

HHS WAIVERS OF THE TWO-YEAR REQUIREMENT: AN OVERVIEW OF CLINICAL AND RESEARCH WAIVER PROGRAMS

by Rita Sostrin *

INTRODUCTION

Obtaining a waiver of the two-year home residence requirement¹ from the U.S. Department of Health and Human Services (HHS)² is one of the more intimidating areas of immigration law. It requires the immigration law practitioner to step outside his or her area of expertise into medical practice and research issues in order to evaluate the client's eligibility and prepare a successful waiver application. This article endeavors to explain the HHS waiver process and to provide logical guidelines to serve the needs of international medical graduates (IMGs) and scientists. It will discuss both HHS waiver programs that are currently in place: (1) the waiver program for physicians practicing in underserved areas; and (2) the waiver program for biomedical researchers performing studies of high priority to HHS.

Exchange visitors (EVs) in J-1 status who are subject to the two-year foreign residence requirement may, instead of returning to their home country, obtain a waiver of the two-year requirement.

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¹ Section 212(e) of the Immigration and Nationality Act of 1952 (INA), Pub. L. No. 82-414, 66 Stat. 163 (codified as amended at 8 USC §1101 *et seq.*).

² Information about the Department of Health and Human Services (HHS) may be obtained at its Web site at www.hhs.gov/.

Several waiver options may be available, depending on the EV's circumstances:

No-objection waiver: by far, the easiest way to avoid fulfilling the requirement is to apply for a statement of no objection from the exchange visitor's home government. This option, however, is not available to IMGs, unless they came to the United States to observe, consult, teach, or conduct research.³

Hardship waiver: to qualify, the EV must demonstrate that his or her departure from the United States would impose exceptional hardship on a U.S. citizen or permanent resident spouse or child.⁴

Persecution waiver: available to those EVs who can demonstrate that they would be subject to persecution on account of race, religion, or political opinion.⁵

Interested Government Agency (IGA) waiver: an EV may qualify for a waiver based on a recommendation from an IGA if a waiver is in the public interest, and compliance with the two-year requirement would be detrimental to a program that is of official interest to the recommending agency.⁶

While any government agency can serve as an IGA, IMGs frequently seek waivers from federal or state agencies in exchange for agreeing to provide full-time clinical services in an area designated as having a shortage of healthcare professionals⁷ for at least three years.⁸ Currently, all 50 U.S. states, as well as the District of Columbia and Guam, have the Conrad State 30 Waiver Program, which allows a state Health Department to grant up to 30 waivers

³ 22 CFR §62.27 (g)(2).

⁴ 8 CFR §212.7(c)(5).

⁵ 8 CFR §212.7(c)(8).

⁶ 22 CFR §41.63(c).

⁷ Public Health Service Act, 42 USC §254e, §332; Public Health Service Act, 42 USC §254c, §330. There are two types of designations of health care shortage: Health Professional Shortage Area (HPSA) and Medically Underserved Area/Medically Underserved Population (MUA/MUP).

⁸ INA §214(l), 22 CFR §41.63(c)(4), 8 CFR §212.7(c)(9); see also Legacy Immigration and Naturalization Service (INS) Memorandum, M. Pearson, "Waivers of the Two-Year Foreign Residence Requirement Under Section 212(c) of the Immigration and Nationality Act," published on AILA InfoNet at Doc. No. 99100490 (posted Oct. 8, 1999).

annually to qualified physicians.⁹ Also, an IMG practicing in a designated area may qualify for a waiver by requesting that another agency, such as the Appalachian Regional Commission (ARC), Delta Regional Authority (DRA), or the U.S. Department of Veterans Affairs (VA), act as an IGA on his or her behalf.¹⁰

HHS, too, has taken on the role of an interested government agency and can recommend waivers on behalf of qualified physicians and scientists. Specifically, in 2002, it initiated processing of waiver applications for physicians practicing primary care medicine or psychiatry in designated areas suffering from a shortage of physicians.¹¹ In addition, since 1984, HHS has been handling waiver applications for researchers, including IMGs, who perform studies that are considered in the public interest and in the interest of the agency.

Thus, HHS has two distinct J-1 waiver programs that are intended to accommodate both clinicians and researchers. These two programs have specific and restrictive eligibility criteria. This article will review both programs in detail with the aim to serve as a guide to practitioners working in this area of immigration law.

⁹ Immigration and Nationality Technical Corrections Act of 1994 (INTCA), Pub. L. No. 103-416, 108 Stat. 4305, §220; INA §214(I).

¹⁰ In the past, the U.S. Department of Housing and Urban Development (HUD) served as an interested government agency (IGA) for physicians practicing in underserved urban areas. On August 26, 1996, HUD issued a moratorium on its J-1 waiver program and suspended the processing of J-1 waivers indefinitely. See "HUD J-I Waiver Approval Policy," published on AILA InfoNet at Doc. No. 96122490 (posted Dec. 24, 1996). Likewise, on March 1, 2002, the U.S. Department of Agriculture (USDA) also announced that it would no longer continue its J-1 waiver program. USDA had sponsored physicians practicing in underserved rural areas since 1994. See "USDA Participation in J-1 Waiver Program," published on AILA InfoNet at Doc. No. 02030671 (posted Mar. 6, 2002).

¹¹ See HHS Exchange Visitor Program, Request for Waiver of the Two-Year Foreign Residence Requirement, 67 Fed. Reg. 77692 (Dec. 19, 2002) (codified at 45 CFR pt. 50); HHS News Release, "HHS to Expand Access to Care in Rural and Other Communities by Reviewing Waiver Requests Involving Foreign Doctors" (Dec. 17, 2002), available at www.hhs.gov/news/press/2002pres/20021217.html.

