. § 15(e)(1). When entitlement to compensation is not found, an award of attorneys' fees and costs is within the special master's discretion, provided that the petition was brought in good faith and had a reasonable basis. *Id.* Good faith is subjective.

Whether a claim has a reasonable basis is determined from an objective standpoint. The claim must be based on more than "unsupported speculation." To determine whether a claim has a reasonable basis, special masters have looked at a number of factors, including the factual basis for the claim, the medical support for it, and other jurisdictional and threshold issues. However, the Federal Circuit has indicated that an impending statute of limitations deadline may not be used to establish a reasonable basis. Reasonable basis must exist at each stage of the case. If a reasonable basis that was sufficient to bring a claim ceases to exist, the claim can no longer be maintained, and fees may not be awarded for work done after that time. For instance, if after filing a claim, a petitioner is unable to obtain an expert medical opinion to support the claim, the reasonable basis for the claim may have ceased to exist.

#### B. Interim Fees and Costs.

Based on decisions from the Federal Circuit, special masters have awarded attorneys' fees and costs on an interim basis. To be awarded fees and costs on an interim basis, a claimant must establish that the circumstances support an interim award. See *infra* Section X, Chapter 6.

## Chapter 2. Determining the Amount Payable.

A special master has considerable discretion in determining what constitutes reasonable fees and costs based on the application and evidence submitted. A well-established body of federal law concerns the meaning of “reasonable attorneys’ fees” and the requirements for establishing such fees and costs.

In the Vaccine Program, special masters determine reasonable fees utilizing the lodestar method, which involves multiplying a reasonable hourly rate by a reasonable number of hours. The special master determines both reasonable hourly rates and reasonable hours for tasks. From this initial calculation, the special master may make an upward or downward departure based on specific findings.

In an effort to resolve fees and costs applications fairly and efficiently, OSM has created an Attorneys’ Fees and Costs (“AFC”) Unit. The AFC Unit consists of a staff attorney and a paralegal who manage most applications for fees and costs within OSM on behalf of the special masters.

### A. Hourly Rates.

To determine whether the requested hourly rates are reasonable, the special master engages in a multi-step inquiry and analysis. Considerations include the geographic location where the work was performed and how the requested rates compare to those of similarly situated attorneys.

If the bulk of the work was performed in the forum (Washington, DC), the special master will compare the requested rates with those prevailing in the forum for attorneys of reasonably comparable skill, experience, and reputation. Beginning with the 2015-2016 Attorneys’ Forum Hourly Rate Fee Schedule, OSM prepared ranges of hourly rates for attorneys/paralegals of varying experience for the purpose of evaluating applications for attorneys’ fees. The 2015-2016 schedule adopted the ranges set forth in *McCulloch v. Sec’y of Health & Human Servs.*, No. 09-293V, 2015 WL 5634323 (Fed. Cl. Spec. Mstr. Sept. 1, 2015), which all sitting special masters endorsed as of October 24, 2016. OSM’s Forum Hourly Rate Fee Schedules, can be found at: <http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters>.

Forum rates are calculated in large part based on the years of experience of the attorney/paralegal and the corresponding hourly rate range. The years of experience listed in the schedules refer to an attorney’s years of experience practicing law, which generally will be calculated based on the year an attorney was admitted to the bar. Individual facts and circumstances may warrant an adjustment to the schedule. The following factors are paramount in deciding a reasonable forum hourly rate: experience in the Vaccine Program, overall legal experience, the quality of work performed, and the reputation in the legal community and the community at large. If needed, the special master will adjust the requested rates.

If the bulk of the work was performed outside Washington, DC, the special master will compare the forum rates with those prevailing in the city where the attorneys provided their services. If the special master finds the local rates are “very significantly” lower than the forum rates, the attorneys will receive local rates. If they are not significantly lower, the attorneys will be eligible for forum rates. Again, the special master will adjust the requested rates as appropriate. Information about establishing a local rate is provided in Section X, Chapter 3(B)(1)(c) below.

#### B. Number of Hours.

Once the special master has determined the appropriate hourly rate, that rate is multiplied by the number of hours reasonably expended by counsel. Determining what constitutes a reasonable number of hours in a given case is largely dependent on the particular circumstances of a case. Considerations include the nature of the task being performed and the experience of the person performing it. The special master may exclude hours that are excessive, redundant, or otherwise unnecessary.

