



U.S. Citizenship
and Immigration
Services



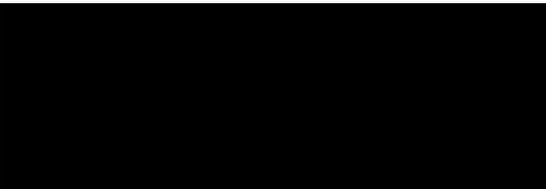
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FILE: WAC 03 266 53681 Office: CALIFORNIA SERVICE CENTER Date: APR 27 2005

IN RE: Petitioner: [Redacted]
Beneficiary: [Redacted]

PETITION: Petition for a Nonimmigrant Worker Pursuant to Section 101(a)(15)(H)(i)(b) of the Immigration and Nationality Act, 8 U.S.C. § 1101(a)(15)(H)(i)(b)

ON BEHALF OF PETITIONER:



PUBLIC COPY

INSTRUCTIONS:

This is the decision of the Administrative Appeals Office in your case. All documents have been returned to the office that originally decided your case. Any further inquiry must be made to that office.

Robert P. Wiemann, Director
Administrative Appeals Office

DISCUSSION: The service center director denied the nonimmigrant visa petition and the matter is now before the Administrative Appeals Office (AAO) on appeal. The appeal will be dismissed. The petition will be denied.

The petitioner is a retail pharmacy that seeks to employ the beneficiary as a clinical affairs specialist. The petitioner endeavors to classify the beneficiary as a nonimmigrant worker in a specialty occupation pursuant to section 101(a)(15)(H)(i)(b) of the Immigration and Nationality Act (the Act), 8 U.S.C. § 1101(a)(15)(H)(i)(b).

The director denied the petition because the proffered position is not a specialty occupation. On appeal, counsel submits a statement.

Section 214(i)(1) of the Act, 8 U.S.C. § 1184(i)(1), defines the term "specialty occupation" as an occupation that requires:

- (A) theoretical and practical application of a body of highly specialized knowledge, and
- (B) attainment of a bachelor's or higher degree in the specific specialty (or its equivalent) as a minimum for entry into the occupation in the United States.

Pursuant to 8 C.F.R. § 214.2(h)(4)(iii)(A), to qualify as a specialty occupation, the position must meet one of the following criteria:

- (1) A baccalaureate or higher degree or its equivalent is normally the minimum requirement for entry into the particular position;
- (2) The degree requirement is common to the industry in parallel positions among similar organizations or, in the alternative, an employer may show that its particular position is so complex or unique that it can be performed only by an individual with a degree;
- (3) The employer normally requires a degree or its equivalent for the position; or
- (4) The nature of the specific duties is so specialized and complex that knowledge required to perform the duties is usually associated with the attainment of a baccalaureate or higher degree.

Citizenship and Immigration Services (CIS) interprets the term "degree" in the criteria at 8 C.F.R. § 214.2(h)(4)(iii)(A) to mean not just any baccalaureate or higher degree, but one in a specific specialty that is directly related to the proffered position.

The record of proceeding before the AAO contains: (1) Form I-129 and supporting documentation; (2) the director's request for additional evidence; (3) the petitioner's response to the director's request; (4) the director's denial letter; and (5) Form I-290B and supporting documentation. The AAO reviewed the record in its entirety before issuing its decision.

