1		TITLE 68: PROFESSIONS AND OCCUPATIONS				
2	CHAPTER VII: DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION					
3		SUBCHAPTER b: PROFESSIONS AND OCCUPATIONS				
4						
5		PART 1330				
6		PHARMACY PRACTICE ACT				
7						
8		SUBPART A: GENERAL PROVISIONS				
9						
10	Section					
11	1330.10	Definitions				
12	1330.20	Fees				
13	1330.30	Unprofessional and Unethical Conduct				
14	1330.40	Violations				
15	1330.50	Vaccinations/Immunizations				
16	1330.60	Internet Pharmacies				
17	1330.70	Granting Variances				
18	1330.80	Renewals				
19	1330.90	Restoration-of a Pharmacist License				
20	1330.100	Continuing Education ("CE")				
21	1330.110	Confidentiality				
22	<u>1330.120</u>	Administration of Tests and Therapeutics				
23						
24		SUBPART B: PHARMACY TECHNICIAN				
25	~ .					
26	Section					
27	1330.200	Application for Certificate of Registration as a Pharmacy Technician				
28	1330.210	Pharmacy Technician Training				
29	1330.215	Minimum Standards for Approved Work Experience Pharmacy Technician				
30	1220 220	Certification				
31	1330.220	Application for Certificate of Registration as a Certified Pharmacy Technician				
32	1330.230	Continuing Education ("CE") for Certified Pharmacy Technicians				
33						
34		SUBPART C: PHARMACIST				
35	a .:					
36	Section	A				
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38	1330.310	Graduates of Programs Outside the United States				
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40	1330.330	Examination for Licensure on the Regis of Examination				
41 42	1330.340 1330.350	Application for Licensure on the Basis of Examination Endorsement				
42	1330.350	Pharmacy Residents				
<del>4</del> 3	1330.300	i naimacy residents				

44		
45		SUBPART D: PHARMACY LICENSURE
46		
47	Section	
48	1330.400	Application for a Pharmacy License
49	1330.410	Pharmacy Licenses
50	1330.420	Emergency Remote Temporary Pharmacy License
51		
52		SUBPART E: TYPES OF PHARMACIES
53		
54	Section	
55	1330.500	Community Pharmacy Services
56	1330.510	Telepharmacy
57	1330.520	Offsite Institutional Pharmacy Services
58	1330.530	Onsite Institutional Pharmacy Services
59	1330.540	Nuclear Pharmacy Services
60	1330.550	Nonresident Pharmacies
61	1330.560	Remote Prescription/Medication Order Processing
62	1330.570	Outpatient Clinic Pharmacy Services
63	10001070	Output of the Francisco
64		SUBPART F: PHARMACY STANDARDS
65		
66	Section	
67	1330.600	Security Requirements
68	1330.610	Pharmacy Structural/Equipment Standards
69	1330.620	Electronic Equipment Requirements for Remote Pharmacies
70	1330.630	Sanitary Standards
71	1330.640	Pharmaceutical Compounding Standards
72	1330.650	Pharmacy Computer Regulations
73	1330.660	Pharmacist-in-Charge
74	1330.670	Compounded Sterile Preparation Standards (Repealed)
7 <del>5</del>	1330.680	Automated Dispensing and Storage Systems
76	1330.000	rationated Dispensing and Storage Systems
77		SUBPART G: PHARMACY OPERATIONS
78		SODI ART G. THARMACT OF ERATIONS
79	Section	
80	1330.700	Patient Counseling
81	1330.700	Reporting Theft or Loss of Controlled Substances
82	1330.710	Transfer of Prescription
83		Drug Prepackaging
		DIUE I ICHACKAEHIE
	1330.730	
84	1330.740	Multi-Med Dispensing Standards for Community Pharmacies

87	1330.765	Requirements for Enrollment in Automated Prescription Refill Programs
88	1330.770	Centralized Prescription Filling
89	1330.780	Changes of Ownership, Name, Location or Operations of a Pharmacy
90	1330.790	Closing a Pharmacy
91	1330.800	Pharmacy Self-Inspection
92		
93	AUTHORIT	Y: Implementing the Pharmacy Practice Act [225 ILCS 85] and authorized by
94	Section 2105	5-15 of the Civil Administrative Code of Illinois (Department of Professional
95	Regulation I	Law) [20 ILCS 2105/2105-15].
96		
97	SOURCE: I	Rules and Regulations Promulgated for the Administration of the Illinois Pharmacy
98	Practice Act	, effective August 20, 1975; amended March 8, 1977; amended at 4 Ill. Reg. 1234,
99	effective July	y 11, 1980; amended at 5 Ill. Reg. 2997, effective March 11, 1981; codified at 5 Ill.
100	Reg. 11049;	emergency amendment at 6 Ill. Reg. 916, effective January 6, 1982, for a maximum
101	of 150 days;	amended at 6 Ill. Reg. 7448, effective June 15, 1982; amended at 7 Ill. Reg. 6496,
102	effective Jun	e 30, 1983; amended at 9 Ill. Reg. 16918, effective October 23, 1985; amended at
103	10 Ill. Reg. 2	21913, effective December 17, 1986; transferred from Chapter I, 68 Ill. Adm. Code
104	330 (Departi	ment of Registration and Education) to Chapter VII, 68 Ill. Adm. Code 1330
105	(Department	of Professional Regulation) pursuant to P.A. 85-225, effective January 1, 1988, at
106	12 Ill. Reg. 2	2957; amended at 12 Ill. Reg. 17394, effective October 14, 1988; amended at 16 Ill.
107	Reg. 19811,	effective December 7, 1992; amended at 21 Ill. Reg. 12600, effective August 29,
108	1997; amend	led at 22 Ill. Reg. 21959, effective December 1, 1998; amended at 23 Ill. Reg.
109	14131, effec	tive November 18, 1999; amended at 24 Ill. Reg. 8548, effective June 9, 2000;
110	amended at 2	26 Ill. Reg. 18338, effective December 13, 2002; amended at 27 Ill. Reg. 19389,
111	effective De	cember 11, 2003; emergency amendment at 29 Ill. Reg. 5586, effective April 1,
112	2005, for a n	naximum of 150 days; amended at 29 Ill. Reg. 13639, effective August 25, 2005;
113	amended at 3	30 Ill. Reg. 14267, effective August 21, 2006; amended at 30 Ill. Reg. 16930,
114	effective Oct	tober 12, 2006; emergency amendment at 31 Ill. Reg. 16045, effective November 19,
115		naximum of 150 days; amended at 32 Ill. Reg. 3262, effective February 21, 2008;
116		32 Ill. Reg. 7116, effective April 16, 2008; old Part repealed at 34 Ill. Reg. 6688,
117		ril 29, 2010; new Part adopted at 34 Ill. Reg. 6690, effective April 29, 2010;
118		39 Ill. Reg. 6267, effective April 23, 2015; amended at 41 Ill. Reg. 10643, effective
119		2017; amended at 42 III. Reg. 20022, effective November 9, 2018; amended at 47 III.
120	•	ffective June 2, 2023; amended at 48 Ill. Reg. 10225, effective June 28, 2024;
121	amended at 4	49 Ill. Reg, effective
122		
123		SUBPART A: GENERAL PROVISIONS
124		
125	Section 1330	0.20 Fees
126		
127	The following	ng fees are not refundable:
128		

129	a)	_	tration as a Pharmacy Technician, Student Pharmacist or Certified Pharmacy
130		Techr	nician
131			
132		1)	The fee for application for a certificate of registration as a pharmacy
133			technician, student pharmacist, or certified pharmacy technician is
134			<u>\$50</u> \$40.
135			
136		2)	The fee for the renewal of a certificate of registration as a pharmacy
137			technician, student pharmacist or certified pharmacy technician shall be
138			calculated at the rate of \$35\$25 per year.
139			
140	b)	Licen	se as a Pharmacist
141	- /		
142		1)	The fee for application for a license as a pharmacist is $$400$ .
143		-/	110 101 upp 101 u 110 u
144		2)	In addition, applicants for any examination as a registered pharmacist shall
145		-/	be required to pay, either to the Division or to the designated testing
146			service, a fee covering the cost of determining an applicant's eligibility
147			and providing the examination. Failure to appear for the examination on
148			the scheduled date, at the time and place specified, after the applicant's
149			application for examination has been received and acknowledged by the
150			Division or the designated testing service, shall result in the forfeiture of
151			the examination fee.
152			the examination ree.
153		3)	The fee for a license as a registered pharmacist, registered or licensed
153		3)	under the laws of another state or territory of the United States, is
155			\$400\\$200.
156			$\frac{94009200}{1}$ .
157		4)	The fee for the renewal of a license shall be calculated at the rate of
157		4)	
159			<u>\$175</u> \$75 per year.
160		5)	The fee for the restoration of a license other than from inactive status is
		3)	
161			\$50 plus all lapsed renewal fees, not to exceed \$450.
162		6)	Applicants for the modificinary disconnection are about he manying dis-
163		6)	Applicants for the preliminary diagnostic examination shall be required to
164			pay, either to the Division or to the designated testing service, a fee
165			covering the cost of determining an applicant's eligibility and providing
166			the examination. Failure to appear for the examination on the scheduled
167			date, at the time and place specified, after the application for examination
168			has been received and acknowledged by the Division or the designated
169			testing service, shall result in the forfeiture of the examination fee.
170		<b>.</b> .	791
171	c)	Licen	se as a Pharmacy

172			
173		1)	The fee for application for a license for a pharmacy under the Act is
174		,	\$600 <mark>\$100</mark> .
175			
176		2)	The fee for the renewal of a license for a pharmacy under the Act shall be
177			calculated at the rate of \$250\$100 per year.
178			
179		3)	The fee for the change of a pharmacist-in-charge is \$25.
180			
181	d)	Gene	ral Fees
182			
183		<del>1)</del>	The fee for the issuance of a license with a change of name or address
184			other than during the renewal period is \$20. No fee is required for name
185			and address changes on Division records when no duplicate certification is
186			<del>issued.</del>
187			
188		<u>1</u> 2)	The fee for a certification of a registrant's record for any purpose is \$20.
189			
190		<u>2</u> 3)	The fee to have the scoring of an examination administered by the
191			Division reviewed and verified is \$20.
192			
193	(Source	ce: Am	nended at 49 Ill. Reg, effective)
194			
195	Section 1330	.30 Un	professional and Unethical Conduct
196			
197	Unprofession	al and ı	unethical conduct by a licensee or registrant shall include, but not be limited
198	to:		
199			
200	a)	Failin	ng to establish and maintain effective controls against diversion of
201		presc	ription drugs.
202			
203	b)	Com	mitting theft or diversion, or attempting to commit theft or diversion, by a
204		regist	rant or licensee.
205			
206	c)		ng or filing a report or record that a pharmacist or pharmacy knows to be
207			or intentionally or negligently failing to file a report or keep records as
208		requi	red by the Act or this Part.
209			
210	d)		vingly dispensing a prescription drug after the death of the person for whom
211		the pr	rescription was written.
212			
213	e)		g or charging for quantities of drugs greater than that which was delivered
214		or cha	arging patients for a brand drug when a generic is dispensed.