#### C. Costs.

Petitioners and their counsel may be reimbursed for costs incurred in the litigation. These include costs of obtaining medical records, filing fees, costs associated with the work of experts, and travel costs. If a petitioner personally incurs costs, those costs must be separately identified and itemized on the application for fees and costs. See Vaccine General Order #9 Statement found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>. Before reimbursement of costs will be made, sufficient supporting documentation, such as invoices, receipts, and billing statements, must be provided.

#### D. Expert Expenses.

Generally, the procedures and practices that apply to the evaluation of attorneys’ fees and costs also apply to experts’ fees and costs. A reasonable hourly rate must be determined and a reasonable number of hours established. Submission of curriculum vitae and information regarding the hourly rate paid to the expert in other fora are helpful in determining the hourly rate to be awarded. A petitioner must demonstrate that the hours expended by experts and the costs incurred were reasonable. The application for payment of experts’ fees and costs must contain the same supporting documentation that is required for attorneys’ fees and costs. In particular, the expert’s services must be identified with particularity in contemporaneous, dated records indicating the amount of time spent on each task. Interim payment of expert fees may be considered on the same bases as interim attorneys’ fees. See *infra* Section X, Chapter 6.

### **Chapter 3. Applications for Fees and Costs.**

#### **A. General Information.**

The fees and costs payable under the Vaccine Program fall into three general categories: (1) fees and costs paid by the attorneys in connection with litigating the matter, *e.g.*, costs of obtaining medical records; (2) costs paid by the petitioner in connection with litigating the matter; and (3) expert witness fees and costs. Supporting documentation is required for each item claimed. With regard to attorneys' fees and experts' fees, the particular tasks for which fees are claimed, the amount of time spent on that task, the person who performed the task, and that person's billed hourly rate must be identified in contemporaneous, dated records. With regard to costs incurred by the petitioner personally, such costs must be identified and supporting documentation provided. If the petitioner has not incurred any such costs, a statement must be provided to that effect.

#### **B. Content of Application.**

In general, a fees application should include:

##### **1. Counsel Fees.**

###### **a. Affidavit of the petitioning attorney.**

The affidavit should include information about the petitioning attorney (*e.g.*, the year of graduation from law school, date of all bar admissions, length of practice, specialties of practice, customary billing practices, and history of hourly rates charged) and a statement that the attached report of hours and costs expended is accurate. Similar information concerning other persons whose time is being billed should be provided.

###### **b. Time Records.**

Contemporaneous time records should indicate the date and specific character of the service performed, the number of hours (or fraction thereof) expended for each service, and the name of the person providing such service. Each task should have its own line entry indicating the amount of time spent on that task. Lumping together several unrelated tasks in the same time entry frustrates the court's ability to assess the reasonableness of the request. Preferred time increments are tenths of an hour.

###### **c. Hourly Rates.**

Supporting documentation for the requested local hourly rates should be provided. Such documentation may include:



(1) The firm's retainer fee agreement that incorporates a "reasonable hourly rate" should the client terminate the agreement;

(2) Affidavits of other attorneys who practice in the same community and in the same general field of practice. Such an affidavit should be complete, *e.g.*, include the affiant's geographical location, years of practice, nature of practice. By far the most useful affidavit will be one that states what the affiant charges and receives on an hourly basis and specifies the nature of services provided for that hourly rate. Vague affidavits merely opining that the claimed rates are "reasonable," without giving the factual basis for such opinion, are of no value;

(3) Relevant case law involving the award of fees; and

(4) Studies and surveys of attorneys' fees by a state or local bar. The information submitted in this regard should be as specific and detailed as possible. Information showing a broad range of hourly rates, without specifying the types of work performed by the attorneys within that range, will be of little help.

## 2. Counsel Costs.

A list of costs incurred by counsel and/or advanced under the petition, *e.g.*, amounts paid for copying records and amounts for travel, along with supporting documentation, should accompany the application. Such expenses, if not self-explanatory, should be explained sufficiently to demonstrate their relation to the prosecution of the petition.