QUALIFYING FOR AN HHS WAIVER

Part 1: HHS Waiver Program for Clinicians in Underserved Areas

Background

On February 27, 2002, the U.S. Department of Agriculture (USDA) ended its waiver program for J-1 exchange visitors,¹² which had sponsored IMGs practicing in underserved rural areas since 1994. With the termination of the USDA waiver program, an important source of IMGs who serve medically underserved rural populations was lost. Perhaps sensing this problem, on December 19, 2002, HHS issued an interim final rule indicating that it would act as an interested government agency on behalf of IMGs willing to practice primary care or general psychiatry in community health centers and rural hospitals located in health professional shortage areas (HPSAs).¹³ This action on the part of HHS was intended to shore up the nation's supply of primary care physicians and psychiatrists, particularly in rural regions of the country. After a brief suspension of the program in early 2003, HHS began accepting applications again on June 12, 2003.¹⁴

Eligibility Requirements

The HHS clinical physician waiver program has outlined specific requirements that must be met by both the IMG and the sponsoring employer. Unlike other similar programs for clinicians working in underserved areas, the HHS waiver program places a number of limitations on applicants, which disqualify many from applying.

Eligibility Requirements for the Physician

To be eligible to apply for the clinical HHS waiver, the IMG must agree to work as a primary care physician or a general psychiatrist. In other words, this program is unavailable to specialist physicians, even if a shortage can be demonstrated. Primary care physicians are physicians practicing gen-

¹² See "USDA Participation in J-1 Waiver Program," *supra* note 10.

¹³ See *supra* note 11.

¹⁴ Applications Available to Request Waiver of the Two-Year Foreign Residence Requirement for Physicians with J-1 Visa Who Will Deliver Health Care Services, 68 Fed. Reg. 35226 (June 12, 2003).

eral internal medicine, pediatrics, family practice, and obstetrics/gynecology.¹⁵

One of the most unusual requirements of the program is that it limits eligible applicants to those who have completed primary care residency training no more than 12 months before the date on which they will begin employment in the underserved area.¹⁶ This restriction effectively eliminates most physicians who have obtained fellowship training subsequent to completing their primary care residency, as many fellowship programs last more than one year. Thus, while the program clearly prohibits specialists from qualifying for a waiver through *practicing* their specialty, its 12-month restriction also prevents them from *applying* even if they are willing to practice primary care medicine.

The IMG must hold a contract with the sponsoring employer obligating him to work in the primary care or mental health HPSA for a three-year period, at least 40 hours per week.¹⁷ The IMG must be qualified to perform the job and should present three reference letters from former employers or colleagues commenting on his professional accomplishments (the referees must be U.S. residents). Because the physician would be required to obtain H-1B status in order to fulfill the terms of his three-year contract,¹⁸ he must be able to meet the H-1B requirements for clinicians. Specifically, to qualify for H-1B status, all IMGs must meet two threshold requirements: (1) possession of a valid medical license, or similar authorization, in the state of intended employment;¹⁹ and (2) graduation from a medical school in the United States or a foreign country.²⁰ In addition, those IMGs who engage in clinical practice also have to demonstrate that they have passed all three steps of the U.S. Medical Licensing Examination (USMLE), which is the current equivalent to the Federal Licensing Examination mandated by the regulations.²¹

¹⁵ HHS Exchange Visitor Program, Request for Waiver of the Two-Year Foreign Residence Requirement, 67 Fed. Reg. 77692, 77693 (Dec. 19, 2002) (codified at 45 CFR pt. 50).

¹⁶ *Id.*

¹⁷ *Id.* at 77692, 77694; HHS, “Requirements for Waiver for Clinical Care,” available at www.globalhealth.gov/exchangevisitorprogram/reqwaiv_clinical.html.

¹⁸ INA §214(l)(1)(C) and 8 CFR §212.7(c)(9)(iv).

¹⁹ 8 CFR §214.2(h)(4)(viii)(A)(1).

²⁰ 8 CFR §214.2(h)(4)(viii)(A)(2).

²¹ INA §212(j)(2)(B)(i); 8 CFR §214.2(h)(4)(viii)(B)(2).

Eligibility Requirements for the Sponsoring Facility

The employer that will sponsor the physician for an HHS waiver also must meet a number of prerequisites in order to qualify to act as the sponsor. Most importantly, the facility at which the IMG will practice must be located in an HPSA or a mental health HPSA for psychiatrists, pursuant to Section 332 of the Public Health Service Act.²² The criteria for HPSA designation are stipulated in Part 5, Title 42, of the Code of Federal Regulations, and are based on geographic and demographic factors established by the Bureau of Health Professions within the Health Resources and Services Administration (HRSA) of HHS.²³ Healthcare facilities located in Medically Underserved Areas²⁴ (MUAs), or serving Medically Underserved Populations (MUPs) were initially eligible to serve as sponsoring employers for the HHS primary care waiver program, but no longer qualify.²⁵

Originally, only facilities located in an HPSA with a score of 14 or higher (indicating particularly severe underservice) could act as sponsoring employers. This eliminated most potential HPSA employers from eligibility to sponsor. However, HHS now accepts applications for waivers from facilities located in HPSAs with a score of seven or higher.²⁶ The health care facility must be a health center²⁷ receiving a grant from HRSA under Section 330 of the Public Health Service Act, a rural health clinic,²⁸ or a Native American/Alaskan Native tribal medical

²² 42 USC §245e.