215		
216	f)	Submitting fraudulent billing or reports to a third party payer or claiming a fee for
217		a service that is not performed or earned.
218		
219	g)	Filling a prescription when a pharmacist knows, or reasonably should know, that
220		no valid physician-patient relationship exists or failing to exercise sound
221		professional judgment with respect to the accuracy and authenticity of any
222		prescription/drug order dispensed.
223		
224	h)	Failing to provide patient counseling in accordance with this Part, failing to
225	,	respond to requests for patient counseling, attempting to circumvent patient
226		counseling requirements, or otherwise discouraging patients from receiving
227		patient counseling concerning their prescription medications.
228		
229	i)	Discriminating in any manner against a person or group based upon that person or
230	,	group's religion, race, creed, color, gender, sexual orientation, age or national
231		origin.
232		
233	j)	Knowingly dispensing a prescription drug without a valid prescription.
234	3/	Dispensing or offering to dispense any drug not approved by the Food and Drug
235		Administration (FDA), found in the USP-NF, or found on the list promulgated by
236		the FDA for bulk drug substances that may be used to compound drug products.
237		and a manufacture of the state
238	k)	Failing to keep one's self and one's apparel clean or to wear identification bearing
239	/	name and designation.
240		mano una designación
241	1)	Directly or indirectly furnishing to a medical practitioner prescription order-
242	-/	blanks that refer to a specific pharmacist or pharmacy in any manner.
243		ciming that rever to a specific priming or priming in any manner.
244	m)	Actively or passively participating in any arrangement or agreement in which a
245	111)	prescription order-blank is prepared, written, or issued in a manner that refers to a
246		specific pharmacist or pharmacy. Pharmacy-branded enrollment forms, when a
247		patient requests his or her prescriptions be filled at a specific pharmacy, and Risk
248		Evaluation and Mitigation Strategies documents containing prescription
249		information are not prohibited by this subsection.
250		information are not promoted by and subsection.
251	n)	Dividing a prescription order unless directed by the prescriber, payer or patient or
252	11)	when the full quantity of that prescription medication is not available at that
253		location.
254		100011
25 <del>5</del>	o)	Committing dispensing errors that result in hospitalization of a patient or
256	0)	demonstrating a pattern and practice of dispensing errors.
257		demonstrating a pattern and practice of dispensing offolis.

258 Committing an act or acts that are of a flagrant and obvious nature so as to p) 259 constitute conduct of such a distasteful nature that accepted codes of behavior or 260 codes of ethics are breached. 261 262 Committing an act or acts in a relationship with a patient that violate common q) 263 standards of decency or propriety. 264 265 Willfully violating, or knowingly assisting in the violation of, any law relating to r) the use of habit-forming controlled substances. 266 267 268 Failing to full comply or respond to a Department subpoena within 60 days. <u>s)</u> 269 270 Committing any other act or omission that breaches the pharmacist's t) 271 responsibility to a patient according to the accepted standard of care in pharmacy 272 practice. 273 274 (Source: Amended at 49 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_) 275 276 Section 1330.80 Renewals 277 278 Every license issued under the Act, except the certificate of registration as a a) 279 student pharmacistpharmacy technician, shall expire on March 31 of each even-280 numbered year. Every certificate of registration as a student pharmacistpharmacy 281 technician issued under the Act shall expire annually on March 31. The holder of 282 a license or certificate of registration may renew the license or certificate during 283 the 60 days preceding the expiration date by paying the required fee. 284 285 It is the responsibility of each registrant to notify the Division of any change of b) address or email address. Failure to receive a renewal form from the Division 286 287 shall not constitute an excuse for failure to renewpay the renewal fee. 288 289 Practicing or operating on a license or certificate that has expired shall be c) 290 considered unlicensed activity and shall be grounds for discipline pursuant to 291 Section 30 of the Act. 292 293 As provided in Section 9 of the Act, registered pharmacy Pharmacy technicians d) 294 shall be required to submit with their second renewal proof of certification as a 295 certified pharmacy technician, proof of enrollment in a first professional degree 296 program in pharmacy, or proof of enrollment in clinical training by a graduate of 297 a foreign pharmacy program for the first renewal or restoration that occurs after the license has been issued for at least 2 years, regardless of whether or not the 298 299 license has been active, inactive, or not renewed, as provided in Section 9 of the

Act. This requirement does not apply to pharmacy technicians licensed prior to

300

301 302		•	08. Failure to provide proof of certification results in non-renewal of technician's registration.
303	ti.	ie pilarinae j	teenmetan b registration.
304	<u>e)</u> <u>C</u>	Certified phar	macy technicians must certify to having completed the continuing
305			airements of Section 1330.230.
306	_		
307	(Source:	Amended at	49 Ill. Reg, effective)
308	`		
309	<b>Section 1330.90</b>	Restoration	n <del>of a Pharmacist License</del>
310			
311	a) A	harmacist pharmacist	seeking restoration of a certificate of registration that has expired
312	fo	or 5 years or	less shall have the license restored upon payment of all lapsed
313	re	enewal fees r	equired by Section 1330.20 and proof of 30 hours of CE (e.g.,
314	C	ertificate of a	attendance or completion) in accordance with Section 1330.100.
315			
316	b) A	harmacist pharmacist	seeking restoration of a certificate of registration that has been
317	p	laced on inac	etive status for 5 years or less shall have the license restored upon
318	p	ayment of the	e current renewal fee and proof of 30 hours of CE (e.g., certificate
319	0	f attendance	or completion) in accordance with Section 1330.100.
320			
321	c) A	harmacist	seeking restoration of a certificate of registration after it has expired
322	0	r been placed	d on inactive status for more than 5 years shall file an application, on
323	fo	orms supplied	d by the Division, together with the fee required by Section 1330.20
324	a	nd proof of 3	0 hours of CE (e.g., certificate of attendance or completion) in
325	a	ccordance wi	ith Section 1330.100.
326			
327	1	) The ph	narmacist shall also submit either:
328			
329		A)	Certification of active practice in another jurisdiction. Evidence
330			shall include a statement from the appropriate board or licensing
331			authority in the other jurisdiction that the registrant was authorized
332			to practice during the term of active practice; or
333			
334		B)	An affidavit attesting to military service as specified in Section 12
335			of the Act. The applicant restoring a license shall be excused from
336			the payment of any lapsed fee or any restoration fees.
337			
338	2	•	macist who is unable to submit proof of satisfaction of either
339		subsec	tion $(c)(1)(A)$ or $(B)$ shall submit proof of completion of:
340			
341		A)	30 hours of CE; and
342			
343		B)	Either:

344			
345		i)	600 hours of clinical practice under the supervision of a
346			licensed pharmacist completed within 2 years prior to
347			restoration; or
348			
349		ii)	Successful completion of the North American Pharmacist
350			Licensure Examination (NAPLEX). To be successful, an
351			applicant must receive a passing score of 75 on the
352			NAPLEX.
353			
354			work or clinical training described in subsections (c)(2)(A) and
355		(c)(2)(B)(i) n	nust have the prior approval of the Board.
356	-		
357	<u>d)</u>	-	ian seeking restoration of a license that is inactive or not
358			application for restoration including payment of the renewal
359		tee and evidence of i	meeting the renewal requirements of Section 1330.80.
360	<u>,</u>	A 1 1 1	
361	<u>e)</u>	-	license has been expired for one year or more may not have
362			ut must apply for a new license and meet all requirements for
363		<u>licensure.</u>	
364 365	fd)	When the ecouracy	of any submitted documentation, or the relevance or
366	<u>f</u> d)	<del>_</del>	of any submitted documentation, or the relevance or ourse work or experience, is questioned by the Division
367		<del>-</del>	aformation, discrepancies or conflicts in information given, or
368			on, the registrant will be requested to:
369		a ficed for clarification	on, the registrant will be requested to.
370		1) Provide infor	rmation as may be necessary; and/or
371		1) Trovide infor	initiation as may be necessary, and or
372		2) Appear for a	n interview before the Board to explain the relevance or
373		, 11	clarify information given, or clear up any discrepancies in
374		information.	
375			
376	(Sour	ce: Amended at 49 Ill	. Reg, effective)
377	`		
378	Section 1330	.120 Administration	of Tests and Therapeutics
379			
380	<u>a)</u>	Requirements	
381			
382		1) A pharmacist	t may administer and order tests or therapeutics to persons for
383		the following	g conditions:
384			
385		<u>A)</u> <u>Influe</u>	enza;
386			

387		<u>B)</u>	SARS-CoV-2;
388 389		<u>C)</u>	Group A Streptococcus;
390 391		<u>D)</u>	Respiratory syncytial virus;
392 393		<u>E)</u>	Adult-stage head louse;
394		IZ)	Health and distance identified has a state of the making bounds.
395 396		<u>F)</u>	Health conditions identified by a statewide public health emergency, as defined in the Illinois Emergency Management
397			Agency Act; and
398 399		<u>G)</u>	Any other health condition authorized by the Act.
400		<u>0)</u>	7 My other health condition authorized by the 7 tet.
401	<u>2)</u>		armacist may delegate the administrative and technical tasks of
402 403		_	rming a test for the health conditions described in this Section to a nacy technician or student pharmacist acting under the supervision
404		_	pharmacist. (Section 3(d)(17) of the Act).
405 406	3)	Pharr	nacists shall practice in accordance with the professional standard of
407	<u>5)</u>		consistent with their education and training. When assuming new
408			al responsibilities or engaging in specialized areas of practice,
409 410			nacists shall possess the necessary knowledge and skills to provide effective, and evidence-based care. Pharmacists may complete a
411		cours	e of training accredited by the Accreditation Council of Pharmacy
412 413		Educ	ation (ACPE) to meet this requirement.
414	<u>4)</u>	The p	pharmacist who is responsible for supervising the pharmacy student
415		-	armacy technician has the sole responsibility of evaluating the
416 417			opriateness of each test prior to its administration and shall maintain ight of the process.
418			
419 420	<u>5)</u>		charmacist shall maintain a current Basic Life Support Certification ealthcare Providers issued by the American Heart Association, the
421		•	rican Red Cross, the Health and Safety Institute, or an equivalent as
422		deter	mined by the Division.
423 424	<u>6)</u>	Each	pharmacy shall have available a current copy or electronic version of
425	<u> </u>	the cu	arrent version of the guidelines of the Centers for Disease Control
426 427			Prevention, guidelines of the United States Preventive Services Task
427 428		FORCE	e, or generally recognized evidence-based clinical guidelines.

129 130 131 132 133		<u>7)</u>	The pharmacist shall ensure that any pharmacy technician or student pharmacist performing administration of testing, under their direct supervision, has been appropriately trained and is competent to perform the test safely and accurately, consistent with the standard of care and manufacturer instructions.
134 135	<u>b)</u>	Patier	nt Health History Intake Form
136 137 138 139		<u>1)</u>	Prior to administering testing or therapeutics, a pharmacist shall have the patient complete a patient health history intake form for the purpose of performing a patient assessment.
140 141 142 143 144			A) The patient health history intake form shall include, at a minimum, basic patient information, including patient contact information, emergency contact information, history of past and present illness, current medications, allergies, and patient consent.
145 146 147 148 149			B) Based upon the results of the patient assessment, the pharmacist shall use their professional and clinical judgment to determine when a patient should be referred to the patient's physician or other appropriate health care provider in lieu of providing testing or therapeutics.
151 152 153 154 155 156 157		<u>2)</u>	Based on the pharmacists professional and clinical judgment, a referral may be issued following an initial or follow-up assessment, directing the patient to a qualified health care provider for further evaluation, diagnosis, or treatment. All referrals under this subsection must be provided in writing and include information advising the patient to seek follow-up care from a health care provider.
158 159 160 161 162 163		<u>3)</u>	Pharmacists shall advise patients to consult with the patient's physician or other appropriate health care provider if their symptoms persist, worsen, or involve physical manifestations, or if a test comes back as inconclusive or the treatment plan is unclear. This disclosure must be documented and signed by the patient or guardian.
164 165 166 167 168		<u>4)</u>	"Therapeutics" are limited to medications approved by the Food and Drug Administration for the treatment of health conditions as described in subsection (a)(1) as established in generally recognized evidence-based clinical guidelines. "Therapeutics" does not include controlled substances.
169 170 171	<u>c)</u>	Recor	rdkeeping and Reporting

472 473 474 475 476 477		The pharmacist shall maintain appropriate records related to the administration of a test or prescribed therapeutics, including but not limited to the information collected under subsection (b), the name of the test or therapeutic administered and the date administered, and the name or unique identifier of the administering pharmacist, pharmacy technician, or student pharmacist.
478 479 480 481 482 483		The pharmacist should make a reasonable effort to notify the patient's healthcare provider, if known, within a timely manner after a therapeutic has been dispensed, in accordance with professional judgment and patient care needs.
484	(Sourc	e: Added at 49 Ill. Reg, effective)
485 486 487	S 4 1220	SUBPART B: PHARMACY TECHNICIAN
488 489	Section 1330.	210 Pharmacy Technician Training
490 491 492	a)	It shall be the joint responsibility of a pharmacy and its pharmacist-in-charge to have trained all of its pharmacy technicians or obtain proof of prior training in all of the following topics as they relate to the practice site:
493 494 495		1) The duties and responsibilities of the technicians and pharmacists.
496		2) Tasks and technical skills, policies and procedures.
497 498 499		3) Compounding, packaging, labeling and storage.
500 501		4) Pharmaceutical and medical terminology.
502 503		5) Recordkeeping requirements.
504 505		6) The ability to perform and apply arithmetic calculations.
506 507 508		7) The administrative and technical tasks of performing a test as provided Section 3(d)(17) of the Act.
509 510 511 512 513 514	b)	Within 6 months after initial employment or changing the duties and responsibilities of a pharmacy technician, it shall be the joint responsibility of the pharmacy and the pharmacist-in-charge to train the pharmacy technician or obtain proof of prior training in the areas listed in subsection (a) as they relate to the practice site or to document that the pharmacy technician is making appropriate progress.