## 3. Petitioner Costs.

Fees applications must include a statement, signed by petitioner, specifying any costs that were borne by petitioner personally rather than by counsel (along with supporting documentation), and stating the amount of any retainer paid by petitioner. If petitioner has not incurred any costs personally, the application must include a statement to that effect. See Vaccine General Order #9 Statement found at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>.

## 4. Expert Costs.

Supporting documentation for expert expenses, such as the cost of obtaining and duplicating medical literature, plane tickets, and meals, must be provided.

### **Chapter 4. Timing of Fees and Costs Applications.**

Pursuant to Vaccine Rule 13, a request for attorneys' fees and other litigation costs must be filed no later than 180 days after the entry of judgment or after the filing of an order concluding proceedings. Requests for extensions of this time period must be filed before the deadline expires.

## **Chapter 5. Responses to Applications for Fees and Costs.**

An application for fees and costs is treated procedurally as a motion under Vaccine Rule 20, giving respondent 14 days to file a response. Petitioner may file a reply within 7 days. Extensions of these deadlines may be obtained by filing a motion for extension of time or contacting the special master's chambers in accordance with the practices of that particular special master.

## **Chapter 6. Awards of Interim Fees and Costs.**

### **A. Interim Awards in General.**

The Federal Circuit has held that the award of attorneys' fees and costs on an interim basis is permitted in the Vaccine Program. Interim awards have been made in the special master's discretion, depending on a variety of factors, including but not limited to the duration of the litigation (*i.e.*, lengthy proceedings), the stage of the proceedings, the amounts sought (demonstrating that substantial costs have been incurred), and the documented need for an interim award (demonstrating undue hardship).

### **B. Interim Awards When Counsel Seeks to Withdraw.**

Interim fees applications are frequently filed when counsel for petitioner seeks to withdraw from the representation before the case is concluded. If interim fees are sought under such circumstances, such applications should be made prior to counsel's withdrawal from the case.

### **C. Computing Amounts of Interim Fee Awards.**

To minimize the amount of time spent on interim requests, interim applications must be well supported and sufficiently documented or the application will be denied. The above guidelines regarding attorneys' fees and costs apply to applications for interim attorneys' fees and costs.

## **Chapter 7. Payment.**

Petitioners' counsel should be aware that checks for payment of attorneys' fees and costs generally will be made payable jointly to petitioner and petitioner's counsel. Checks for reimbursement of costs incurred only by petitioner will be made payable solely to petitioner.

## **Chapter 8. Judicial Review of Special Master's Fees Decision.**

A special master's ruling on a fees request constitutes a separate decision by the special master. Therefore, a party may seek judicial review by the Court of Federal Claims by filing a separate motion for review under Vaccine Rule 23. If the parties do not intend to file a motion for review, the parties may expedite the entry of judgment by each party filing a notice (or both parties filing a joint notice) renouncing the right to seek review of the special master's decision by a Court of Federal Claims judge. See Vaccine Rule 11(a). A form for such a notice is available at <http://www.uscfc.uscourts.gov/vaccine-sample-filings>. Once judgment has entered on a fees decision, however, there is no need to file an election to accept or reject the fees judgment.

## **SECTION XI. REQUESTS FOR RECONSIDERATION**

Vaccine Rule 10(e) provides that either party may file a motion for reconsideration of a special master's decision within 21 days after issuance, provided that judgment has not been entered and no motion for review under Vaccine Rule 23 has been filed. The special master may seek a response from the nonmoving party, specifying both the method and timing for the response.

Reconsideration may be granted in the discretion of the special master. If reconsideration is granted, the special master will withdraw the challenged decision and issue a superseding decision, but only if there has been no judgment entered or motion for review filed regarding the original decision. A special master may not issue a superseding decision reaching a different result without affording the nonmoving party an opportunity to respond to the moving party's arguments.

If a party believes that an important point of law or a crucial fact has not been addressed in a special master's decision, that party may seek reconsideration of the special master's decision. In such instances, a request for reconsideration may avoid the delays attendant to a motion for review and subsequent remand. Otherwise, motions for reconsideration should generally be limited to cases (1) that may be affected by changes in law which occurred after the decision was issued, (2) in which new facts are discovered that could not have been discovered with due diligence prior to issuance of the decision, or (3) in which reconsideration is necessary to prevent manifest injustice.