²³ Health Professional Shortage Designation Criteria, available at www.bhpr.hrsa.gov/shortage/hpsacrit.htm.

²⁴ Public Health Service Act, 42 USC §245e, §330(b)(3)–(6).

²⁵ R. Aronson, D. Ware, A. Brown, & G. Siskind, “Update on Interested Government Agency Waivers for J-1 Physicians,” *Immigration Options for Physicians* 67 (AILA 2004 Ed.).

²⁶ HHS News Release, “HHS to Expand Access to Care in Rural and Other Communities by Reviewing Waiver Requests Involving Foreign Doctors” (Dec. 17, 2002), available at www.hhs.gov/news/press/2002pres/20021217.html.

²⁷ The term “health center” means “an entity that serves a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing....” Public Health Service Act, 42 USC §254b, §330, available at <http://bphc.hrsa.gov/about/legislation/section330.htm>.

²⁸ As defined under sections 1102 and 1871 of the Social Security Act, ch. 531, 49 Stat. 620 (current version at 42 USC ch. 7).

facility.²⁹ HHS will accept applications only from these facilities and will reject applications from other HPSA clinics. If an employer has posted a position on the National Health Service Corps (NHSC) Opportunities List, the employer may not offer that position to an IMG on a J-1 visa unless it remains unfilled by an NHSC scholar or loan repayer eligible for placement at the end of the NHSC Placement Cycle.

Application Process

Obtaining an HHS waiver is a three-step application process involving three federal agencies, starting with HHS (3–6 months), proceeding to the U.S. Department of State (DOS) (4–8 weeks), and finally culminating with U.S. Citizenship and Immigration Services (USCIS) (2–6 months). Obviously, processing timelines may vary, and practitioners should check with these agencies prior to filing the application about current processing times. All IMGs seeking a waiver must first obtain a case number by submitting an online application to the DOS Waiver Review Division, followed by a hard copy of the bar-coded form with the supporting documents and filing fee check.³⁰ Once issued, the DOS case number must be included on every page of the final waiver application.

The Supplementary Applicant Information published by HHS on its website lists the specific documentary and informational requirements that applicants must meet in order to succeed in applying for the clinical HHS waiver.³¹ To meet the requirements of the waiver, the IMG must practice primary care medicine or general psychiatry for a minimum of three years, 40 hours per week, in a designated primary care or mental health HPSA. The waiver application must include a formal, executed employment contract, reflecting these terms, that is dated and signed by the head of the sponsoring medical facility and the IMG.³² The employment con-

tract cannot include a non-compete clause or restrictive covenant, and it cannot be terminable by mutual agreement until completion of the three-year service requirement.³³ The IMG should be paid in accordance with the prevailing wage for a similar position in the locality. In this regard, a prevailing wage determination from the appropriate State Workforce Agency certifying the wage that the IMG must be paid should be submitted as part of the waiver application.³⁴ Also, the application packet must include a letter in support of the waiver or an acknowledgment statement from the State Health Department in the state where the job site is located.

The sponsoring health care facility must establish that it has actively, but unsuccessfully, recruited for “non-foreign physicians”³⁵ in the recent past, both regionally and nationally.³⁶ In addition to the actual proof of advertising the position, recruitment documentation has to include names of the “non-foreign physicians” who applied for the job, and the reasons why they were not hired. The medical facility must also indicate that it provides care on a sliding fee scale for persons at or below 200 percent of the poverty income level, and that it does not discriminate against any individuals who are unable to pay for medical services.³⁷

Further, the employing health care facility must provide a supporting letter elucidating the need for the physician’s services in the area. This letter should contain the following:

- An explanation of the nature of the medically underserved area;

HHS, “Requirements for Waiver for Clinical Care,” available at www.globalhealth.gov/exchangevisitorprogram/reqwaiv_clinical.html.

²⁹ HHS Exchange Visitor Program, Request for Waiver of the Two-Year Foreign Residence Requirement, 67 Fed. Reg. 77692, 77694 (Dec. 19, 2002) (codified at 45 CFR pt. 50).

³⁰ HHS, “Requirements for Waiver for Clinical Care,” available at www.globalhealth.gov/exchangevisitorprogram/reqwaiv_clinical.html.

³¹ While most other immigration benefits that require recruitment efforts call for recruitment of a “U.S. worker” or use similar terminology, HHS requires evidence of recruitment of “non-foreign physicians.” It is unclear whether this includes U.S. permanent residents, refugees or asylees.

³² HHS Exchange Visitor Program, Request for Waiver of the Two-Year Foreign Residence Requirement, 67 Fed. Reg. 77692, 77694 (Dec. 19, 2002) (codified at 45 CFR pt. 50).

³³ *Id.* at 77692, 77697.

²⁹ As defined in the Indian Self-Determination and Education Assistance Act, 25 USC §450.

³⁰ U.S. Department of State (DOS), available at <https://j1visa waiver recommendation.state.gov/>.

³¹ HHS, “Application for Waiver of the Two-Year Foreign Residence Requirement of the Exchange Visitor Program,” available at www.globalhealth.gov/exchangevisitorprogram/j-1_supplement-b_clinical.doc.

³² HHS Exchange Visitor Program, Request for Waiver of the Two-Year Foreign Residence Requirement, 67 Fed. Reg. 77692, 77694 (Dec. 19, 2002) (codified at 45 CFR pt. 50);

- Information about the medical services the facility offers;
- Confirmation of the facility's HPSA designation or that it is located within a geographic HPSA;
- An explanation of the IMG's qualifications³⁸ to practice primary care medicine or psychiatry;
- A description of the scope of patient services the IMG will provide;
- Documentation of recruitment efforts conducted to fill the available physician position; and
- Description of the effect on the HPSA location and surrounding communities if the waiver application were denied.

