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| Healthcare/Hospital Facilities Liability Application |
| Pharmacy Compounding Supplement |
| * Ace American Insurance Company * Illinois Union Insurance Company * Westchester Surplus Lines Insurance Company |
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**Instructions:**

The requested information is necessary before a quotation can be obtained.

Type or print clearly.

Answer ALL questions completely, leaving no blanks. If any questions, or part thereof, do not apply, print “N/A” in the appropriate space. Any spaces left blank will be interpreted to not apply.

Provide any supporting information on a separate sheet and reference the applicable question number.

Use 🗷 for Yes or No answers and other selections.

This application must be completed, dated and signed by an authorized representative of the applicant. Underwriters will rely on all statements made in this application.

The information requested in this application is for underwriting purposes only and does not constitute notice to the Company under any Policy of a claim or potential claim. All such notices must be submitted to the Company pursuant to the terms of the Policy, if and when issued.

***NOTICE:* This supplement is part of the main Healthcare/Miscellaneous Liability Application and is subject to the same warranties, representations and conditions. All relevant sections of the main application also apply to, and shall contemplate, applicants subject to this supplement. This includes but is not limited to the main application sections for Loss Experience, Coverage Requested, Exposures (prospective and historical Professional Liability, General Liability, Home Health Care and/or Hospice Services, Staffing Agency Services, Aircraft Liability, Automobile Liability, Watercraft Liability, and Employer’s Liability), Excess Liability, Professional Employees and Staff, License/Certification Information, Risk Management, Employment Practices, Previous Insurance, Prior Acts Warranty (if applicable), Fraud Warning, Declaration & Certification, and Signature.**

# Section A. – Background

1. Legal name of the parent entity to be first named insured exactly as it shall be shown on the policy.

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| First Named Insured | Street Address |
|  |  |
| City, State, Zip Code | County |
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| 1. Number of pharmacists employed or contracted: |  |
| 1. Number of pharmacy technicians employed or contracted: |  |
| 1. Does the applicant dispense preparations across state lines?   If yes, to which states? | Yes  No |
| 1. Are all compounded products produced under valid prescriptions for individually identified patients? | Yes  No |

# Section B. – Certification

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| 1. Please list all current accreditations by the following organizations |  |
| The Joint Commission | Exp Date: |
| Pharmacy Compounding Accreditation Board | Exp Date: |
| Utilization Review Accreditation Commission | Exp Date: |
| 1. List any other registrations below: |  |
| DEA Registration No. |  |
| FDA Registration No. |  |
| 1. Is the applicant licensed and in good standing with all state boards of pharmacy in which it is dispensing medications? | Yes  No |
| 1. Are all pharmacists, technicians, and contracted personnel licensed and registered in the state in which they practice? | Yes  No |
| 1. Are the pharmacists-in-charge licensed and in good standing in all states where the pharmacy operates? | Yes  No |
| 1. Has the applicant or any person(s) or organization(s) proposed for this insurance been the subject of disciplinary or investigatory proceedings or reprimanded by a licensing, administrative, or governmental agency? (ex FDA Form 483 or Warning Letter) If yes, explain: | Yes  No |

# Section C. – Sterile Compounding

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| 1. Does the applicant dispense compounded sterile preparations?   If yes, to which states are they dispensed? | Yes  No |
| 1. What is your total annual revenue from all compounding? |  |
| 1. What is your total annual revenue from sterile compounding? |  |
| 1. Indicate the approximate number of compounded sterile preparations that the pharmacy dispenses per day: |  |
| 1 to <25 sterile compounded preparations per day |  |
| 26 to <100 sterile compounded preparations per day |  |
| 100 to <250 sterile compounded preparations per day |  |
| ≥250 sterile compounded preparations per day |  |
| 1. What USP categories of compounded sterile preparations does the applicant prepare? |  |
| Immediate-Use Risk |  |
| Low Risk |  |
| Medium Risk |  |
| 1. Is the applicant registered as an outsourcing facility? | Yes  No |
| 1. If registered as an outsourcing facility, has the applicant been inspected by the FDA? Date: | Yes  No |
| 1. Does the applicant monitor, test, and document sterile compounding preparations according to USP 797 standards? | Yes  No |

# Section D. – Risk Management

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| 1. Does the applicant have standard operating procedures consistent with USP in place for all phases of the compounding process, including preparing, packaging, delivering, storing, recalling, and disposing of products? | Yes  No |
| 1. Does the applicant have standard operating procedures consistent with current good manufacturing practices (cGMP) in place for all phases of the compounding process, including preparing, packaging, delivering, storing, recalling, and disposing of products? | Yes  No |
| 1. Do standard operating procedures require verification of the strength, quality, purity, integrity, and, if applicable, sterility of all preparations? | Yes  No |
| 1. Are all adverse events, potential and actual, promptly reported to the FDA and/or other patient safety organizations? | Yes  No |
| 1. Are there written job descriptions outlining functions and responsibilities for all staff? | Yes  No |
| 1. Are staff competencies, including aseptic technique, verified periodically?   If so, how? | Yes  No |
| 1. What changes in processes and procedures have been instituted since the 2012 fungal meningitis outbreak? |  |

**THE APPLICANT WARRANTS TO THE COMPANY THAT ALL STATEMENTS MADE IN THIS SUPPLEMENT ARE TRUE AND COMPLETE AND NO MATERIAL FACTS HAVE BEEN MISREPRESENTED OR MISSTATED IN THIS SUPPLEMENT OR HAVE BEEN CONCEALED OR SUPPRESSED.**

**THE APPLICANT UNDERSTANDS THAT THIS FORM IS PART OF THE MAIN HEALTHCARE /MISCELLANEOUS FACILITIES LIABILITY APPLICATION AND IS SUBJECT TO THE SAME WARRANTIES, REPRESENTATIONS AND CONDITIONS.**

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| Name of Applicant |  | Signature of Applicant |
|  |  |  |
| Title |  | Date |
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