The petitioner is seeking the beneficiary's services as a clinical affairs specialist. Evidence of the beneficiary's duties includes: the I-129 petition; the petitioner's September 16, 2003 letter in support of the petition; and the petitioner's response to the director's request for evidence. According to this evidence, the beneficiary would perform duties that entail: analyzing developments in specific fields to determine the need for revisions, corrections, and changes in previously published materials, and developing new material; interpreting and responding to clinical inquiries generated by clients, prospective clients or staff and researching internal and external written documentation and preparing a response for the client using new and/or existing documentation; evaluating the value of pharmacy volume to purchases, using a financial return on investment model; evaluating the retention of the proposed pharmacy volume; achieving targeted "file buy goals as determined by SVP Rx Operations and SEVP Store Operations," including number of deals, number of prescriptions and retention percentages; fully performing knowledge base maintenance activities; reading and interpreting coding system updates and guideline changes; translating changes into existing knowledge bases; resolving conflicts in the knowledge base; identifying errors/inconsistencies/omissions through observation or routine data analysis; working with pharmacy development managers, district managers and regional vice presidents to locate purchase opportunities; coordinating all activities on acquisition dates to ensure a smooth transition into the petitioner's business; participating in knowledge base reviews that involve isolated or focused reviews prompted by client inquiries or product reviews and enhancements; identifying sources of clinical input and background information; providing timely responses to any and all issues associated with a deal, including needs assessment, content development, investigation of therapeutic areas, analysis of competitive pharmacological treatments, and participating in the production process of formatting and reviewing; designing, planning and developing clinical research projects, including coordinating the activities of the investigators, ensuring compliance with protocol, interfacing with reps from key functional groups and determining study objectives, strategy and schedule; evaluating data; providing input for post-clinical activities; authoring studies; managing budgets/product distribution; processing and evaluating adverse event information; acting as product safety lead on product project teams and managing within cross-functional teams the product's safety profile; ensuring compliance with federal regulations and SOPs; collaborating with medical staff regarding adverse event/safety issues and communicating with investigators and other staff on AE information; reviewing timelines for past due key milestones and soliciting appropriate updates from the teams; setting up and maintaining standardized budget spreadsheet, reporting out monthly by reviewing and reconciling invoices and spends to the budget systems; reading and interpreting coding system updates and guideline changes; translating changes into existing knowledge bases; requesting contract agreements, including budget payment schedules, reviewing and negotiating modifications; providing input for development, design and format study conduct tools; interacting with management in planning and tracking of drug/non-drug clinical supplies and patient recruitment plans; reviewing medical meeting programs and conference summaries for reporting opportunities; preparing and creating slide presentations, audio-conferences and other direct-to-clinician communications; reviewing and analyzing the latest evidence-based data by therapeutic area and disease state and serving as the medical liaison between the petitioner and the account executives and pharmaceutical clients; and establishing and cultivating relationships with medical researchers and key opinion leader physicians. The petitioner indicated that a qualified candidate for the job would possess a bachelor's degree in pharmacy.

The director found that the proffered position was not a specialty occupation because the job is most like a pharmacy technician. Citing to the Department of Labor's *Occupational Outlook Handbook (Handbook)*,

2002-2003 edition, the director noted that the minimum requirement for entry into the position was not a baccalaureate degree or its equivalent in a specific specialty. The director found further that the petitioner failed to establish any of the criteria found at 8 C.F.R. § 214.2(h)(4)(iii)(A).

On appeal, counsel states that the director erred in describing the proffered position as a pharmacy technician and as an administrative assistant. He states that the position is more specialized than that of a pharmacy technician, and that the director's assessment disregarded the evidence submitted by the petitioner.

Upon review of the record, the petitioner has established none of the four criteria outlined in 8 C.F.R. § 214.2(h)(4)(iii)(A). Therefore, the proffered position is not a specialty occupation.

The AAO turns first to the criteria at 8 C.F.R. § 214.2(h)(4)(iii)(A)(1) and (2): a baccalaureate or higher degree or its equivalent is the normal minimum requirement for entry into the particular position; a degree requirement is common to the industry in parallel positions among similar organizations; or a particular position is so complex or unique that it can be performed only by an individual with a degree.

Factors often considered by CIS when determining these criteria include: whether the *Handbook* reports that the industry requires a degree; whether the industry's professional association has made a degree a minimum entry requirement; and whether letters or affidavits from firms or individuals in the industry attest that such firms "routinely employ and recruit only degreed individuals." See *Shanti, Inc. v. Reno*, 36 F. Supp. 2d 1151, 1165 (D.Minn. 1999)(quoting *Hird/Blaker Corp. v. Sava*, 712 F. Supp. 1095, 1102 (S.D.N.Y. 1989)).