Also, the waiver application packet should include proof of the sponsoring facility's existence (e.g., listing in the local phone book, photographs, etc.); three letters of support from community leaders confirming the need for an additional physician; and three recommendation letters confirming the IMG's qualifications from the IMG's colleagues. Form HHS 426, Application for Waiver of the Two-Year Foreign Residence Requirement of the Exchange Visitor Program, must accompany the application packet.

Once finalized, the application should be assembled and submitted as one unstapled copy to:

Michael K. Berry
 Bureau of Health Professions
 Health Resources and Services Administration
 Department of Health and Human Services
 Parklawn Building, Room 8A-55
 Rockville, MD 20857

If HHS supports the waiver application, it will issue a recommendation letter and forward the application to DOS for further review. If DOS issues a recommendation that the waiver should be granted, it will forward the application to USCIS, which will undertake final adjudication of the case. USCIS will

normally grant the waiver if the DOS recommended it.³⁹

After HHS Recommendation

After HHS issues its recommendation that a waiver should be granted, the physician must start making plans to commence work in the underserved area. Similar to other J-1 waivers that are based on medical underservice (i.e., Conrad, VA, ARC, DRA), the HHS clinical waiver requires a three-year commitment to the underserved area in an H-1B status. The IMG may not apply for adjustment of status until the three-year obligation is fulfilled.⁴⁰ However, a physician who agrees to work in a federally designated healthcare shortage area for a period of five years may qualify for a national interest waiver (NIW).⁴¹ The IMG who seeks a NIW on this basis may file both the immigrant visa petition (form I-140) and the adjustment of status application (form I-485), together with other interim benefits (advance parole and employment authorization document applications), at the same time. However, the adjustment application will not be approved until the physician demonstrates completion of the five years of service in the medically underserved area.

Part 2: HHS Waiver Program for Researchers

Background

HHS has acted as an IGA on behalf of persons engaged in research in health, biomedical, or other related fields of interest to HHS since 1984.⁴² Through this program, the U.S. government has attracted numerous expert scholars to U.S. academic institutions who are currently making valuable contributions to U.S. scientific interests.

Eligibility Requirements

To qualify for a favorable recommendation from this HHS waiver program, the regulations require applicants to demonstrate that: (1) their research program is of high priority or significance in an area

³⁸ As part of the application process, HHS will verify the IMG's professional and educational credentials. IMG applicants must complete "J-1 Visa Waiver Applicant Credentials Verification Enrollment Data Sheet" included in Supplement B—Clinical Care on the HHS Exchange Visitor Program website and submit the document as part of the waiver application.

³⁹ See, e.g., *Dina v. Attorney General*, 793 F.2d 473 (2d Cir. 1986); *Silverman v. Rogers* 437 F.2d 102 (1st Cir. 1970), cert. denied, 402 U.S. 983 (1971); *Matter of Tayabji*, 19 I&N Dec. 264 (BIA 1985).

⁴⁰ INA §214(l)(1)(C) and 8 CFR §212.7(c)(9)(iv).

⁴¹ INA §203(b)(2)(B)(ii). Note that this provision also applies to physicians who commit to work at a VA facility for five years.

⁴² 45 CFR §50.

of interest to HHS; (2) they are an essential part of the program without whom the program, or a major part of it, would discontinue; and (3) they can make original and significant contributions to the program and possess outstanding qualifications, training and experience beyond the usually expected accomplishments at the graduate, postgraduate, and residency levels.⁴³

The HHS regulations provide some, albeit minimal, guidance with respect to what is necessary to meet the requirements and prepare a successful application for a waiver. The applicant in this process is the employing institution, and not the researcher; thus, the employer must play an active role in qualifying the EV for a waiver. The Supplementary Information published by HHS on its website lists specific documentary and informational requirements to be addressed by the applicant.⁴⁴ The application must include a detailed description of the foreign national's accomplishments and role in the research program, as well as an analysis of the program's significance and benefit to the national or international interests and the interests of the agency.

Specifically, the Supplementary Information guidelines ask that the applicant demonstrate the following:⁴⁵

- Program in which the exchange visitor is engaged serves the national or international public interest;
- Exchange visitor is essential to the program and will contribute to the program long-term;
- Program is collaborative in nature, and the exchange visitor's expertise is unique, compared to other personnel engaged in the program;
- Applying institution made efforts to recruit for the exchange visitor's position at a fair market rate and was unable to find a suitable replacement;

- Loss of the exchange visitor's services will seriously restrain the success of the program or a major part of the program;
- Applying institution has made long-range plans for the exchange visitor; and
- Exchange visitor is uniquely equipped to make original contributions to the program based on his outstanding qualifications and special accomplishments, as confirmed by external recommendation letters.

These evidentiary requirements must be aimed to satisfy the following three regulatory criteria, as defined by 45 CFR §50.4.

Program Must Be of High Priority and of National or International Significance in an Area of Interest to HHS

This requirement has two elements, both of which must be addressed by the applicant: (1) program's high priority and national or international significance; and (2) HHS's interest in the program.⁴⁶

The first element appears to sound similar to the standards articulated by the national interest waiver⁴⁷ requirements and calls for an explanation of how the research program will benefit the United States and, potentially, the world. HHS is generally opposed to recommending waivers for individuals engaged in research that carries geographically limited benefits and will reject cases where national or international value is not adequately demonstrated. For this reason, in the past, HHS strongly favored basic research (*i.e.*, research performed in the lab) over clinical research (*i.e.*, research performed on human subjects). This is because the results of basic research studies can lead to discoveries that can subsequently be adapted nationwide, while clinical results, on first glance, only benefit the specific patients under treatment. Today, with translational research (studies involving a combination of the bench and the bedside) taking on a more significant role in the way scientific progress is achieved, HHS has come to recognize the value of the clinical component.