515		
516	c)	All pharmacies shall maintain an up to date training program describing the duties
517		and responsibilities of a pharmacy technician.
518	٦/	All about size shall exects and maintain nationable records of training an areaf
519 520	d)	All pharmacies shall create and maintain retrievable records of training or proof
520 521		of training as required in this Section.
522	e)	Ensuring registered pharmacy technicians and certified pharmacy technicians are
523	C)	properly trained shall be the responsibility of the pharmacy, the pharmacist-in-
524		charge, and the pharmacy technician.
525		enange, and the pharmacy teemmeran.
526	(Source	ce: Amended at 49 Ill. Reg, effective)
527	G 1000	
528		.215 Minimum Standards for Approved Work Experience Pharmacy
529 520	Technician C	Certification
530 531	A phormooy t	echnician certification program shall meet the following requirements:
532	A pharmacy t	echnician certification program shan meet the following requirements.
533	a)	This Section applies to pharmacy technicians licensed beginning January 1, 2024.
534	,	1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
535	b)	The curriculum must include at least 500 hours of supervised experience.
536		
537	c)	The work experience training under subsection (b) must be completed by the
538		pharmacy technician's 2 <sup>nd</sup> renewal.
539	•	
540	d)	Curriculum must include didactic and practical experience for each area of
541		instruction. At minimum of 100 hours must be applied toward the didactic
542 542		portion of the training.
543 544	e)	A graduate shall be competent in:
54 <del>4</del> 545	6)	A graduate shan be competent in.
546		1) The knowledge, skills, abilities, and behaviors beyond those of a
547		pharmacy technician;
548		r,
549		2) Functioning in a variety of pharmacy practice settings; and
550		
551		3) Self-management and the management of the pharmacy.
552		
553	f)	The curriculum must include the following areas of instruction:
554		1) 17 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
555 556		1) Knowledge and Skills:
556 557		A) Ethioge
557		A) Ethics;

558			
559		B)	Conflict resolution;
560			
561		C)	Customer service;
562			
563		D)	Communication with individuals, staff, and other healthcare
564			professionals;
565			
566		E)	Self-management skills; and
567			
568		F)	Problem solving.
569			
570	2)	Contin	uing Competency:
571			
572		A)	Continuing education;
573			
574		B)	Pharmacy technician's role and other occupations' roles in the
575			healthcare environment;
576			
577		C)	Basics in anatomy, pharmacology, and physiology relevant to
578			pharmacy technician role;
579			
580		D)	Pharmacy technician's role in the medication-use process;
581			
582		E)	Infection control procedures;
583			
584		F)	Protocols for vaccine administration;
585			
586		G)	Common allergies; and
587			
588		H)	Hygiene, personal protection equipment (PPE), cleaning and
589			maintaining equipment.
590			
591	3)	Medic	ation Orders:
592			
593		A)	Medication storage;
594			
595		B)	Medication ordering;
596 		~`	
597 500		C)	Recordkeeping;
598 500		D)	NA 12 /2 1 1 12
599		D)	Medication labeling;
600			

601		E)	Special handling procedures;
602			
603		F)	Prescription entry and interpretation;
604			
605		G)	Generic/brand names;
606		\	
607		H)	Compounding sterile preparations per applicable, current USP
608			chapters;
609		T)	N. 1
610		I)	Moderate and high level non-sterile compounding as defined by
611			USP (e.g., suppositories, tablets, complex creams);
612		Τ\	
613		J)	Chemotherapy/hazardous drug preparations per applicable, current
614			USP chapters;
615 616		K)	Billing for complex and/or specialized pharmacy services and
617		K)	goods;
618			goods,
619		L)	Purchasing pharmaceuticals, devices, and supplies;
620		L)	r dichasing pharmaceuticais, devices, and supplies,
621		M)	Inventory control of medications, equipment, and devices;
622		111)	inventory control of incurcations, equipment, and devices,
623		N)	Administration of immunizations and other injectable medications;
624		/	
625		O)	Current technology/automation related to safety and accuracy of
626		ĺ	medication dispensing; and
627			
628		P)	Dosage forms.
629			
630	4)	Patient	Care:
631			
632		A)	Pharmacy technicians' role under the Joint Commission of
633			Pharmacy Practitioners' Pharmacists' Patient Care Process;
634			
635		B)	Patient and medication safety practices;
636			
637		C)	Emergency patient situations;
638			
639		D)	Medication reconciliation process;
640		<b></b>	3.6.19
641		E)	Medication management services;
642		17/	Macanamanta manamatian and anti-site
643		F)	Measurements, preparation, and packaging;

644							
645			G)	Point of care testing;			
646							
647			H)	Patient confidentiality;			
648			Τ)	E			
649 650			I)	Error prevention;			
650 651			Τ\	Cofety event negotines and			
651 652			J)	Safety event reporting; and			
653			K)	Different insurance plan types, coupons, and prior authorizations.			
654			K)	Different insurance plan types, coupons, and prior authorizations.			
655		5)	Regul	atory Knowledge:			
656		3)	Regui	atory Knowledge.			
657			A)	Review of State and federal laws pertaining to processing,			
658			11)	handling, and dispensing of medications, including controlled			
659				substances;			
660				substances,			
661			B)	Review of State and federal laws pertaining to pharmacy			
662			2)	technicians;			
663				toommonano,			
664			C)	Occupational Safety and Health Administration (OSHA)			
665			,	requirements;			
666				1			
667			D)	USP requirements, including USP 795 and 797 training;			
668			,				
669			E)	The Institute for Safe Medication Practices (ISMP);			
670							
671			F)	The Joint Commission;			
672							
673			G)	Risk Evaluation and Mitigation Strategies (REMS);			
674							
675			H)	Look-Alike/Sound-Alike (LASA) High Alert;			
676							
677			I)	Health Insurance Portability and Accountability Act (HIPAA);			
678							
679			J)	Facility maintenance; and			
680							
681			K)	Medication disposal.			
682	`	C 1	,				
683	g)			ust be competent in providing appropriate life support measures			
684 68 <b>5</b>			including Basic Life Support (BLS) and automated external defibrillators (AED)				
685 686		ior m	edicai e	mergencies that may be encountered in pharmacy practice.			
686							

687 688 689 690	h)	(ACPE)	grams accredited by the Accreditation Council for Pharmacy Education and the American Society of Health System Pharmacists (ASHP) meet mum curriculum criteria set forth in this Section and are, therefore, d.
691 692	(Sour	ce: Amen	ided at 49 Ill. Reg, effective)
693 694 <b>S</b>	Section 1330	0.230 Con	ntinuing Education ("CE") for Certified Pharmacy Technicians
695			·
696	a)	CE Req	uirements
697		4.	
698		1) 1	Number of Hours of CE Required
699 700			A) F-1
700		1	A) Each person who applies for renewal of a license as a certified
701 702			pharmacy technician shall complete 2010 hours of CE during the 2412 months preceding the expiration date of the license, in
703			accordance with Section 9.5 of the Act.
704			accordance with Section 7.5 of the Act.
705		1	B) A renewal applicant is not required to comply with CE
706		-	requirements for the first renewal after original licensure.
707			<b>1</b>
708		2) I	Required Topics for CE
709		•	•
710		1	A) At least one hour of continuing pharmacy education must be on the
711			subject of pharmacy laws, pharmacy rules and ethics;
712			
713		]	B) At least one hour of continuing pharmacy education must be on the
714			subject of patient safety; and
715			
716		(	C) Any other applicable CE requirements under 68 Ill. Adm. Code
717			1130.
718 719	1-)	<b>A</b>	-1 CE
719 720	b)	Approve	CE
720 721		1)	The completion of courses offered by providers approved by the
722		,	Accreditation Council on Pharmacy Education or another standardized
723			nationally approved education program approved by the Department, may
724			be completed outside the State of Illinois are approved CE courses.
725		·	1 President of the second of t
726		2)	The pharmacist-in-charge and the certified pharmacy technician must
727			maintain records showing proof of training that constituted the pharmacy
728			rechnician's CE.
729			

730	c)	Certifi	cation o	f CE R	equirements
731					
732		1)	Each re	enewal	applicant shall certify on the renewal application full
733			compli	ance wi	th CE requirements set forth in this Part.
734			•		•
735		2)	The Di	vision 1	nay require additional evidence demonstrating compliance
736		,			quirements (e.g., certificates of attendance, certificates of
737					ourse registration). It is the responsibility of each renewal
738			-		tain or otherwise produce evidence of the compliance.
739					be required in the context of the Division's random audit in
740					th Section 9.5 of the Act.
741			accord	unce wi	in Section 7.5 of the ret.
742	d)	The co	ma CE 1	houre of	annot be used to fulfill the CE requirement for more than
743	u)		newal pe		unior de usea to furmi the CE requirement for more than
743 744		One rei	iewai po	errou.	
745	e)	Waiwa	r of CE	Doguir	amanta
745 746	6)	vv ai ve	OICE	Kequii	ements
747		1)	Any re	newal a	pplicant seeking to renew their license without having fully
748		1)	•		these CE requirements shall file with the Division a
749			-		eation, along with the required fee, a statement setting forth
750					erning noncompliance and a request for waiver of the CE
750 751					with facts explaining the basis of the request. A request for
752					e made prior to the renewal date. If the Division, upon the
752 753					mendation of the Board, finds from the affidavit or any other
754					nitted that good cause has been shown for granting a waiver,
75 <del>4</del> 755					nall waive enforcement of the CE requirements for the
756					I for which the applicant has applied.
757			TCHCWa	ii perioc	Tor which the applicant has applied.
757 758		2)	Good	ougo ch	all he defined as an inability to fulfill the CE requirements
759		2)			all be defined as an inability to fulfill the CE requirements licable period because of:
760			during	ше арр	nicable period because of.
			<b>A</b> )	Eull tir	me service in the armed forces of the United States of
761 762			A)		
				Amen	ca during the applicable period; or
763			D)	Entro	a bandahin suhiah ahall ha datamuin ad an an individual
764			B)		he hardship, which shall be determined on an individual
765 766				Dasis D	y the Board and shall be limited to documentation of:
766				:)	An incompaignting illness decompanded by a sugmently
767				i)	An incapacitating illness, documented by a currently
768					licensed physician;
769				::>	Discourse in the little of the site of the
770				ii)	Physical inability to travel to the sites of approved
771					programs, as documented by a currently licensed physician;
772					or

773		
774		iii) Any other similar extenuating circumstances (e.g., illness
775		of a family member).
776		•
777		3) If a renewal applicant requests an interview before the Board at the time
778		the waiver request is submitted, the Board shall not deny the waiver
779		request before an interview is conducted. The renewal applicant
780		requesting a waiver shall be given at least 20 days written notice of the
781		date, time, and place of the interview by mail or email.
782		
783		4) Any renewal applicant who submits a request for waiver pursuant to
784		subsection (e)(1) shall be deemed to be in good standing until the final
785		Division decision on the application has been made.
786		
787	(Source	ce: Amended at 49 Ill. Reg, effective)
788		
789		SUBPART E: TYPES OF PHARMACIES
790		
791	Section 1330	.500 Community Pharmacy Services
792		
793	a)	Pharmacies that engage in general or specialty community pharmacy practice and
794		are open to, or offer pharmacy service to, the general public shall, in addition to
795		any other requirements of the Act and this Part, comply with this Section. A
796		community pharmacy that, in addition to offering pharmacy services to the
797		general public, provides institutional services shall also comply with Section
798		1330.520.
799		
800	b)	Staffing of the Pharmacy
801		
802		1) Whenever the hours of the pharmacy differ from those of the
803		establishment in which the pharmacy is located, the schedule during which
804		pharmacy services are provided shall be conspicuously displayed.
805		
806		2) Whenever a pharmacy is open and a pharmacist is not present and
807		available to provide pharmacy services, a sign stating that situation shall
808		be conspicuously displayed.
809		
810		3) No prescription may be dispensed when a pharmacist is not physically
811		present in the establishment.
812		
813	c)	Recordkeeping Requirements for Dispensing Prescription Drugs
814		

