

The Life Care Plan and the Vaccine Injury Compensation Program

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KEY WORDS

Life Care Plan, Vaccine Injury Compensation Program

The life care plan is now utilized and endorsed as a damages tool within a variety of settings: civil litigation (personal injury and medical malpractice); reserve setting by insurance companies; managed care, workers' compensation, facility discharge planning, estate planning, and trust management; and the Vaccine Injury Compensation Program (VICP). In perhaps a lesser-known venue, the U.S. Court of Federal Claims obtains the information necessary to establish a VICP award by utilizing a life care plan, presented by both the petitioner (injured party) and respondent (U.S. Department of Health and Human Services represented by the U.S. Department of Justice), or, on occasion, an agreed-upon, single life care planner. In the VICP setting, the life care planner's role, as allowed by the Special Master, is adaptable, open, and supportive to the goal of "...a swift, flexible, and less adversarial alternative to the often costly and lengthy civil arena of traditional tort litigation" (Office of Special Masters Homepage, 2005).

Today, childhood vaccines protect against 11 diseases. Smallpox has been eradicated in the United States, and the last indigenous transmission of wild poliovirus in the U.S. occurred in 1979. According to the 2003 National Immunization Survey, more than 93% of children 19 to 35 months of age in all races received three or more doses of any diphtheria, tetanus toxoid, and pertussis (DPT) vaccines (Morbidity Mortality Weekly, 2004).

In the early 1980s, the safety of the DPT vaccine was called into question, as harmful side effects from the vaccine began to evidence themselves. Lawsuits were filed against the vaccine manufacturers and the health care providers administering the vaccines, and vaccination rates declined. Companies producing the vaccines began to leave the marketplace, causing a shortage in the vaccine supply and culminating in a serious potential threat to the nation's health.

In response to this impending public health issue, Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act) and subsequently created the Vaccine Injury Compensation Program (VICP) in October 1988. The Vaccine Act protected vaccine manufacturers and health care providers from liability and stabilized the vaccine market. Additionally, an adverse event reporting system was developed as a component of the Vaccine Act, to facilitate the research and development of newer and safer vaccinations.

Covered Vaccines

The VICP was designed as a no-fault system to resolve vaccine injury claims and to compensate those injured as a result of vaccinations recommended by the Centers for Disease Control (CDC). According to the Department of Health and Human Services (HHS), vaccines currently covered under the VICP are: diphtheria, tetanus, pertussis, (DTP, DTaP, DT, TT, or Td), measles, mumps, rubella (MMR or any components), polio (OPV or IPV), hepatitis B, Haemophilus influenzae type b, varicella (chicken pox),

rotavirus, pneumococcal conjugate, and hepatitis A (Fact Sheet, 2005), whether administered alone or in combination.

On December 1, 2004, hepatitis A was added to the Vaccine Injury Table under Category XIV. Trivalent Influenza vaccines were added to this same category, effective July 1, 2005 (Table 1). Anthrax and smallpox vaccines are not covered under VICP. If injury or death results from the administration of one of the covered vaccines, the individual, a parent, guardian, or a trustee on behalf of a child or incapacitated person can file a claim/petition for compensation.

The escalating incidence of autism and its alleged relationship to Thimerosal, the mercury preservative in vaccines, has been hotly debated in the medical literature and in the news, as recently as June 2005 in Gardiner and O'Connor's *On Autism's Cause, It's Parents v. Research* (Gardiner and O'Connor, 2005). The VICP saw a dramatic increase in petitions, from 18 to 768, alleging this relationship between 2001 and 2002, and peaking in 2003 with 2,438 petitions filed (Post-1988 Monthly Statistics Report, 2005). The Court consequently established a special procedure for dealing with claims that allege vaccines or Thimerosal cause child autism or a similar disorder. The "Omnibus Autism Proceeding" essentially groups autism claims together (Autism Update, 2005).

VICP Claims Process

The process of claims resolution through the VICP is intended to be less adversarial and more efficient than a civil lawsuit. The HHS, the U. S. Court of Federal Claims (Court) and the U. S. Department of Justice (DOJ) co-administer the program. The claims process follows this course:

1. File a petition for compensation with the Court and with the Secretary of HHS identified as defendant.
2. The VICP/HHS physician reviews the petition to determine whether it meets the medical criteria for compensation and makes a recommendation on compensability.