The AAO routinely consults the *Handbook* for its information about the duties and educational requirements of particular occupations. The AAO notes that the director never referred to the position as an administrative assistant in his decision, but concurs with counsel that the proffered position is not similar to a pharmacy technician. The petitioner did not establish that this retail pharmacy would utilize a clinical affairs specialist. There is no evidence in the record that the petitioner is involved in many of the activities included among the duties of the proffered position. For instance, 35 percent of the beneficiary's time would include clinical research projects and clinical trials, coordinating activities of investigators, determining study objectives, strategy and schedule, and acting as the product safety lead. There is nothing in the record to indicate that the petitioner is involved in clinical research in any way. Another 15 percent of the beneficiary's time would include working with pharmacy development managers, district managers and regional vice presidents to locate purchase opportunities. The petitioner is a single outlet retail pharmacy with 12 employees. Its organizational chart does not include any positions for pharmacy development managers, district managers or regional vice presidents. The beneficiary's duties also include reviewing medical meeting programs and conference summaries, although there is no evidence that the petitioner or its staff participates in such events. Simply going on record without supporting documentary evidence is not sufficient for the purpose of meeting the burden of proof in these proceedings. *Matter of Treasure Craft of California*, 14 I&N Dec. 190 (Reg. Comm. 1972).

Since the duties of the proffered position are not like any of the positions described in the *Handbook*, and no other documentary evidence establishes the first criterion, the AAO must look to the other criteria to determine whether the position is a specialty occupation.

Regarding parallel positions in the petitioner's industry, the petitioner submitted Internet job postings for a clinical affairs specialist, a client implementation specialist, a pharmacy rebate specialist, a manager of clinical services, a clinical data specialist, and a senior clinical research specialist. There is no evidence, however, to show that the employers issuing those postings are similar to the petitioner, or that the advertised positions are parallel to the instant position. Thus, the advertisements have little relevance.

The petitioner also submitted a letter from another pharmacy, which states that its "hiring requirement for this position [clinical affairs specialist] is a Bachelor's Degree or it's [sic] Equivalent in the same [sic] related field." The individual writing the letter did not establish that it has ever hired a clinical affairs specialist or, if it has, what degree the person possessed, or what duties the person performed.

The record also does not include any evidence from professional associations regarding an industry standard, or documentation to support the complexity or uniqueness of the proffered position. The petitioner has, thus, not established the criteria set forth at 8 C.F.R. § 214.2(h)(4)(iii)(A)(1) or (2).

The AAO now turns to the criterion at 8 C.F.R. § 214.2(h)(4)(iii)(A)(3) – the employer normally requires a degree or its equivalent for the position. It appears that this is a new position, and that the petitioner would not be able to meet this criterion.

Finally, the AAO turns to the criterion at 8 C.F.R. § 214.2(h)(iii)(A)(4) – the nature of the specific duties is so specialized and complex that knowledge required to perform the duties is usually associated with the attainment of a baccalaureate or higher degree.

To the extent that they are depicted in the record, the duties do not appear so specialized and complex as to require the highly specialized knowledge associated with a baccalaureate or higher degree, or its equivalent, in a specific specialty. As noted, many of the duties do not relate to the petitioner's business as described in the evidence of record. The petitioner did not establish that it would utilize a clinical affairs specialist as described in the position description. Therefore, the evidence does not establish that the proffered position is a specialty occupation under 8 C.F.R. § 214.2(h)(4)(iii)(A)(4).

As related in the discussion above, the petitioner has failed to establish that the proffered position is a specialty occupation. Accordingly, the AAO shall not disturb the director's denial of the petition.

The burden of proof in these proceedings rests solely with the petitioner. Section 291 of the Act, 8 U.S.C. § 1361. The petitioner has not sustained that burden.

ORDER: The appeal is dismissed. The petition is denied.