815 816 817 818 819	1)	For every prescription dispensed, the prescription record shall contain the name, initials or other unique identifier of the pharmacist who dispenses the prescription drugs. No prescription may be dispensed after 15 months from the date of the original issuance of the prescription by the prescriber.
820 821 822 823 824 825 826	2)	Whenever a prescription is dispensed by a registered pharmacy technician or certified pharmacy technician under the supervision of a pharmacist, the prescription record shall contain the names, initials or other unique identifier of both the supervising pharmacist and the registered pharmacy technician or certified pharmacy technician who dispenses the prescription.
827	<u>3)</u>	An invoice is required for all pharmacy to pharmacy drug transfers.
828		
829	<u>4</u> 3)	Refilling a Prescription
830 831		A) Each refilling of a prescription shall be entered on the prescription
832		or on another appropriate, uniformly maintained, readily
833		retrievable record that indicates, by the number of the prescription,
834		the following information:
835		
836		i) The name and dosage form of the drug;
837		
838		ii) The date of each refilling;
839 840		iii) The quantity dispensed;
841		in) The quantity dispensed,
842		iv) The name or initials of the pharmacist and the pharmacy
843		technician, if applicable, in each refilling; and
844		
845		v) The total number of refills remaining for the prescription.
846		
847		B) If the pharmacist does not otherwise indicate in a uniformly
848		maintained record, the pharmacist shall be deemed to have
849 850		dispensed a refill for the full face amount of the prescription.
851	<u>5</u> 4)	Presentation of a written prescription copy or prescription label shall be
852	<u></u> ,	for information purposes only and has no legal status as a valid
853		prescription order. The recipient pharmacist of the copy or prescription
854		label shall contact the prescribing practitioner to obtain a new prescription
855		order.
856		

857	<u>6</u> 5)	-	_	scriptions given to an ultimate consumer shall be marked
858		"For Ir	ıformat	ion Purposes Only".
859	<b>5</b> ()	a		
860	<u>7</u> 6)			etion 18 of the Act, any information required to be kept
861		-		at Section may be recorded and stored in a computerized
862		-		al information system that meets the standards of
863		-		stated in the regulations of the Drug Enforcement
864				in (21 CFR 1306; 2014), except as provided in subsection
865		(c)(7),	and sha	all include the capability to:
866				
867		A)		ve the original prescription order information for those
868			prescr	iption orders currently authorized for refilling;
869				
870		B)		ve the current prescription orders, including, at a minimum,
871				of drug, date of refill, quantity dispensed, name and
872			identif	fication code of the manufacturer in the case of a generically
873				n prescription or a generic interchange, name or initials of
874			the dis	spensing pharmacist and technician for each refill, and the
875			total n	umber of refills dispensed to date;
876				
877		C)	Supply	y documentation of refill information entered by the
878			pharm	acist using the system through a hard copy printout of each
879			day's 1	refill data that has been verified for correctness. This printout
880			must i	nclude for each prescription filled at least the following
881			inform	nation:
882				
883			i)	The name and dosage form of the drug;
884				
885			ii)	The date of each refilling;
886				
887			iii)	The quantity dispensed;
888				
889			iv)	The name or initials of the pharmacist in each refilling and
890				the pharmacy technician, if applicable;
891				
892			v)	The patient's name;
893				
894			vi)	The prescriber's name; and
895				
896			vii)	The prescription number for the prescription.
897				-
898	<u>8</u> 7)	In lieu	of the	printout required by subsection (c)(6), the pharmacy shall
899		mainta	in a bo	und log book, or separate file, in which each individual

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pharmacist involved in the dispensing shall sign a statement each day, attesting to the fact that the refill information entered into the computer that day has been reviewed and is correct as shown. The book or file must be maintained at the pharmacy employing the system for a period of 5 years after the date of dispensing the appropriately authorized refill.

- All refill data shall be maintained by the pharmacy on the premises for 5 years, in accordance with Section 18 of the Act. The pharmacy shall have the appropriate equipment on the premises to provide readily retrievable information in the course of an on-site inspection. A hard copy printout shall be provided to the Division, upon request, within 48 hours.
- d) Any drug that is dispensed pursuant to prescription, other than vaccinations administered in the pharmacy, shall have affixed to its container a label as provided in Section 22 of the Act.
- e) No person shall establish or move to a new location any pharmacy unless the pharmacy is licensed with the Division and has on file with the Division a verified statement that:
  - 1) The pharmacy is or will be engaged in the practice of pharmacy; and
  - 2) The pharmacy will have in stock and will maintain sufficient prescription drugs and materials to protect the public it serves within 30 days after opening of the pharmacy.
- f) Pharmacies have a duty to deliver lawfully prescribed drugs to patients and to distribute nonprescription drugs approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies, or to substitute a generic drug as permitted in Section 25 of the Act in a timely manner, or to contact the prescriber to obtain authorization to dispense a different drug that produces a similar clinical effect in a timely manner, except for the following or substantially similar circumstances:
  - When, in the pharmacist's professional judgment, after screening for potential drug therapy problems due to therapeutic duplication, drugdisease contraindications, drug-drug interactions (including, but not limited to, serious interactions with nonprescription or over-the-counter drugs), drug-food interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, or clinical abuse or misuse, pursuant to Section 3(aa) of the Act, the pharmacist determines that the drug should not be dispensed due to one of the foregoing clinical reasons;

943		2) National or State emergencies or guidelines affecting availability, usage or
944		supplies of drugs;
945		
946		3) Lack of specialized equipment or expertise needed to safely produce, store
947		or dispense drugs, such as certain drug compounding or storage for
948		nuclear medicine;
949		
950		4) Potentially fraudulent prescriptions;
951		C) II 1111 C1
952		5) Unavailability of drug; or
953		
954		6) The drug is not typically carried in similar practice settings in the State.
955		
956	g)	Nothing in this Section requires pharmacies to dispense a drug without payment
957		of their usual and customary or contracted charge.
958		
959	h)	All pharmacies shall be required to maintain the following current resource
960		materials, either in hard copy or electronic format:
961		
962		1) Copies of the Act and this Part;
963		A
964		2) Illinois Controlled Substances Act and 77 Ill. Adm. Code 3100;
965		
966		3) Title 21 of the United States Code of Federal Regulations (Food and
967		Drugs); and
968		
969		4) Hypodermic Syringes and Needles Act [720 ILCS 635].
970		
971	i)	If the lawfully prescribed drug or nonprescription drug approved by the U.S. Food
972		and Drug Administration for restricted distribution by pharmacies is not in stock
973		or is otherwise unavailable, or the prescription cannot be filled pursuant to
974		subsection (f)(1) or (f)(6), the pharmacy shall provide the patient or agent a timely
975		alternative for appropriate therapy that, consistent with customary pharmacy
976		practice, may include obtaining the drug. These alternatives include but are not
977		limited to:
978		
979		1) Contact the prescriber to address concerns such as those identified in
980		subsection (f)(1);
981		
982		2) If requested by the patient or the patient's agent, return unfilled lawful
983		prescriptions to the patient or agent; or
984		

985		3) If requested by the patient or the patient's agent, communicate or transmit,
986		as permitted by law, the original prescription information to a pharmacy of
987		the patient's choice that will fill the prescription in a timely manner.
988	:\	A server the advantagement of the constitution of the transition of the transition of the transition of the transition of the constitution of the
989	j)	Any mail order pharmacy that provides services in Illinois shall provide, during
990		its regular hours of operation, but not less than 6 days per week for a minimum of
991 992		40 hours per week, a toll-free telephone service to facilitate communication
992 993		between patients in this State and a pharmacist retained by the mail order pharmacy who has access to the patient's records. The toll free number must be
993 994		disclosed on the label affixed to each container of drugs dispensed to residents of
99 <del>4</del> 995		the State.
996		the State.
997	k)	Engaging in or permitting any of the following shall constitute grounds for
998	K)	discipline or other enforcement actions:
999		discipline of other emoteement detroits.
000		1) Intentionally destroying unfilled lawful prescriptions;
001		-,,,,,
002		2) Refusing to return unfilled lawful prescriptions;
003		
004		3) Violating a patient's privacy;
005		, 5 1 1 2,
006		4) Discriminating against patients or their agents in a manner prohibited by
007		State or federal laws;
800		
009		5) Intimidating or harassing a patient; or
010		
011		6) Failing to comply with the requirements of this Section.
012		
013	(Source	e: Amended at 49 Ill. Reg, effective)
014		
015	Section 1330.	510 Telepharmacy
016		
017	a)	Telepharmacy shall be limited to the types of operations described in this Section.
018		Each site where such operations occur shall be a separately licensed pharmacy.
019		Home pharmacies that are located outside of Illinois must be licensed as a
020		nonresident pharmacy. Nonresident pharmacies shall abide by all Illinois laws and
021		rules when filling prescriptions for Illinois residents, except that the dispensing
022		pharmacist and the pharmacist-in-charge shall not be required to be licensed in
023		Illinois, except as otherwise provided in this Part.
024	• •	D (D' ' C')
025	b)	Remote Dispensing Site
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- Written prescriptions presented to the remote dispensing site shall be scanned into the electronic data processing equipment to ensure initial dispensing and each refill and the original prescription may be viewed on the monitor at both the remote dispensing site and home pharmacy site.

  Records shall be maintained at the remote dispensing site.
- 2) A remote site is considered to be under the supervision of the pharmacistin-charge of the home pharmacy. Each home pharmacy may supervise no more than 3 remote sites that are simultaneously open.
- 3) The remote site shall use its home pharmacy and pharmacy management system.
  - A) The system shall assign consecutive prescription numbers.
  - B) Prescriptions dispensed at the remote site shall be distinguishable from those dispensed from the home pharmacy.
  - C) Daily reports must be separated for the home and remote site.
- 4) <u>Unless staffed by an onsite pharmacist, aA</u> pharmacist at the home pharmacy must verify each prescription before it leaves the remote site.
  - A) Pharmacist and pharmacy technician initials or unique identifiers must appear on the prescription record and the prescription label.
  - B) A pharmacist shall electronically compare via video link the stock bottle, drug dispensed, the strength and its beyond use date. The entire label must be checked for accuracy on the video link.
  - C) The remote dispensing site shall utilize a barcode system that prints the barcode of the stock bottle on the label of the dispensed drug. If the stock bottle does not have a barcode, the pharmacy shall create one. The technician shall scan both the stock bottle and the label of the dispensed drug to verify that the drug dispensed is the same as the drug in the stock bottle for each prescription dispensed.
  - D) A pharmacy may utilize a different electronic verification system that accomplishes the same purpose after review and approval of the Division.