3. The HHS physician recommendation is provided to the Court through a report filed by the DOJ, although it is not binding.
4. A DOJ attorney represents the HHS position in hearings before a "Special Master" who makes the initial decision for compensation under the VICP. The Court appoints Special Masters. The Office of Special Masters consists of one chief and five associates who are appointed for four-year terms. The Special Master is responsible for conducting all proceedings, ...including requiring such evidence as may be appropriate, in order to prepare a decision, including findings of fact and conclusions of law, determining whether an award of compensation should be made under the Vaccine Act and the amount of any such award. The Special Master shall determine the nature of the proceedings expeditious, flexible and less adversarial while at the same time affording each

party and full and fair opportunity to present its case and creating a record sufficient to allow review of the special master's decision [sic] (Vaccine Rules, 2002).

5. Decisions by the Special Master may be appealed to a judge of the Court, then to the Federal Circuit Court of Appeals, and then finally to the Supreme Court.

The Rules of the Court are very specific and must be strictly followed throughout the process. Though an attorney is not required, one may be advisable. The Vaccine Act does provide for recovery of reasonable attorney fees and costs.

Compensation through VICP

In order to qualify for compensation through the VICP, it must be proved that: (a) an injury found on the Vaccine Injury Table (Table 1) occurred; or (b) the vaccine caused the condition; or (c) the vaccine significantly aggravated a pre-existing condition.

Table 1: The Vaccine Injury Table, effective 12/1/04 and modified w/ 7/1/05 update.

Vaccine	Adverse Event	Time Interval
I. Tetanus toxoid-containing vaccines (e.g., DTaP, DTP-Hib, DT; Td, or TT)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Brachial neuritis	2-28 days
	C. Any acute complication or sequela (including death) of above events	Not applicable
II. Pertussis antigen-containing vaccines (e.g., DTaP, DTP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Encephalopathy (or encephalitis)	0-72 hours
	C. Any acute complication or sequela (including death) of above events	Not applicable
III. Measles, mumps and rubella virus-containing vaccines in any combination (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Encephalopathy (or encephalitis)	5-15 days
	C. Any acute complication or sequela (including death) of above events	Not applicable
IV. Rubella virus-containing vaccines (e.g., MMR, MR, R)	A. Chronic arthritis	7-42 days
	B. Any acute complication or sequela (including death) of above even	Not applicable
V. Measles virus-containing vaccines (e.g., MMR, MR, M)	A. Thrombocytopenic purpura	7-30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	0-6 months
	C. Any acute complication or sequela (including death) of above events	Not applicable
VI. Polio live virus-containing vaccines (OPV)	A. Paralytic polio	
	— in a non-immunodeficient recipient	0-30 days
	— in an immunodeficient recipient	0-6 months
	— in a vaccine-associated community case	Not applicable
	B. Vaccine-strain polio viral infection	
	— in a non-immunodeficient recipient	0-30 days
	— in an immunodeficient recipient	0-6 months
	— in a vaccine-associated community case	Not applicable
	C. Any acute complication or sequela (including death) of above events 4	Not applicable
VII. Polio inactivated-virus containing vaccines (e.g., IPV)	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Any acute complication or sequela (including death) of above event	Not applicable
VIII. Hepatitis B antigen- containing vaccines	A. Anaphylaxis or anaphylactic shock	0-4 hours
	B. Any acute complication or sequela (including death) of above event	Not applicable
IX. Hemophilus influenzae type b polysaccharide conjugate vaccines)	A. No condition specified for compensation	Not applicable
X. Varicella vaccine	A. No condition specified for compensation	Not applicable
XI. Rotavirus vaccine	A. No condition specified for compensation	Not applicable
XII. Vaccines containing live, oral, rhesus-based rotavirus	A. Intussusception	0-30 days
	B. Any acute complication or sequela (including death) of above event	Not applicable
XIII. Pneumococcal conjugate vaccines	A. No condition specified for compensation	Not applicable
XIV. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by Secretary, HHS of a notice of coverage.—see b, c below	A. No condition specified for compensation	Not applicable

b On December 1, 2004, the Secretary published a notice in the Federal Register announcing the addition of hepatitis A Vaccines to the Vaccine Injury Table under Category XIV with an effective date of December 1, 2004. (69 Fed. Reg. 69945-46 (December 1, 2004)).

c On April 12, 2005, the Secretary published a notice in the Federal Register announcing the addition of Trivalent Influenza Vaccines to the Vaccine Injury Table under Category XIV with an effective date of July 1, 2005 (70 Fed. Reg. 19092-19093 (April 12, 2005)).