It is true that clinical *practice* may only benefit the specific patients. However, clinical *research* is often part of a translational study that applies basic research concepts in a clinical setting—moving it from the lab into the real world—and has potential

⁴³ 45 CFR §50.4.

⁴⁴ HHS, Exchange Visitor Program, "Application for Waiver of the Two-Year Foreign Residence Requirement of the Exchange Visitor Program, Supplementary Information—A (Research)," available at www.globalhealth.gov/exchange-visitor-program/j-1-supplement-a-research.pdf.

⁴⁵ For a detailed review of each criterion in the Supplementary Information, see S. Seltzer, "Demystifying the HHS Waiver Process," *Immigration & Nationality Handbook* 285 (AILA 2007–08 Ed.).

⁴⁶ 45 CFR §50.4(a).

⁴⁷ INA §203(b)(2)(A).

benefits for all patients suffering from a particular condition. When laboratory research is successful, the next step is clinical trials, as the ultimate objective of any basic study is to be able to apply the resulting discoveries to treat human medical conditions. For instance, molecular biologists working on understanding the mechanisms of brain tumors must collaborate with the neurosurgeons to implement the clinical trials. Thus, a neurosurgeon working as principal investigator (PI) on such a project, while not heavily involved in the primary lab research, may have sufficient grounds for a waiver. Such cases involving translational studies can result in a favorable recommendation, provided that all other elements of HHS waiver processing are met. To evaluate this issue, HHS requires that the waiver application include information about percentage of effort that the exchange visitor devotes to each area of work (basic research, translational research, and purely clinical practice).⁴⁸

An issue that immigration practitioners frequently face in representing IMGs involved in medical research is that much of their work is, in fact, clinical practice, with some, often minimal, time spent doing research. While HHS has never articulated an official position against recommending waivers for clinicians, it holds a view that clinicians' work impacts only their patients, the employing institutions and the immediate geographical area. Serving local interests or alleviating local shortage, no matter how severe, will not suffice for a waiver recommendation.

For example, an internationally renowned, highly skilled pediatric heart transplant surgeon performing cutting-edge surgical procedures on babies with nonhereditary heart conditions will likely not qualify for an HHS waiver. A surgeon's work is, by definition, geographically limited, as he or she performs surgical procedures one at a time, at a particular hospital. In other words, while this surgeon may save the lives of many infants, he or she does not contribute to the advancement of knowledge nationwide because people, other than his or her patients, cannot benefit from the surgeon's talents. Of course, an argument can be made that, if the surgery itself is experimental and proves successful, other surgeons could subsequently apply it nationally and internationally. HHS is likely to reject such a case,

⁴⁸ See J. Jones, Executive Secretary of the Exchange Visitor Waiver Review Board of HHS, "The J-1 Research Waiver," reproduced in the Appendix section of this book.

arguing that once the procedure is developed, a surgeon who is a "non-foreign" worker can be taught to perform it, thereby eliminating the necessity to hire the exchange visitor. Additionally, treatment of nonhereditary conditions is of little interest to HHS because, once again, it affects only the patients involved and cannot be used to benefit other patients with the same condition. Research of congenital conditions and conditions with epidemic proportions, on the other hand, is favored by HHS. Once treatment is developed or causes are found, this information can be used to treat and prevent disease in all affected patients.

Most clinicians have few, if any, publications, as their work is generally dedicated to medical practice, not research. These individuals, no matter how prominent, are poor candidates for HHS research waivers. In other words, while HHS will allow some clinical work to be performed, it is the research component that will lead to a waiver recommendation.

Furthermore, even where HHS finds a research topic to be of high priority and of national or international interest, it may consider it to be of little interest to the agency itself. Not all research programs in the field of health or biomedicine will qualify for HHS sponsorship, as HHS expresses official agency interest in very specific areas of science. The most convincing way to demonstrate agency interest is to show that HHS has actually granted funding for the research program, which is headed by the alien. HHS funds research endeavors through the National Institutes of Health (NIH), which is part of HHS and is the primary federal agency for conducting and supporting medical research.⁴⁹ NIH's specific mission is to uncover new knowledge and to support medical research through funding studies that are in the interest of HHS. Therefore, where an exchange visitor is leading a research project that has received NIH funding, this serves as *prima facie* evidence of HHS's interest in the project.

Often, however, clients seeking an HHS waiver do not possess NIH funding, as the standards for getting it are extremely high, and the application process is lengthy. However, those who have received grants from other sources may still be engaged in research considered in the interest of HHS. Even projects supported by industry grants can be considered of interest to HHS, provided that the ensuing study results have national implications. HHS

⁴⁹ www.nih.gov.

has advised that even where a study did not qualify for NIH funding, the foreign national leading it may still qualify for an HHS waiver.⁵⁰

The question is how to prove that the agency is interested in such research endeavors. The NIH Office of Extramural Research, in lieu of the Federal Register and in compliance with the official notice requirement by the Administrative Procedures Act, publishes the annual NIH Guide for Grants and Contracts listing all Program Announcements (PAs) and Requests for Applications (RFAs). An analysis of the NIH Office of Extramural Research Grant and Contract Opportunities Archives⁵¹ that comprise years of PAs and RFAs reveals definite trends in funding opportunities with the agency. From those documents, we can deduce what areas of research are considered in the interest of HHS. A comparative review of the evolving trends in research interests shows how the agency's views have changed over the years. While HHS has consistently maintained strong interest in certain topics, such as addiction and cancer (these have remained constant for many years), a number of fields have surfaced on and/or disappeared from the list.