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- 5) Counseling must be done by a pharmacist via video link and audio link. Pursuant to Section 1330.700, the pharmacist providing counseling, pursuant to this subsection, must be employed or contracted by the home pharmacy or by a pharmacy contracted with the home pharmacy and have access to all relevant patient information maintained by the home pharmacy.
- 6) A pharmacist-in-charge or a designated pharmacist must complete monthly inspections of the remote site. Inspection criteria must be included in the policies and procedures for the site. The inspection report must be available on site for pharmacy investigator inspection.
- 7) Controlled substances shall be kept at the remote site in accordance with the Act and this Part. All records must be stored at the remote site.
- 8) There shall be a working computer link, video link and audio link to a pharmacist at a home pharmacy whenever the prescription area is open to the public. The communication link must be checked daily and the remote site pharmacy must be closed if the link malfunctions, unless a pharmacist is physically present at the remote site.
  - A) The pharmacy technician located at the remote dispensing site must have one year of experience and be registered as a certified pharmacy technician, or be a student pharmacist.
  - B) New prescriptions received at the remote dispensing site may be entered into the remote computer system with all verification, interaction, checking and profile review by the pharmacist at the home pharmacy.
  - C) Each pharmacist at the home pharmacy may electronically supervise no more than 3 remote sites that are simultaneously open.
- 9) The facility must have a sign clearly identifying it as a remote dispensing site.
- 10) The facility shall have an area for patient consultation, exclusive of any waiting area.
- A remote dispensing site must maintain a log with the date and time when a pharmacist is working onsite.

1112	c)	Remo	ote Consultation Site
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1114		1)	These sites have no prescription inventory.
1115			
1116		2)	Only filled prescriptions, filled at the home pharmacy, with final patient
1117			labeling attached are allowed at these sites.
1118			
1119		3)	These sites must be staffed with a pharmacy technician or certified
1120			pharmacy technician who has the knowledge necessary to use computer
1121			audio/video link for dispensing and consultation to occur. Pharmacist and
1122			pharmacy technician initials or unique identifiers must appear on the
1123			prescription record and the prescription label.
1124			
1125		4)	Written prescriptions may be received at a remote consultation site. All
1126			written prescriptions presented at a remote consultation site shall be
1127			delivered to the home pharmacy within 72 hours.
1128			
1129		5)	Security of filled prescriptions must be maintained by storing them in a
1130			separate lock drawer or cabinet.
1131			
1132		6)	Recordkeeping shall be conducted by the pharmacist (time/date) when
1133			dispensing and counseling occurred.
1134			
1135		7)	The site shall have an area a room for patient consultation exclusive of any
1136			waiting area.
1137			
1138		8)	The site must have a sign clearly identifying it as a remote consultation
1139			site.
1140			
1141	d)	Auto	mated Pharmacy Systems (Section 22(b) of the Act)
1142			
1143		1)	Remote Automated Pharmacy Systems (RAPS)
1144			
1145			A) These devices shall maintain a prescription drug inventory that is
1146			controlled electronically by the home pharmacy or, when operated
1147			by a pharmacy contracted with the home pharmacy, by the
1148			contracted pharmacy, which shall be utilized to dispense patient
1149			specific prescriptions.
1150			
1151			B) These systems shall have prescription inventory, which must be
1152			secured in an automated pharmacy system and electronically
1153			connected to and controlled by the home pharmacy.
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- C) A pharmacist must approve all the prescription orders before they are released from the RAPS.
- D) Dispensing and counseling are performed by a pharmacist employed or contracted by the home pharmacy via audio and video link.
- E) All filled prescriptions must have a label that meets the requirements of the Act attached to the final drug container.
- F) The pharmacist-in-charge of the home pharmacy, or a designated registrant, shall conduct and complete monthly inspections of the RAPS. Inspection criteria must be included in the policies and procedures for the site. The report must be available to the pharmacy investigators when requested.
- G) The RAPS must be licensed with the Division as an automated pharmacy system and will be subject to random inspection by pharmacy investigators. Notwithstanding that the RAPS shall possess a license, the home pharmacy shall remain responsible for inventory control and billing. For purposes of random inspections, a pharmacist with access to the system must be available at the site within one hour, or as otherwise approved by the drug compliance investigator. In the event the Department's Chief Pharmacy Coordinator determines that the RAPS poses a significant risk of patient harm, the RAPS must be disabled until such time as the pharmacist with access to the system is available to the site.
- H) Medication dispensed at the automated pharmacy system site may only be packaged by a licensed manufacturer or repackager, or prepackaged by a licensed pharmacy in compliance with this Section. Prepackaging must occur at the home pharmacy, a pharmacy sharing common ownership with the home pharmacy, or a pharmacy that has contracted with the home pharmacy to perform prepackaging services. The following requirements shall apply whenever medications are prepackaged by a pharmacy other than the home pharmacy:
  - i) The prepackaging pharmacy shall be licensed in Illinois as a resident or nonresident pharmacy.
  - ii) The prepackaging pharmacy shall share a common database with the home pharmacy, or have in place an

1198				electronic or manual process to ensure that both pharmacies
1199				have access to records to verify the identity, lot numbers
1200				and expiration dates of the prepackaged medications
1201				stocked in the RAPS.
1202				
1203			iii)	The prepackaging pharmacy shall maintain appropriate
1204				records to identify the responsible pharmacist who verified
1205				the accuracy of the prepackaged medication.
1206				
1207		I)	Written	n prescriptions may be received at a RAPS. All written
1208			prescri	ptions presented to a RAPS shall be scanned utilizing
1209			imagin	g technology that permits the reviewing pharmacist to
1210			_	ine its authenticity. The sufficiency of the technology shall
1211				ermined by the Department. If sufficient technology is not
1212			used, the	he written prescriptions must be delivered to the home
1213			pharma	acy and reviewed by a pharmacist prior to being dispensed
1214			-	patient.
1215			•	
1216	2)	Kiosk		
1217	,			
1218		A)	A kios	k is a device that maintains individual patient prescription
1219		,		hat were verified and labeled at the home pharmacy.
1220			Č	1
1221		B)	A hom	e pharmacy may only use the kiosk with prior approval of a
1222		,	patient	
1223			•	
1224		C)	A kios	k located on the same premises or campus of the home
1225		ŕ		acy shall operate under the same license as the home
1226			-	acy. However, a kiosk must be licensed with the Division if
1227			-	t so located.
1228				
1229		D)	A kios	k shall:
1230				
1231			i)	When located on the same premises or campus as the
1232			,	pharmacy, inform a patient, if using the device when the
1233				pharmacy is open, that the patient may address questions
1234				and concerns regarding the prescription to a pharmacist at
1235				the pharmacy;
1236				
1237			ii)	When not located on the same premises or campus as the
1238			•	pharmacy, inform a patient, if using the device when the
1239				pharmacy is closed, that he or she may immediately direct
1240				any questions and concerns regarding the prescription to a

1241					licensed pharmacist via a pharmacy provided audio/video
1242					link;
1243				•••	
1244				iii)	Inform a patient that a prescription is not available to be
1245					delivered by the device if the pharmacist desires to counsel
1246					the patient in person regarding the prescription.
1247					
1248		3)	-	-	may use an automated pharmacy system to deliver
1249			presc	riptions	to a patient when the device:
1250					
1251			A)	Is sec	cured against a wall or floor;
1252					
1253			B)	Provi	des a method to identify the patient and delivers the
1254				presc	ription only to that patient or the patient's authorized agent;
1255					
1256			C)	Has a	dequate security systems and procedures to prevent
1257				unaut	chorized access, to comply with federal and State regulations,
1258				and to	o maintain patient confidentiality;
1259					•
1260			D)	Reco	rds the time and date that the patient removed the prescription
1261			,		the system.
1262					•
1263		4)	A lice	ensed au	atomated pharmacy system shall not be utilized by
1264		,			Nothing in this Section shall prevent a prescriber from
1265			-		automated pharmacy system in connection with his or her own
1266				_	However, a prescriber may not utilize or access an automated
1267			_	_	stem licensed pursuant to this Section.
1268			Pilari	nacy by	stem needed parsuant to this section.
1269	e)	All nl	harmaci	sts nerf	Forming services in support of a remote dispensing site,
1270	0)				site, kiosk, or RAPS must display a copy or electronic image
1270					ne remote site where they provide services, or shall otherwise
1271					isible to the patient, and be licensed in this State, unless
1272					nacy licensed in Illinois as a nonresident pharmacy, in which
1273 1274		-		-	providing the services shall hold an active license as a
			-		
1275		-			tte in which the nonresident pharmacy is located and only the
1276		pnarn	nacist-ii	n-cnarg	e of the remote site must be licensed in Illinois.
1277	^	г 1		٠,	
1278	f)	Each	remote	site mu	st display a sign, easily viewable by the customer, that states:
1279		1.			
1280		1)		•	s a telepharmacy supervised by a pharmacist located at
1281			(addr	ess); an	d
1282					

1283			2)	_	narmacist is required to talk to you, over an audio/visual link, each
1284				time yo	ou pick up a <u>new</u> prescription.
1285		,	2.7	. •.	
1286		g)			e may be open when the home pharmacy is closed, unless a
1287					aployed or contracted by the home pharmacy, or by a pharmacy
1288					h the home pharmacy, is present at the remote site or is remotely
1289			provid	ing supe	ervision and consultation as required under this Section.
1290					
1291		(Source	e: Ame	ended at	49 Ill. Reg, effective)
1292					
1293	Section	n 1330.	.520 Of	ffsite In	stitutional Pharmacy Services
1294					
1295		a)			at are not located in the facilities they serve and whose primary
1296				_	provide services to patients or residents of facilities licensed under
1297				_	ome Care Act, the Hospital Licensing Act, the University of Illinois
1298					the Ambulatory Surgical Treatment Center Act, or the Illinois
1299			Depar	tment of	f Human Services shall, in addition to any other requirements of the
1300			Act an	d this P	art, comply with this Section.
1301					
1302		b)	Record	dkeeping	g Requirements for Dispensing Prescriptions or Orders
1303					
1304			1)	Every	prescription or order dispensed shall be documented with the name,
1305				initials	or other unique identifiers of the pharmacist (and student
1306				pharma	acist or pharmacy technician if one is used) authorized to practice
1307				pharma	acy under the provisions of the Act who dispenses the prescription
1308				or orde	er. For purposes of the Act, an authorized person is:
1309					
1310				A)	A pharmacist licensed in the State of Illinois; or
1311					
1312				B)	A pharmacy technician, certified pharmacy technician or student
1313					pharmacist under the supervision of a pharmacist.
1314					
1315			2)	Each p	harmacy must maintain records for 5 years that contains the
1316				inform	ation in subsection (b)(3). This information shall be readily
1317				retriev	able and in a format that provides enforcement agents a concise,
1318				accura	te and comprehensive method of monitoring drug distribution via an
1319				audit ti	rail. This system may require 2 or more documents that, when read
1320				togethe	er, will provide all the information required by federal (e.g., the
1321				regulat	tions of the Drug Enforcement Administration (21 CFR 1300;
1322				2014))	and State (e.g., the Pharmacy Practice Act and the Illinois
1323					olled Substances Act [720 ILCS 570]) statute.
1324					

1325	3)		ition to the recordkeeping requirements of subsection (b)(2), a
1326			mly maintained, readily retrievable hard copy record or back-up
1327			entation of each prescription or order dispensed shall be maintained
1328		by the	pharmacy for 5 years and shall include:
1329			
1330		A)	Name of resident;
1331			
1332		B)	Date of order;
1333			
1334		C)	Name, strength and dosage form of drug, or description of the
1335			medical device ordered;
1336			
1337		D)	Quantity dispensed (a separate record should be maintained when
1338			the quantity billed differs from the quantity dispensed, e.g., unit
1339			dose transfer systems);
1340			·
1341		E)	Directions for use;
1342			
1343		F)	Quantity billed;
1344			
1345		G)	Prescriber's name;
1346			
1347		H)	Prescriber's signature and/or DEA number when required for
1348			controlled substances; and
1349			
1350		I)	The drug name and identification code or the manufacturer in case
1351			of a generically ordered medication or a generic interchange.
1352			
1353	4)	No pre	escription may be filled or refilled for a period in excess of 15
1354		month	s from the date of the original issuance of the prescription or order
1355		by the	prescriber.
1356			
1357	5)	Subjec	et to Section 18 of the Act, any information required to be kept
1358		pursua	nt to this Section may be recorded and stored in a:
1359			
1360		A)	computerized pharmaceutical information system that meets the
1361			standards of performance required by the regulations of the Drug
1362			Enforcement Administration (21 CFR 1306; 2014) and shall
1363			include the capability to:
1364			
1365			i) Retrieve the original medication order information for
1366			those medication orders that are currently authorized;
1367			