In the VICP, compensation may be awarded for vaccine-related death or injury. These awards are funded from a trust fund created by an excise tax of \$.75 on every dose of covered vaccine that is purchased, if the vaccine was administered on or after October 1, 1988 (How is VICP Funded?, 2005). For a vaccine-related death, an award of up to \$250,000 may be provided to the estate of the deceased if the claim is filed per instructions and time guidelines. Within 36 months after the first symptoms from a vaccine appear, the Vaccine Act indicates that a claim can be filed for vaccine-related injury (Guidelines & VICP Compensation, 2004). The symptoms must have lasted for at least 6 months after the vaccine administration, or the injury must have resulted in inpatient hospitalization and surgical intervention. Reasonable compensation for past and future “nonreimbursable” [sic] medical, custodial and rehabilitative costs, \$250,000 (cap) for actual and projected pain and suffering, lost earnings, and attorney fees and costs may be awarded for vaccine injury. Should a claim be determined non-compensable by the VICP, or the award be rejected, the petitioner still has the option to sue the vaccine administrator or manufacturer.

Statistics from the Health Resources and Services Vaccine Injury Compensation Program indicate that awards have ranged up to \$9.13 million but average \$974,393 (Post 1988- Monthly Statistics Report, 2005). The range of awards is influenced by diagnosis, but specifically by the services included in an individual plan. The need for ongoing supportive or nursing care is one of the largest dollar figures in any life care plan. For instance, the need for 6-8 hours of daily attendant care, at \$16.50/hour, amounts to \$42, 157 per year. Over a 20- to 30-year life expectancy, this attendant care alone totals \$1,053,957. As a point of comparison, physician care—though higher-priced per unit—is not required at the same frequency and regularity and, consequently, represents a lower annual and lifetime figure in the life care plan. Quarterly visits with a psychiatrist [psychiatrist?] (at \$100/visit) amount to an annual figure of \$400, which for the same 20- to 30-year life expectancy translates to \$10,000. Injuries such as autism, paralytic polio (Table 1, Item VI-A), and encephalitis (Table 1, Item III-B) are examples of vaccine injuries that may warrant the need for attendant care or nursing services. Conversely, a brachial neuritis from a tetanus vaccine (Table 1, Item I-B) may result in a loss of function in the affected extremity, requiring intensive acute care and treatment, but later resolve to require some adaptive aids, housekeeping assistance with aging, and periodic physician follow up: roughly \$3,000 a year, or \$75,000 for the same 20-30 year life expectancy previously mentioned.

The Life Care Plan

The life care planner’s role in the VICP setting, as in the civil litigation environment, is to aid in assessing damages and establishing the level of compensation necessary for an injured individual. The VICP, Office of Special Masters Damage Order defines the damages process and specifically

mentions, “In Vaccine Act cases, damages issues are typically resolved by a process in which petitioner, begins by obtaining a ‘Life Care Plan’ that sets forth petitioner’s future needs” (Damages Order, 1997).

A life care plan is a dynamic document based upon published standards of practice, comprehensive assessment, data analysis and research, which provides an organized, concise plan for current and future needs with associated costs, for individuals who have experienced catastrophic injury or have chronic health care needs (Weed, 2004).

Through review of pertinent medical records, direct assessment and observation of the petitioner, and collaboration with treatment providers and experts, the life care planner identifies and researches recommended services or equipment required for the individual, when such services or equipment are required, and for how long. Subsequently, the cost and cost sources are researched and identified. Though not all-inclusive, common categories of need outlined in a life care plan include: physician care, therapy, counseling, medications, diagnostic testing, durable medical equipment, supplies, home modifications, transportation needs, residential/attendant care, future surgeries or procedures, and potential complications.

In other settings, the rationale and basis for each of the life care planner’s recommendations are typically attained through expert deposition or trial testimony. In the absence of expert testimony, the VICP life care plan must clearly define these details, as well as the manner in which the costs were attained. The Office of Special Masters Damage Order specifies the details required in the life care plan. Background information on the injured person includes the sources of information used to determine the level of care: conversations with the family, past level of care, physician recommendations, and school assessments. The current treatment plan is documented, and, if future care recommendations differ from the current treatment plan, the rationale for those recommendations is clarified in the report.