The following is a comparison of the most funded areas of research during the past 20 years:

- 2008: Alcohol/Drug Addiction; Cancer; HIV/AIDS; Mental Health; Disease Prevention.
- 1998: Alcohol/Drug Addiction; Cancer; HIV/AIDS; Mental Health; Genetics.
- 1988: Cancer; Neurological Disorders; Diabetes; Heart, Lung, Blood Diseases.

This short list exhibits a definite and increasing interest in addiction and mental health issues in the past decade. While HIV/AIDS and infectious diseases was one of the most highly funded topics of research in the mid-1990s, there were only a few RFAs for projects devoted to these issues just a few years later. Genetics and diabetes, however, emerged as new topics at the forefront of federally funded research in the past few years. Also, disease prevention is currently a hot topic with a substantial number of active RFAs in 2008. It is this kind of analysis that may convince the Exchange Visitor Waiver Re-

view Board that the alien's research study, although not funded by NIH, may nevertheless be in the interest of HHS.

Exchange Visitor Must Be an Integral Part or Essential Component of the Program

In order to file an approvable HHS waiver application, the applying institution must establish that the EV is so important to the research program that the success of the program, or a major part of it, would be jeopardized, should the foreign national be required to leave.⁵² This prerequisite calls for showing specific adverse effects on the success of the program, or its portion, caused by the researcher's potential departure. The mere "participation" or "involvement" in the project will not secure a waiver. Likewise, HHS will not approve a case where the foreign national's departure will cause a mere inconvenience to the sponsoring institution. HHS wants evidence demonstrating that national and, potentially, international benefits that would result from the EV's research will be lost, should he be required to depart the program.

For instance, where a researcher is involved in a collaborative program where the findings of each scientist directly affect the ability of other scientists to perform their studies, his departure could severely cripple the program. This is why the HHS waiver Supplementary Information guidelines ask for a description of the current personnel engaged in the program.⁵³ A detailed listing of other scientists involved in the project, their duties, and how the EV fits into the framework provides HHS with the ability to determine whether anyone else is qualified to perform the alien's duties and whether the EV is, in fact, as essential as it is claimed.

The most obvious example of a scientist being an integral part of a research program is the Principal Investigator (PI) on a project. Clearly, a research study relies heavily on its PI's guidance, leadership, and generation of ideas in order to exist and progress. Without the PI's direct involvement, the program could be required to cease operations. A potential problem here, however, is the fact that NIH, the most desirable funding source in the context of HHS waivers, places limitations on foreign nationals applying for funding as PIs. Historically, the NIH did

⁵⁰ Telephone interview of Joyce Jones, Executive Secretary of the Exchange Visitor Waiver Review Board of HHS, by Rita Sostrin, on Oct. 22, 2001.

⁵¹ HHS, Funding Opportunities and Notices, available at <http://grants.nih.gov/grants/guide/>.

⁵² 45 CFR §50.4(b).

⁵³ www.globalhealth.gov/exchangevisitorprogram/j-1_supplement-a_research.pdf.

not fund noncitizens whose stay in the United States was limited by visa status.⁵⁴ This, practically, eliminated all foreign nationals. The NIH later revised its grant policy and currently shows a more lenient attitude toward foreign nationals. While some NIH awards continue to carry a U.S. citizenship or permanent residence requirement, most NIH awards only require that the foreign national be in valid status that will allow him to remain in this country long enough to be productive on the research project.⁵⁵ Those researchers who are able to remain in the United States beyond the validity of their J-1 visas usually secure O-1 status, which initially can be granted for three years. Given the fact that many NIH-funded research projects last longer than three years, this criterion may be difficult to satisfy for most foreign nationals working in the United States. However, because O-1 status can be extended with no maximum limit, many EVs have successfully argued that their visas will allow them to remain in the country long enough “to be productive on the project” and have qualified themselves as PIs on NIH grants.

Alternatively, in reviewing waiver applications, HHS has been lenient with such titles as co-PI or Leading Investigator on NIH grants and has considered those as “integral” and “essential” for the purposes of the waiver. Furthermore, HHS will be willing to consider special circumstances where, for instance, the foreign national who was not listed on the grant award letter, nevertheless, played an integral role. Specifically, in a case where the foreign national was hired to replace the retiring PI on an already existing grant, HHS was willing to recommend a waiver.

Those exchange visitors who are unable to acquire funding as PIs may try to argue their essentiality to the project by demonstrating that they have highly unusual and innovative research skills that are indispensable to the success of the project. This is a much weaker case than that of a PI, as technical skills can be demonstrated to another researcher who may then replace the foreign national without jeopardizing the study. HHS’s position on this issue is that, while scientific genius cannot be taught, technical skills can.⁵⁶ One may argue in this situation

that the EV’s training is unique and that the length of time it would take to train another individual will jeopardize the success of the program. Unless it can be established that training another specialist would take so long that the project would have to terminate, and that a suitable replacement cannot be found through recruitment, such a case is likely to be denied. The question that arises from this argument is how long is “too long.” Presumably, one can successfully argue that two years or more would be considered “too long.” Logically, if a two-year gap in a scientific project were generally acceptable, then HHS would simply deny all waiver applications and send the exchange visitors home to fulfill the two-year requirement.