368				ii)	Retrieve the current history of medication orders that shall,
369					at a minimum, include the name of drug, the date of filling,
1370					the quantity dispensed, the name and identification code of
371					manufacturer in the case of a generically written
1372					prescription or a generic interchange, for each filling, and
1373					the total number of refills when read in conjunction with
374					any off-line hard copy of the history of medication orders
375					dispensed to date; and
376					3-3F
1377				iii)	Supply documentation of the correctness of filling
378				/	information entered into a system must be provided by the
1379					pharmacist using the system by way of a hard copy printout
1380					of each day's filling data that has been verified, dated and
381					signed by the dispensing pharmacist; or
382					signed by the dispensing pharmaeist, or
1383			B)	bound	logbook, or separate file, in which each individual
384			D)		acist involved in dispensing shall sign a statement each day
1385				_	ng to the fact that the refill information entered into the
1386					uter that day has been reviewed by the individual pharmacist
1387				_	correct as shown. The book or file must be maintained at
1388					armacy employing the system for a period of 5 years after
1389				_	te of dispensing the appropriately authorized refill.
1390				tiic da	te of dispensing the appropriately additionized ferm.
1391	c)	In the	avant the	a long	term care facility changes pharmacy provider services, their
1391	C)			_	btain the orders from the long-term care facility and verify
1392		-			· · · · · · · · · · · · · · · · · · ·
1393		uie auu	nemacity	y anu a	accuracy of the orders with the prescriber.
1394	d)	Staffin	g of the	Dharm	nacy. When the pharmacy is closed the public and any
1393	u)		_		nacy. When the pharmacy is closed, the public and any
				_	ered under the Act are to be prohibited access to the filling
1397		and dis	pensing	area.	
398	2)	Lobolin	a Dagu		<b>1</b>
1399	e)	Labelli	ng Requ	пешег	ILS
400		1\	N		
401		1)	Medica	ttions i	For Future Use
402			<b>A</b> >	D.	
403			A)		teral solutions to which a drug or diluent has been added or
404					re not in their original manufacturer's packaging shall contain
405				the fo	llowing information on the outer label:
406				• <	
407				i)	Name, concentration and volume of the base parenteral
408					solution;
409				•••	
410				ii)	Name and strength of drugs added;

1411				
1412			iii)	Beyond use date and date of the admixture. Beyond use
1413				date, unless otherwise specified in the individual
1414				compendia monograph shall be not later than the beyond
1415				use date on the manufacturer's container or one year from
1416				the date the drug is repackaged, whichever is earlier; and
1417			:>	D-f
1418			iv)	Reference code to identify source and lot number of drugs
1419				added.
1420		D)	Non a	soundands non-alread for fature was about by identified with
1421		B)	-	parenterals repackaged for future use shall be identified with
1422			the 10	llowing information:
1423			:\	Duand and/an associa name.
1424 1425			i)	Brand and/or generic name;
1425 1426			::)	Strongth (if applicable):
1420 1427			ii)	Strength (if applicable);
1427 1428			iii)	Payand use data. Unless otherwise specified in the
1428 1429			111)	Beyond use date. Unless otherwise specified in the individual monograph, the beyond use date shall be not
1429				later than the beyond use date on the manufacturer's
1430 1431				container or one year from the date the drug is repackaged.
1431				whichever is earlier; and
1433				whichever is earner, and
1434			iv)	Reference code to identify source and lot number.
1435			10)	Reference code to identify source and for number.
1436	2)	Media	rations I	Prepared for Immediate Use
1437	2)	Micun		repared for infinediate ose
1438		A)	A11 m	edications prepared by the pharmacy for immediate
1439		11)		using to a specific resident or patient in the facility shall be
1440				nsed in a container identified with:
1441			disper	ised in a container identified with.
1442			i)	Name of the resident;
1443			-/	Traine of the resident,
1444			ii)	Resident's room and bed number;
1445			/	1.001.00.00 100.00 minu out nome out,
1446			iii)	Dispensing date;
1447			111)	2 is princing unit;
1448			iv)	Name, strength and dosage form of drug, or description of
1449				the medical device ordered;
1450				,
1451			v)	Quantity dispensed;
1452			,	
1453			vi)	Directions for use;
			,	,

1454				
1455			vii)	Prescriber's name; and
1456				
1457			viii)	Beyond use date if less than 60 days from date of
1458				dispensing.
1459				
1460		B)	Pharn	nacies dispensing medications to a specific resident or patient
1461			in the	facility via unit dose shall label each order with the
1462			follov	ving information:
1463				
1464			i)	Name of the resident;
1465				
1466			ii)	Resident's room and bed number;
1467				
1468			iii)	Date of order;
1469				
1470			iv)	Name, strength and dosage form of drug, or description of
1471				the medical device ordered;
1472				
1473			v)	Directions for use; and
1474			ŕ	
1475			vi)	Prescriber's name.
1476				
1477	f)	Pharmacies tha	t com	pound and dispense sterile products shall comply with
1478	,	Section 1330.6		
1479				
1480	g)	Medication Dis	spensi	ng in the Absence of a Pharmacist. The availability of
1481	O,		-	as for immediate therapeutic use during those hours when the
1482		•		y is not open shall be met in the following manner:
1483		-		
1484		1) An afte	r-houi	cabinet, which is a locked cabinet or other enclosure located
1485				pharmacy area containing a minimal supply of the most
1486				quired medication, may be utilized provided that only
1487		-	•	cifically authorized by the institution in which the pharmacy
1488		-		y obtain access and it is sufficiently secure to deny access to
1489				persons. After-hour cabinets shall only be used in the
1490				pharmacist. When medication is removed from the cabinet or
1491			-	valid practitioner's order-written physician's orders
1492				ne removal of the medication shall be placed in the cabinet or
1493			_	log shall be maintained within the cabinet or enclosure and
1494				rsonnel removing medication shall indicate on the log the
1495			-	he authorized personnel removing the medication, the name
1496		_		tion removed, the strength (if applicable), the quantity

1497 removed and the time of removal. An automated dispensing and storage 1498 system may be used as an after hours cabinet. This use shall be in compliance with Section 1330.680. 1499 1500 1501 2) Emergency kits containing those drugs that may be required to meet the 1502 immediate therapeutic needs of the patient, and that are not available from 1503 any other source in sufficient time to prevent risk of harm to patients by 1504 delay resulting from obtaining the drugs from the other source, may be utilized. Emergency kits shall be supplied and maintained under the 1505 supervision of a pharmacist. Drugs shall be removed from emergency kits 1506 1507 only by authorized pharmacy personnel or persons authorized to 1508 administer medication pursuant to a valid order by a practitioner licensed to prescribe in Illinois. Emergency kits shall be sealed in some manner 1509 1510 that will indicate when the kit has been opened. A label shall be affixed to 1511 the outside of the emergency kit indicating the beyond use date of the emergency kit. The beyond use date of the emergency kit shall be the 1512 earliest beyond use date of any drug contained in the kit. After an 1513 1514 emergency kit has been used or upon discovery that the seal has been broken or upon the occurrence of the beyond use date, the kit shall be 1515 secured and returned to the pharmacy to be checked and/or restocked by 1516 the last authorized user. If the pharmacy is closed at that time, the kit shall 1517 be returned when it opens. An automated dispensing and storage system 1518 may be used as an emergency kit. This use shall be in compliance with 1519 1520 Section 1330.680. 1521 1522 3) Whenever any drug is not available from night cabinets or emergency kits, 1523 and the drug is required to treat the immediate needs of a patient, the drug may be obtained from the pharmacy in sufficient quantity to meet the 1524 immediate need by an authorized nurse. When medication is removed 1525 1526 from the pharmacy by an authorized nurse, a copy of the licensed 1527 practitioner's order authorizing the removal of the medication shall be conspicuously placed in the pharmacy with the container from which the 1528 1529 drug was removed so that it will be found by a pharmacist and checked 1530 promptly. A form shall be available in the pharmacy upon which shall be recorded the signature of the authorized nurse who removed the 1531 1532 medication, the name, strength (if applicable) and quantity of medication 1533 removed. 1534 (Source: Amended at 49 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_) 1535 1536 1537

1537 Section 1330.530 Onsite Institutional Pharmacy Services 1538

1539	a)	Onsite	e Pharn	nacies. A pharmacy located in facilities licensed under the Nursing
1540		Home	Care A	Act, the Hospital Licensing Act, or the University of Illinois Hospital
1541		Act, o	r that a	re operated by the Department of Human Services or the Department
1542		of Co	rrection	ns, and that provide pharmacy services to residents, patients,
1543		emplo	yees, p	prescribers and students of these facilities, shall, in addition to other
1544		requir	ements	of the Act and this Part, comply with this Section.
1545				
1546	b)	Recor	dkeepii	ng Requirements
1547			-	
1548		1)	Every	prescription or medication order filled or refilled shall contain the
1549		ŕ	•	, initials or other unique identifier of the pharmacist (and pharmacy
1550				ician if one is used) who fills or refills the prescription or medication
1551				, or the name, initials or other unique identifier may be recorded on
1552				er appropriate, uniformly maintained and readily retrievable record
1553				ndicates, at least, the following information:
1554				
1555			A)	The name and dosage form of the drug;
1556				
1557			B)	The date of filling or refilling; and
1558			ŕ	
1559			C)	The quantity dispensed.
1560				
1561		2)	No pr	rescription may be dispensed for a period in excess of 15 months
1562			from	the date of the original issuance of the prescription by the prescriber.
1563				
1564		3)	The p	pharmacist-in-charge shall maintain or have access to the following
1565			record	ds for at least 5 years or as otherwise required by law:
1566				
1567			A)	Records of medication orders and medication administration to
1568				patients;
1569				
1570			B)	Procurement records for controlled substances;
1571				
1572			C)	Records of packaging, bulk compounding or manufacturing; and
1573				
1574			D)	Records of actions taken pursuant to drug recalls.
1575				
1576	c)	Label	ing Rec	quirements
1577				
1578		1)	All m	nedication repackaged by the pharmacy for future use inside the
1579			institu	ution or facility and not intended for immediate dispensing to a
1580			specif	fic patient shall be identified as follows:
1581				

1582		A)	_	dose or multi-dose drugs, except sterile solutions to which a
1583			drug h	as been added, shall be labeled with:
1584				
1585			i)	Brand and/or generic name;
1586				
1587			ii)	Strength (if applicable);
1588				
1589			iii)	Beyond use date; and
1590				
1591			iv)	Reference code to identify source and lot number.
1592				
1593		B)	Sterile	solutions to which drugs have been added shall contain on
1594			the out	ter label:
1595				
1596			i)	Name, concentration and volume of the base sterile
1597			,	solution;
1598				,
1599			ii)	Name and strength of drugs added;
1600			,	
1601			iii)	Beyond use date and time of the admixture; and
1602			111)	20 joine 450 and and and of the administration, and
1603			iv)	Reference code to identify source and lot number of drugs
1604				added.
1605				added.
1606	2)	A11 m	edicatio	n prepared by the pharmacy for immediate dispensing to a
1607	2)			at or resident in the institution or facility shall be identified
1608		as fol	-	it of resident in the institution of facility shall be facilitied
1609		as 101	iows.	
1610		A)	Single	dose or multi-dose drugs, except parenteral solutions to
1610 1611		A)	_	a drug has been added, shall be identified with:
1612			WIIICII	a drug has been added, shan be identified with.
1612 1613			i)	Brand and/or generic name; and
1613 1614			1)	brand and/or generic name, and
1614 1615			::7	Strongth (if applicable)
			ii)	Strength (if applicable).
1616 1617		D)	C4amila	as lutions to which down born bean added shall be identified
1617		B)		solutions to which drugs have been added shall be identified
1618			with:	
1619			• \	
1620			i)	Name, concentration and volume of the base sterile
1621				solution;
1622			•••	
1623			ii)	Name and strength of drugs added; and
1624				

