☐ Ace American Insurance Company
☐ Illinois Union Insurance Company
☐ Westchester Surplus Lines Insurance Company

Healthcare/Miscellaneous Facilities Liability Application
Pharmacy Compounding Supplement

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 ý 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.

First Named Insured Street Address

City, State, Zip Code County

2. Number of pharmacists employed or contracted: _____

3. Number of pharmacy technicians employed or contracted: _____

4. Does the applicant dispense preparations across state lines? Yes No
If yes, to which states? _____

5. Are all compounded products produced under valid prescriptions for individually identified patients? Yes No

SECTION B. – Certification

6. Please list all current accreditations by the following organizations:

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6. 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:_____

7. List any other registrations below:

DEA Registration No. _____
FDA Registration No. _____

8. Is the applicant licensed and in good standing with all state boards of pharmacy in which it is dispensing medications? Yes No

9. Are all pharmacists, technicians, and contracted personnel licensed and registered in the state in which they practice? Yes No

10. Are the pharmacists-in-charge licensed and in good standing in all states where the pharmacy operates? Yes No

11. 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) Yes No

If yes, explain: _____

SECTION C. – Sterile Compounding

12. Does the applicant dispense compounded sterile preparations? Yes No

If yes, to which states are they dispensed? _____

13. What is your total annual revenue from all compounding? _____

14. What is your total annual revenue from sterile compounding? _____

15. 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

16. What USP categories of compounded sterile preparations does the applicant prepare?

Immediate-Use Risk
Low Risk
Medium Risk
High Risk

17. Is the applicant registered as an outsourcing facility? Yes No

18. If registered as an outsourcing facility, has the applicant been inspected by the FDA? Yes No

Date: _____

19. Does the applicant monitor, test, and document sterile compounding preparations according to USP 797 standards? Yes No

SECTION D. – Risk Management

20. 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

21. 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

(cGMP) in place for all phases of the compounding process, including preparing, packaging, delivering, storing, recalling, and disposing of products? Yes No

22. Do standard operating procedures require verification of the strength, quality, purity, integrity, and, if applicable, sterility of all preparations? Yes No

23. Are all adverse events, potential and actual, promptly reported to the FDA and/or other patient safety organizations? Yes No

24. Are there written job descriptions outlining functions and responsibilities for all staff? Yes No

25. Are staff competencies, including aseptic technique, verified periodically? Yes No

If so, how?

26. What changes in processes and procedures have been instituted since the 2012 fungal meningitis outbreak?