Whether the exchange visitor serves as the official PI or as an irreplaceable mastermind on a program, it is imperative to prove that the sponsoring institution has made a vigorous recruitment effort and was unable to find another individual to perform the job. The Waiver Review Board evaluates the recruitment efforts in relation to the field of research, the foreign national’s qualifications, and his contributions to the program. For instance, if a foreign national works in a rare and narrow field that has few expert specialists, one advertisement in an appropriate medical journal may be sufficient. Otherwise, additional recruitment may be required. *JAMA* and *Science* are considered the most suitable journals for advertisement of positions for scientific researchers, although HHS would accept ads from other leading publications. Obviously, the ad should not be designed for the applicant and should request relevant credentials and experience. While a current recruitment effort can certainly be helpful, original recruitment done prior to granting the appointment to the exchange visitor can be successfully used in HHS waiver applications.

An exchange visitor’s essentiality to the project should be further demonstrated by establishing that the sponsoring institution has a long-range strategy and plans to employ him long term. While HHS does not specifically state that it requires a permanent position, tenured or tenure-track positions are definitely preferred. Specifically, the position must be indefinite and not limited by a contract. This is why Fellows, Postdoctoral Scholars, Adjunct Professors and Visiting Professors will not qualify for a favorable recommendation. However, HHS would arguably recommend a waiver for a Researcher in a non-professorial position who is employed on a long-term basis, provided that he qualifies under the rest of the criteria.

⁵⁴ National Institutes of Health (NIH) Grants Policy Statement of March 2001, at 41.

⁵⁵ NIH Grants Policy Statement of December 2003, Part II.

⁵⁶ Telephone interview of Joyce Jones, *supra* note 50.

Exchange Visitor Must Have Outstanding Qualifications, Training, and Experience Well Beyond Usually Expected Accomplishments at Graduate, Postgraduate, and Residency Levels, and Demonstrate Capability to Make Original and Significant Contributions

Exchange visitors attempting to qualify for HHS waivers must show that they possess outstanding credentials, compared to their peers at the same educational level, so as to enable them to make original and significant contributions to the research program.⁵⁷ While we, as practitioners, are used to making similar claims to USCIS of “sustained national or international acclaim” in the O-1 and EB-1-1 contexts, or “international recognition” in the EB-1-2 context, it is important to keep in mind that HHS waivers are peer reviewed. That is to say that puffery will not be adequate to guarantee a recommendation letter. All assertions of outstanding qualifications, training, and experience must be substantiated by specific examples of the researcher’s achievements. In fact, HHS has specifically stated that application materials for an O-1 visa are not relevant to this process.⁵⁸ Only the documents requested in the Supplementary Information guidelines should be submitted as part of the waiver application. HHS is interested in attracting the best brains in medical research from around the world and has the tools to make such a judgment, as each case first goes through a rigorous review process. To put it in HHS’s own words, “quality, not quantity, is preferred.”⁵⁹

Undoubtedly, because HHS places a strong emphasis on outstanding research achievements and capabilities, the foreign national’s list of publications is an important part of the application. When interviewing a potential client interested in obtaining an HHS waiver, practitioners must carefully review his Curriculum Vitae. To determine the EV’s true reputation as a researcher, it is imperative to evaluate whether he published as first or second author, the quality and prestige of the journals where the publications appeared, the length of the publications, and the number of reviews or citations they generated. Further, review articles will not be considered as noteworthy as articles reporting original research results. The Waiver Review Board wants to ensure

that the foreign national’s overall scientific vision, not just his prior academic record, will benefit the program.

To determine whether an exchange visitor possesses outstanding qualifications and the capability to make original contributions, the Board examines his level of seniority, uniqueness of training and experience, quality of the publication record in relation to his level of training, and his unique, original and significant contributions to the project or the field. Absence of any of these factors may result in a denial. In order to secure a recommendation, an exchange visitor must succeed at convincing the Board that he is an independent thinker making original contributions to his project and the overall advancement of science. Obtaining several external reference letters from experts in the field or former employers or colleagues can assist in demonstrating that the exchange visitor is uniquely qualified to make significant contributions to the institution’s research program.⁶⁰

Application Process

After the DOS issues a case number, one unbound (except for publications) copy of the waiver application may be filed with:

Joyce E. Jones, Executive Secretary
Exchange Visitor Waiver Review Board
Hubert H. Humphrey Building
Department of Health and Human Services
200 Independence Avenue, SW, Room 639-H
Washington, D.C. 20201

HHS has issued specific instructions regarding the documentation required for a successful application in the Supplementary Information guidelines.⁶¹ Applications must include HHS Form 426 and a detailed letter from the applicant institution addressing all points required by the Supplementary Information. Even in a case represented by an attorney, HHS will accept information regarding the merits of the case only from the applying institution and will disregard any such data supplied by the attorney.⁶²

The HHS regulations specifically state that eligible applicants include only private or non-federal

⁵⁷ 45 CFR §50.4(c).

⁵⁸ J. Jones, “The J-1 Research Waiver,” *supra* note 48.

⁵⁹ *Id.*

⁶⁰ Teleconference with Joyce Jones, Executive Secretary of the Exchange Visitor Waiver Review Board of HHS, by the National Healthcare Access Coalition on May 30, 2008.

⁶¹ www.globalhealth.gov/exchangevisitorprogram/j-1_supplement-a_research.pdf.