1625			iii) Beyond use date and time of the admixture.
1626			
1627		C)	All medication dispensed to a specific patient in the institution
1628			shall be dispensed in a container identified with the name of the
1629			patient and the patient's location. Those institutions or facilities
1630			utilizing a unit-dose and medication cart system may identify the
1631			name of the patient and the patient's location on the outside of the
1632			bin of the medication cart, when those carts are filled by the
1633			pharmacy.
1634			
1635	3)	Label	s on all medications dispensed by the pharmacy for immediate
1636		disper	nsing to a patient being discharged, emergency room patient and/or
1637		emplo	yee shall contain the following:
1638			
1639		A)	The name and dosage form of the drug;
1640			
1641		B)	The date filled;
1642			
1643		C)	The quantity dispensed; and
1644			
1645		D)	Directions for use.
1646			
1647	4)	Invest	tigational new drugs, authorized by the U.S. Food and Drug
1648		Admi	nistration, shall be dispensed pursuant to a valid prescription order of
1649		the pr	incipal physician-investigator or the principal physician-
1650			igator's authorized clinician. All investigational drugs shall be
1651			I in and dispensed from the pharmacy and shall be identified with the
1652		follov	ving information:
1653			
1654		A)	Name of drug and strength (if applicable);
1655			
1656		B)	Beyond use date;
1657			
1658		C)	Reference code to identify source and lot number;
1659			
1660		D)	A label indicating "For Investigational Use Only"; and
1661		<b></b>	
1662		E)	Name and location of the patient. Those institutions or facilities
1663			utilizing a unit-dose and medication cart system may identify the
1664			name of the patient and the patient's location on the outside of the
1665			bin of the medication cart, when those carts are filled by the
1666 1667			pharmacy.
1667			

1668 1669 1670 1671 1672 1673 1674		5)	for the original issued prescri	rmacist providing a copy of a prescription to an ultimate consumer e purpose of transfer or any other purpose shall cancel the face of the all prescription and record the date the copy is issued, to whom , and the pharmacist's signature on the face of the original iption. Copies of prescriptions shall be marked "For Information sees Only" and require prescriber authorization to fill.
1675 1676	d)	Staffin	ng of the	e Pharmacy
		1)	Thoma	composibilities of the pharmonist in abores shall include:
1677 1678		1)	The re	esponsibilities of the pharmacist-in-charge shall include:
1679			A)	Supervision of all the activities of all employees as they relate to
1680				the practice of pharmacy;
1681				
1682			B)	Establishment and supervision of the method and manner for
1683			,	storage, dispensing and safekeeping of pharmaceuticals in all areas
1684				of the institution or facility, including maintenance of security
1685				provisions to be used when the pharmacy is closed. The following
1686				security provisions shall be utilized:
1687				became provisions shall be attribute.
1688				i) The pharmacy shall be staffed at all times by a registered
1689				pharmacist during open hours; and
1690				pharmaeist during open nours, and
1691				ii) Only registered, certified, and licensed individuals under
1692				this Part shall have access to the pharmacy, except as
1693				provided in Section 1330.530(e)(1);
1694				provided in Section 1330.330(c)(1),
1695			C)	Establishment and supervision of the recordkeeping system for the
1696			C)	purchase, sale, delivery, possession, storage and safekeeping of
1697				drugs;
1698				diugs,
1699			D)	The development and implementation of a procedure to be utilized
1700			2)	in the event of a drug recall that can be readily activated to assure
1701				that all drugs included on the recall are returned to the pharmacy
1702				for proper disposition;
1703				for proper disposition,
1704			E)	Establishment of specifications for the procurement of all drugs
1705			<b>L</b> )	that will be dispensed by the pharmacy; and
1706				that will be dispensed by the pharmacy, and
1707			F)	Establishment and supervision of a method of documenting an oral
1708			• /	prescription from a practitioner licensed to prescribe to a
1709				pharmacist and for transmission of that information to the

1710		appropriate members of the nursing staff of the institution or
1711		facility.
1712		
1713	2)	The operations of the pharmacy and the maintenance of security
1714		provisions are the responsibility of the pharmacist-in-charge whether the
1715		owner is a sole proprietor, partnership, association, corporation or any
1716		other entity.
1717		·
1718	<del>3)</del>	Within 30 days after the change of a pharmacist-in-charge, the Division
1719	,	shall be notified in writing by the departing pharmacist-in-charge.
1720		
1721	4)	The departing pharmacist in charge shall, on the effective date of the
1722	,	change, inventory the following controlled substances:
1723		
1724		A) All Schedule II drugs, as defined in the Illinois Controlled
1725		Substances Act, by actual physical count; and
1726		The state of the s
1727		B) All other scheduled drugs, as defined in the Illinois Controlled
1728		Substances Act, by estimated count.
1729		~, · , ·
1730	<del>5)</del>	The inventory shall constitute, for the purpose of this Section, the closing
1731	- /	inventory of the departing pharmacist in charge and the initial inventory
1732		of the incoming pharmacist in charge. This inventory record shall be
1733		preserved in the pharmacy for a period of 5 years. An affidavit attesting to
1734		the completion and preservation of the inventory record bearing the date
1735		of the inventory and the signatures of the departing and incoming
1736		pharmacist in charge shall be submitted to the Division, at its principal
1737		office, within 30 days after the change in the pharmacist in charge.
1738		,
1739	<del>6)</del>	Failure on the part of a registrant to provide the affidavit required in
1740	- /	subsection (d)(5) shall be grounds for denying an application or renewal
1741		application for a pharmacy license or for disciplinary action against a
1742		registrant. Denial shall be based on the recommendation of the Board.
1743		registration between the control of the board.
1744	<del>7)</del>	In the event the departing pharmacist-in-charge refuses to complete the
1745	,,	inventory as provided for in subsection (d)(4), or that pharmacist-in-
1746		charge is incapacitated or deceased, the initial inventory for the incoming
1747		pharmacist in charge shall be the inventory as completed by the incoming
1748		pharmacist in charge. The incoming pharmacist in charge will not be
1749		responsible for any discrepancy that may exist in the inventory prior to
1750		initial inventory.
1751		
-· <b>v</b> -		

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- When the accuracy, relevance or completeness of any submitted documentation is reasonably questioned by the Division because of lack of information, discrepancies or conflicts in information given, or a need for clarification, the registrant will be required to:
  - A) Provide information as may be necessary; and/or
  - B) Appear for an interview before the Board to explain the relevance or sufficiency, clarify information given or clear up any discrepancies or conflicts in information.
- Pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue or resale dispensed medications, chemicals, poisons or medical devices, except for:
  - A) Medical devices that can be properly sanitized prior to reuse, resale or re-rent; and
  - B) Medications that are dispensed and stored under conditions defined and supervised by the pharmacist and are unopened in sealed, intact and unaltered containers that meet the standards for light, moisture and air permeation as defined by a current United States Pharmacopeia National Formulary published by the United States Pharmacopeial Convention, Inc.
- e) Medication Dispensing in the Absence of a Pharmacist. The availability of necessary medications for immediate therapeutic use during those hours when the institutional pharmacy is not open shall be met in the following manner:
  - An after-hour cabinet, which is a locked cabinet or other enclosure located outside of the pharmacy area containing a minimal supply of the most frequently required medication, may be utilized provided that only personnel specifically authorized by the institution in which the pharmacy is located may obtain access and it is sufficiently secure to deny access to unauthorized persons. After-hour cabinets shall only be used in the absence of a pharmacist. When medication is removed from the cabinet or enclosure, a valid practitioner's order written physician's orders authorizing the removal of the medication shall be placed in the cabinet or enclosure. A log shall be maintained within the cabinet or enclosure and authorized personnel removing medication shall indicate on the log the signature of the authorized personnel removing the medication, name of the medication removed, the strength (if applicable), the quantity removed and the time of removal. An automated dispensing and storage system may be used as an

after hours cabinet. This use shall be in compliance with Section 1330.680.

- 2) Emergency kits containing those drugs that may be required to meet the immediate therapeutic needs of the patient, and that are not available from any other source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining the drugs from the other source, may be utilized. Emergency kits shall be supplied and maintained under the supervision of a pharmacist. Drugs shall be removed from emergency kits only by authorized pharmacy personnel, persons authorized to administer medication pursuant to a valid order by a practitioner licensed to prescribe in Illinois. Emergency kits shall be sealed in some manner that will indicate when the kit has been opened. A label shall be affixed to the outside of the emergency kit indicating the beyond use date of the emergency kit. The beyond use date of the emergency kit shall be the earliest beyond use date of any drug contained in the kit. After an emergency kit has been used or upon discovery that the seal has been broken or upon the occurrence of the beyond use date, the kit shall be secured and returned to the pharmacy to be checked and/or restocked by the last authorized user. If the pharmacy is closed at such time, the kit shall be returned when it opens. An automated dispensing and storage system may be used as an emergency kit. This use shall be in compliance with Section 1330.680.
- Whenever any drug is not available from night cabinets or emergency kits, and the drug is required to treat the immediate needs of a patient, the drug may be obtained from the pharmacy in sufficient quantity to meet the immediate need by an authorized nurse. When medication is removed from the pharmacy by an authorized nurse, a copy of the licensed practitioner's order authorizing the removal of the medication shall be conspicuously placed in the pharmacy with the container from which the drug was removed so that it will be found by a pharmacist and checked promptly. A form shall be available in the pharmacy upon which shall be recorded the signature of the authorized nurse who removed the medication, the name, strength (if applicable) and quantity of medication removed.
- 4) Drugs may be dispensed from the emergency room only by a practitioner licensed to prescribe and dispense, and only to patients treated in the institution. This shall occur only during hours in which outpatient institutional pharmacy services are not available. The quantity dispensed should be limited to no more than a 72 hour supply, except for antimicrobial drugs and unit of use packages (e.g., inhalers, ophthalmic,

1838		otics, etc.), to meet the immediate needs of the patient until pharmacy
1839		services are available. Drugs dispensed in this manner must meet all
1840		labeling requirements pertaining to community pharmacies as specified in
1841		Section 1330.500. There shall be written policies and procedures,
1842		approved by the medical staff, regarding the dispensing of drugs from the
1843		emergency room.
1844		
1845	f)	Pharmacies that compound and dispense sterile products shall comply with
1846		Section 1330.640.
1847		
1848	g)	Pharmacies that utilize automated dispensing and storage systems shall comply
1849		with Section 1330.680.
1850	<b>.</b> ~	
1851	(Sourc	ee: Amended at 49 Ill. Reg, effective)
1852	G 41 1220	
1853	Section 1330.	570 Outpatient Clinic Pharmacy Services
1854	- \	Octobring Citate Discourse in the design of the second second in the
1855 1856	<u>a)</u>	Outpatient Clinic Pharmacies are defined as those pharmacies not located in or
		servicing patients of a facility licensed as defined in Section 1330.520(a), whether
1857 1858		located in a health care facility or another location that provides outpatient
1859		treatment or care.
1860		1) An outpatient is an ambulatory patient who comes to an outpatient clinic
1861		to receive health care services related to the objectives of the outpatient
1862		clinic and departs within 24 hours.
1863		ennie and departs within 21 nours.
1864		2) An outpatient drug order is defined as an order written by a medical
1865		practitioner engaged in the practice of that clinic and ordered for services
1866		received in that clinic in conjunction with health care services related to
1867		the objectives of that clinic.
1868		
1869	<u>b)</u>	Contracting Services. Outpatient clinic pharmacies may contract with outpatient
1870	_	clinics to provide pharmacy services. The contract must define the scope of
1871		pharmacy services to be provided and delineate the specific duties and
1872		responsibilities of each party.
1873		
1874	<u>c)</u>	Investigational new drugs, authorized by the U.S. Food and Drug Administration,
1875		shall be dispensed pursuant to a valid drug order of the principal physician-
1876		investigator or the principal physician-investigator's authorized clinician. All
1877		investigational drugs shall be stored in and dispensed from the pharmacy and shall
1878		be identified with the following information:
1879		
1880		1) Name of drug and strength (if applicable);