Recommendation, Documentation

Residential and attendant care recommendations in the VICP life care plan are accompanied by a thorough explanation as to how the level of care was determined for a particular individual and why that level of care is necessary. For nurse life care planners, determining this level of care is multi-factorial. The nursing process is utilized to assess an individual through medical record review, direct client interview and observation, and contact with the current care providers or expert physicians. Specifics about the individual’s need for assistance with activities of daily living, hygiene, medication administration, behavior management, safety needs, and skilled nursing tasks are thus determined, and the appropriate nursing diagnosis assigned. The family’s preferences regarding who provides the care and where care is provided are also taken into consideration. Attendant or nursing care hours are delineated in the plan, with specifics

about potential care providers. The number of care hours is determined by assessing of the number of tasks, the time entailed in each task, the timing of the task during a given day, the availability of services within a geographic area, and the potential restrictions imposed in the community by agencies as to minimum number of hours. Finally, the skill level is determined by interpreting these issues within the confines of the nurse practice act and community care legislation of an individual state.

If residential care is recommended, a list of local residential care facilities providing the recommended level of care is noted with price, and details of the services are included for the noted price. Additionally, the life care planner must provide documentation of the specific dialogue used to identify the injured party to the facility, so it is clear that the level of care and cost has been accurately defined. This is necessary because disputes about facility care have typically centered on the issue of the descriptive information provided to the facility to establish the level of care (Damages Order, 1997). For instance, a recommendation for a low-cost facility that does not offer the intensity of care needed for the disabled individual could result in such a circumstance. If a facility is rejected as an option, the rationale for that rejection is also provided in the life care plan.

Since the VICP provides “reasonable compensation for past and future nonreimbursable [sic] medical, custodial and rehabilitative costs” (National Vaccine Injury Compensation Program: Compensation, 2005), the petitioner’s planner must make note of insurance benefits anticipated for each of the services recommended in the life care plan, as well as the availability of state or local benefits. Noting these collateral sources of reimbursement, in essence, leaves the plan with only those expenses for which there is no anticipated reimbursement—or the bottom line, for the VICP.

As an example, the state of California requires that Regional Center and California Children’s Services benefits are noted to offset the recommended services. Additionally, the VICP requires the life care planner to make note of therapy or services that are provided by the school district, another collateral source of reimbursement, through the Education of Individuals with Disabilities Act (Damages Order, 1997). If the school district does not provide services, the plan should explain why this is not occurring. Any other sources of financial aid currently or potentially available to offset the requested costs should also be noted in the plan. Conversely and proportionately, the effect of a VICP award on these benefits should also be included in the plan.

In the VICP environment, the petitioner and respondent life care planners work on a relative equal footing as compared to the plaintiff and defense planners in civil litigation. Both planners within the VICP have access to the injured person and the current providers. In one case example, the DOJ planner visited directly with providers outside of the plaintiff planner’s presence. In another example, phone conference calls were recorded with both planners questioning the

providers. This constitutes a significant variation from the civil arena, where the defense planner often does not have direct access to the injured person or the providers who treat him/her. Because the respondent planner is afforded this access, issues of dispute between plans can be directly addressed and potentially resolved with the providers.

The character of the dialogue between the provider and the life care planner directly affects the logic and methodology of how conclusions are derived for the plan. The types of questions posed, the manner in which the questions are asked, and the way the planner responds to the provider’s comments or recommendations with additional questions to clarify all affect the outcome of the discussion and ultimately the life care plan. In one case example, teleconferences with treating physicians and providers were arranged and mediated by the petitioner’s planner for the respondent planner. Both planners then participated in the dialogue with the provider, one after the other, and thus heard the same information. Areas of ambiguity were cleared up quickly.

The Office of Special Masters specifically encourages expert-to-expert dispute resolution. In one case, the petitioner and respondent planners reviewed their plans, noted areas of disagreement, developed plans for compromise, and resolved the differences in a collaborative fashion via teleconference. This process minimizes the adversarial atmosphere and thereby brings an expedited resolution of damages issues. In the instance where residual differences cannot be resolved, the Special Master may call a hearing in order to reach a decision.

Conclusion

The goal of “...a swift, flexible, and less adversarial alternative” dispute resolution (Office of Special Masters Homepage, 2005) in the Vaccine Injury Compensation Program provides an opportunity for the life care planner to function in a less typical and expanded capacity. It requires the planner to be thorough and creative in the approaches undertaken to present the life care plan and resolve differences. The flexibility offered by the Special Master to resolve differences directly between experts provides an interesting model for consideration in other arenas.

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