⁶² Telephone interview of Joyce Jones, *supra* note 50.

institutions, or a component of HHS. Exchange visitors or other U.S. government agencies (with few exceptions) are considered ineligible applicants.⁶³ Therefore, HHS will honor only Forms G-28 signed by the applying institution and will ignore G-28s signed by the exchange visitor. All applications must also contain a signature and phone number of the individual who oversees immigration applications within the institution.

The Exchange Visitor Waiver Review Board holds the authority to review waiver applications and recommend issuance of waivers, as granted by applicable regulations.⁶⁴ Currently, the Board receives approximately 75 applications per year,⁶⁵ which is just a fraction of the 150 to 200 applications per year it received previously.⁶⁶ Once received by the Exchange Visitor Waiver Review Board, an application goes through a tripartite review process. Initially, it is examined by the Board's Executive Secretary for compliance with the guidelines (*i.e.*, completeness of forms, appropriateness of submitted documents, propriety of signatures). It is then forwarded for technical review to one of 27 institutes or centers of the NIH with the expertise in the exchange visitor's field. The technical review includes an appraisal of the EV's funding, the relevance of his studies, and his importance within the research program. After the technical review is finished, the application is returned to the Executive Secretary who forwards it to two Board members of her choice for a final independent review.⁶⁷

The Waiver Review Board consists of the Chairman and three Board members. The Board members are scientists on staff at the NIH or scientists emeritus who are experts in various scientific disciplines. Each case is reviewed by two Board members who are chosen by the Executive Secretary of the Board, based on their field of expertise. Their part of the review process is to ensure that the application complies with the mission of the waiver program and interests of the agency. The Board members do not meet and decide each case independently. If they arrive at conflicting conclusions, the Executive Secretary sends the application back to the Board members for further examination. If they are still unable to reach a unanimous

decision, the case will be denied and a negative recommendation sent to the DOS. The review process can take up to 12 months.

The Board approves approximately 75 percent of the waiver applications it reviews.⁶⁸ If the Board denies a waiver application, the sponsoring employer may request a written explanation of the reasons for the denial. The Chairman of the Waiver Review Board will respond to this request with a letter detailing the application's shortcomings. The applicant may then ask for reconsideration and supply new evidence that responds directly to the reasons for denial (reconsideration requests should come from the original application signatories). The Board will allow only one reconsideration request per application. The reconsideration process takes three to four months.⁶⁹ Approximately 70 to 80 percent of denials are reversed upon reconsideration.⁷⁰ HHS will keep a copy of the application on file for at least two years after a decision is rendered.

After HHS Recommendation

When a review of an application results in a recommendation letter, the Board sends it directly to the DOS using the DOS case number supplied with the application. The DOS will ordinarily issue a concurring decision and submit it to USCIS for a final decision. USCIS will grant a waiver if the DOS makes a favorable recommendation to USCIS.⁷¹

Unlike waivers recommended by State Health Agencies, ARC, DRA or VA, and unlike the HHS clinical waivers, an HHS research waiver does not obligate the exchange visitor to be employed by the sponsoring institution for a particular period of time.⁷² In 1999, then-Executive Associate Commissioner of the legacy Immigration and Naturalization Service's (INS) Office of Field Operations, Michael Pearson, issued a Memorandum⁷³ that erroneously

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Dina v. Attorney General*, 793 F.2d 473 (2d Cir. 1986); *Silverman v. Rogers* 437 F.2d 102 (1st Cir. 1970), *cert. denied*, 402 U.S. 983 (1971); *Matter of Tayabji*, 19 I&N Dec. 264 (BIA 1985).

⁷² INA §214(l)(1)(C) and 8 CFR §212.7(c)(9)(iv) do not apply.

⁷³ Legacy INS Memorandum, M. Pearson, "Waivers of the Two-Year Foreign Residence Requirement Under Section 212(c) of the Immigration and Nationality Act," *published*

⁶³ 45 CFR §50.02.

⁶⁴ 45 CFR §50.02.

⁶⁵ Teleconference with Joyce Jones, *supra* note 60.

⁶⁶ Telephone interview of Joyce Jones, *supra* note 50.

⁶⁷ J. Jones, "The J-1 Research Waiver," *supra* note 48.

suggested otherwise. This is an incorrect interpretation of INA §214(I), which makes an exception for recipients of the HHS research waiver and exempts them from the three-year commitment to the sponsoring employer.⁷⁴ However, should the EV depart the program after HHS issues a favorable waiver recommendation but before USCIS issues an approval, the HHS recommendation may be revoked.

It is not clear exactly how long a waiver recipient must remain employed by the sponsoring institution after the final approval of the waiver by USCIS. Because HHS requires that the applying institution demonstrate specific long-range plans for the exchange visitor, it can, presumably, revoke a waiver based on misrepresentation where the alien terminates employment immediately after waiver approval. Arguing that your client will continue to perform the same research at another institution may not override the revocation, as the HHS regards the employer, and not the foreign national, as the applicant in the waiver process.

CONCLUSION

Due to the complexity of the HHS waiver process, practitioners often avoid handling cases for exchange visitors who are subject to the two-year home residence requirement. However, HHS waivers for IMGs working in HPSA areas or researchers performing studies in an academic setting remain available as solid strategies for long-term immigration planning. While these applications could be labor intensive, requiring extensive preparation and research, eligible applicants should consider this option. If all IMGs were required to fulfill the two-year requirement, it is almost certain that many patients in desperate need of medical services would go without treatment, and medical advances that took place in the United States would have happened elsewhere.

on AILA InfoNet at Doc. No. 99100490 (posted Oct. 8, 1999).

⁷⁴ INA §214(I)(1)(D).