However, filing a motion for reconsideration does not toll the running of the 30-day deadline for seeking review of a special master's decision under Vaccine Rule 23, unless and until the special master grants reconsideration, and/or withdraws the decision.

## SECTION XII. POST-JUDGMENT RELIEF

After the court's judgment has been entered in a case, in certain extraordinary circumstances, a new trial, rehearing, amendment of judgment, reconsideration of judgment, or relief from judgment may be available under RCFC 59 or 60 (*i.e.*, the Court of Federal Claims' Rules, not the Vaccine Rules in Appendix B).

Under Vaccine Rule 36(a), a motion made under RCFC 59 or 60 will be referred by the Clerk's Office to a specific judge of the court if that judge previously reviewed the petition on appeal pursuant to Vaccine Rule 23. If neither party appealed the special master's decision to a judge of the Court of Federal Claims under Vaccine Rule 23, the Clerk's Office will refer the motion to the Office of Special Masters for disposition.

A motion filed under RCFC 59 or 60 should be accompanied by a full explanation of the situation giving rise to the motion, and must explain which specific provision of RCFC 59 or 60 is thought to give the court authority to grant the relief requested. In motions referred to the Office of Special Masters, the non-moving party will have the same opportunity to respond to this motion as with any other motion brought before the court. See Vaccine Rule 20. For motions referred to a judge of the Court of Federal Claims, the non-moving party's opportunity to respond to the motion is governed by the terms specified in RCFC 59 or 60.

### **SECTION XIII. MOTIONS FOR REVIEW**

The decision of a special master becomes final, without any need for further review, unless a party files a motion for review within 30 days. The procedures for review are clearly set forth in the Vaccine Rules. Only a few comments and highlights of the procedures follow.

First, counsel should note that to obtain review, the motion, with accompanying memorandum, must be filed within 30 days after the filing date of the decision. There can be no extension of this deadline. See Vaccine Rule 23. Although the special master's decision may reach a petitioner by mail, there is no provision for extending the 30-day period on account of mail delivery or for any unusual delays in delivery. A motion is filed on the day the Clerk of Court receives it.

Finally, because the ruling of a special master on an attorneys' fee request will constitute a decision of the special master separate from the decision on the merits, review by a Court of Federal Claims judge is obtained by a separate motion for review pursuant to Vaccine Rule 23. Similarly, a Court of Federal Claims judgment denying or awarding fees will be considered a judgment separate from the judgment on the merits, so that a separate appeal to the Federal Circuit must be taken pursuant to Vaccine Rule 32.

## SECTION XIV. OBTAINING PROGRAM INFORMATION

General procedural questions concerning the Program should be directed to the Office of the Clerk of the Court of Federal Claims at (202) 357-6400. Also, general information and special master decisions since 1997 are available on the court's website at [www.uscfc.uscourts.gov](http://www.uscfc.uscourts.gov), and under the Office of Special Masters portion of the website at <http://www.cofc.uscourts.gov/vaccine-programoffice-special-masters>.

There are several sources from which to obtain judicial precedent concerning the Program. Decisions of the Court of Federal Claims judges and of the Federal Circuit in vaccine cases are published in the West Publishing Company's "United States Court of Federal Claims Reporter" and "Federal Reporter, 3d Series," respectively. These decisions, in addition to the published decisions of the special masters, are also available through Westlaw and Lexis.

Another source of information for petitioners is the Vaccine Injured Petitioners Bar Association, its website is [www.vipbar.org](http://www.vipbar.org); and its e-mail address is [info@vipbar.org](mailto:info@vipbar.org). The providing of this contact information is not an endorsement by the Office of Special Masters or the Court of Federal Claims of the advice or services provided by this voluntary bar organization.

The court maintains a list of attorneys who are willing to accept vaccine injury cases. The most recent version of this referral list may be found at: <http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters>. *Pro se* petitioners and potential petitioners are not limited to retaining attorneys on this list, and the court does not endorse representation by attorneys on the list. Attorneys on the list are not required to accept clients who contact them.