1881			
1882		<u>2)</u>	Beyond use date;
1883			
1884		<u>3)</u>	Reference code to identify source and lot number;
1885			
1886		<u>4)</u>	A label indicating "For Investigational Use Only"; and
1887			
1888		<u>5)</u>	Name and location of the patient. Those institutions or facilities utilizing
1889			a unit-dose and medication cart system may identify the name of the
1890			patient and the patient's location on the outside of the bin of the
1891			medication cart, when those carts are filled by the pharmacy.
1892			
1893	<u>d)</u>	The ph	narmacist-in-charge of the outpatient clinic pharmacy or his/her pharmacist
1894			ee may, in the best interest of the patients served, establish one or more lists
1895			kind and quantity of drugs to be kept in one or more automatic dispensing
1896		machir	nes at all times within the outpatient clinic. A copy of the list of items
1897			in automatic dispensing machines must be kept by the pharmacist-in-
1898		charge	or his/her pharmacist designee.
1899			
1900	<u>e)</u>	Staffin	ag of the Pharmacy
1901			
1902		<u>1)</u>	Each outpatient clinic pharmacy shall be directed by a pharmacist-in-
1903			charge, who is knowledgeable in and thoroughly familiar with the
1904			specialized functions of outpatient clinic pharmacy.
1905			
1906		<u>2)</u>	The pharmacist-in-charge shall ensure that all staff shall be adequately
1907			trained. The pharmacist-in-charge shall develop and implement written
1908			policies and procedures to specify the duties to be performed by each
1909			employee.
1910			
1911		<u>3)</u>	All functions and activities of pharmacy technicians shall be personally
1912			and directly supervised by an adequate number of licensed pharmacists to
1913			ensure that all such functions and activities are performed competently.
1914			
1915		<u>4)</u>	The pharmacist-in-charge shall meet the requirements of 1330.660 in
1916			addition to the following:
1917			
1918			A) The pharmacist-in-charge of an outpatient clinic pharmacy shall be
1919			assisted by a sufficient number of additional pharmacists and
1920			personnel, as may be required to operate such pharmacy
1921			competently, safely, and to meet the needs of the patients of the
1922			clinic facility.
1923			

1924			<u>B)</u>	Establishment and supervision of the method and manner for
1925				storage, dispensing and safekeeping of pharmaceuticals in all areas
1926				of the outpatient clinic, including maintenance of security
1927				provisions to be used when the pharmacy is closed.
1928				
1929			<u>C)</u>	The development and implementation of a procedure to be utilized
1930				in the event of a drug recall that can be readily activated to assure
1931				that all drugs included on the recall are returned to the pharmacy
1932				for proper disposition.
1933				
1934	<u>f)</u>	Recor	<u>dkeepin</u>	g Requirements
1935			_	
1936		<u>1)</u>		drug order filled shall contain the name, initials or other unique
1937			•	fier of the pharmacist (and pharmacy technician if one is used) who
1938				r refills the drug order, or the name, initials or other unique identifier
1939			_	e recorded on another appropriate, uniformly maintained and readily
1940			retriev	vable record that indicates, at least, the following information:
1941				
1942			<u>A)</u>	The name and dosage form of the drug;
1943			D)	The data of filling or refilling, and
1944 1945			<u>B)</u>	The date of filling or refilling; and
1943 1946			<u>C)</u>	The quantity dispensed.
1947			<u>C)</u>	The quantity dispensed.
1948		<u>2)</u>	The pl	harmacist-in-charge shall maintain or have access to the following
1949		<u>=</u> /	_	ls for at least 5 years or as otherwise required by law:
1950				
1951			<u>A)</u>	Records of drug orders;
1952				
1953			<u>B)</u>	Records of packaging, bulk compounding or manufacturing; and
1954				
1955			<u>C)</u>	Records of actions taken pursuant to drug recalls.
1956				
1957	<u>g)</u>	<u>Labeli</u>	ng Req	<u>uirements</u>
1958				
1959		<u>1)</u>		edication repackaged by the pharmacy for future use inside the
1960				tion or facility and not intended for immediate dispensing to a
1961			specif	ic patient shall be identified as follows:
1962				
1963			<u>A)</u>	Single dose or multi-dose drugs, except sterile solutions to which a
1964				drug has been added, shall be labeled with:
1965				
1966				i) Brand and/or generic name;

1967				
1968			<u>ii)</u>	Strength (if applicable);
1969				
1970			<u>iii)</u>	Beyond use date; and
1971				
1972			<u>iv)</u>	Reference code to identify source and lot number.
1973				
1974		<u>B)</u>	-	solutions to which drugs have been added shall contain on
1975			the ou	ter label:
1976			• \	N
1977			<u>i)</u>	Name, concentration and volume of the base sterile
1978				solution;
1979 1980			:::\	Name and atmosphile of draws added.
1980			<u>ii)</u>	Name and strength of drugs added;
1982			iii)	Beyond use date and time of the admixture; and
1983			<u>111)</u>	beyond use date and time of the admixture, and
1984			<u>iv)</u>	Reference code to identify source and lot number of drugs
1985			<u>1V)</u>	added.
1986				dddd.
1987	2)	All m	nedicatio	n prepared by the pharmacy for immediate dispensing to a
1988	<u>=7</u>			nt or resident in the institution or facility shall be identified
1989			llows:	
1990				
1991		A)	Single	dose or multi-dose drugs, except parenteral solutions to
1992			which	a drug has been added, shall be identified with:
1993				
1994			<u>i)</u>	Brand and/or generic name; and
1995				
1996			<u>ii)</u>	Strength (if applicable).
1997				
1998		<u>B)</u>	Sterile	solutions to which drugs have been added shall be identified
1999			with:	
2000				
2001			<u>i)</u>	Name, concentration and volume of the base sterile
2002				solution;
2003			•••	
2004			<u>ii)</u>	Name and strength of drugs added; and
2005			****	Description data and the section of
2006			<u>iii)</u>	Beyond use date and time of the admixture.
2007	2)	Λ 11	nodiactic	n diamongad to a amogific nations in the institution shall be
2008 2009	<u>3)</u>			n dispensed to a specific patient in the institution shall be
Z009		uispe	insed in a	container identified with the name of the patient and the

2010		patient's location. The	hose outpatient clini	cs utilizing a unit-dose and
2011		medication cart syste	em may identify the	name of the patient and the
2012		patient's location on	the outside of the bi	n of the medication cart, when
2013		those carts are filled	by the pharmacy.	
2014				
2015	<u>h)</u>	Storage. Pharmacies license	d under this Part sha	all comply with Sections
2016		1330.600, 1330.610, 1330.6	30, and 1330.680.	
2017				
2018	(Sou	rce: Added at 49 Ill. Reg	, effective	)
2019		_		
2020		SUBPART F: P	HARMACY STAN	DARDS
2021				
2022	Section 133	0.610 Pharmacy Structural/I	<b>Equipment Standa</b>	rds
2023				
2024	All pharmac	eies must comply with the follo	wing provisions:	
2025				
2026	a)	Notification shall be submit	ted to the Division t	hat an existing pharmacy will be
2027		remodeled. Approval is req	uired prior to initiat	ion of any remodel.
2028				
2029	b)			lispensing, and drug storage areas
2030		of the pharmacy must be con	ntiguous and have a	connecting door for access
2031		between the pharmacy and d	lrug storage area.	
2032				
2033	c)	The pharmacy area and all s	tore rooms shall be	well-lighted and properly
2034		ventilated.		
2035				
2036	d)	•		rescription drugs. No personal or
2037			•	efrigeration shall be capable of
2038		0 1	•	ble with the proper storage of
2039		drugs requiring refrigeration	or freezing.	
2040				
2041	e)	•		of merchandise that interferes
2042		with the practice of pharmac	cy.	
2043	0			
2044	f)	Suitable current reference so		
2045		•	* *	all include Facts and Comparisons
2046		<u>-</u>		e references determined by the
2047		Division to be pertinent to the	ne practice carried o	n in the licensed pharmacy.
2048		A . 1 1 1 11 1 1 1	1	
2049	g)	A telephone shall be immed	nately accessible in	the pharmacy area.
2050	1 \		d dialog as a second	and the second s
2051	h)	i nese requirements are in ac	action to any other	requirements found in this Part.
2052				

2053	i)	At a	minimum, the equipment and references listed in Section 1330.640 must be
2054		main	tained at all dispensing pharmacies.
2055			
2056	(Sour	ce: An	nended at 49 Ill. Reg, effective)
2057			
2058	Section 1330	).660 F	Pharmacist-in-Charge
2059			
2060	a)	No p	harmacy shall be granted a license without a pharmacist being designated on
2061		the p	harmacy license as pharmacist-in-charge.
2062			
2063	b)	A ph	armacy shall have one pharmacist-in-charge who shall be routinely and
2064		activ	ely involved in the operation of the pharmacy.
2065			
2066	c)	A ph	armacist may be the pharmacist-in-charge for more than one pharmacy;
2067	,	-	ever, the pharmacist-in-charge must work an average of at least 8 hours per
2068			at each location where the pharmacist is the pharmacist-in-charge. If the
2069			macist-in-charge is not involved in verifying or dispensing prescriptions, the
2070		-	s worked in the pharmacy must be documented. If a pharmacist-in-charge is
2071			leave of more than 90 days, a new pharmacist-in-charge must be designated.
2072			
2073	d)	The r	responsibilities of the pharmacist-in-charge shall include:
2074	,		
2075		1)	Supervision of all activities of all employees as they relate to the practice
2076		,	of pharmacy;
2077			1
2078		2)	Establishment and supervision of the method and manner for storage and
2079		,	safekeeping of pharmaceuticals, including maintenance of security
2080			provisions to be used when the pharmacy is closed (see Section 1330.600);
2081			and
2082			
2083		3)	Establishment and supervision of the recordkeeping system for the
2084		- /	purchase, sale, delivery, possession, storage and safekeeping of drugs.
2085			r
2086	e)	The o	operations of the pharmacy and the establishment and maintenance of
2087	- /		rity provisions are the dual responsibility of the pharmacist-in-charge and the
2088			er of the pharmacy.
2089		0 1110	a or the primitine).
2090	f)	With	in 30 days after a change of a pharmacist-in-charge, the Division shall be
2091	-/		ied in writing by the departing pharmacist-in-charge and the pharmacy
2092			se holder.
2093			
_			

2094	g)	In addition to notifying the Division within 30 days, the incoming departing
2095		pharmacist-in-charge shall, on the effective date of the change, inventory the
2096		following controlled substances:
2097		
2098		1) All Schedule II drugs, as defined in the Illinois Controlled Substances Act,
2099		by actual physical count; and
2100		
2101		2) All other scheduled drugs, as defined in the Illinois Controlled Substances
2102		Act, by estimated count.
2103		
2104		3) The pharmacy license holder is equally responsible for ensuring that such
2105		inventory is completed.
2106		
2107	h)	The inventory described in subsection (g) shall constitute, for the purpose of this
2108	,	Section, the closing inventory of the departing pharmacist-in-charge and the
2109		initial inventory of the incoming pharmacist-in-charge. This inventory record
2110		shall be preserved in the pharmacy for a period of 5 years. An affidavit attesting
2111		to the completion of the inventory and preservation of the inventory record,
2112		bearing the date of the inventory and the name and signatures of the departing and
2113		the incoming pharmacist-in-charge, shall be submitted to the Division at its
2114		principal office within 30 days after the change in the pharmacist in charge.
2115		
2116	<u>i)</u>	Failure on the part of a pharmacy to provide notification of a change in
2117	<del></del>	pharmacist-in-charge required in subsection (f) shall be grounds for denying an
2118		application or renewal application for a pharmacy license or for disciplinary
2119		action against a pharmacy.
2120		
2121	j <del>i</del> )	In the event the departing pharmacist-in-charge refuses to complete the inventory
2122	<i>#</i> /	as provided for in subsection (g), or that pharmacist-in-charge is incapacitated or
2123		deceased, the initial inventory for the incoming pharmacist-in-charge shall be the
2124		inventory as completed by the incoming pharmacist-in-charge. The incoming
2125		pharmacist-in-charge will not be responsible for any discrepancy that may exist in
2126		the inventory prior to his or her initial inventory.
2127		
2128	<u>k</u> j)	When the accuracy, relevance or completeness of any submitted documentation is
2129	_3/	questioned by the Division, because of a lack of information, discrepancies or
2130		conflicts in information given, or a need for clarification, the registrant will be
2131		required to:
2132		•
2133		1) Provide information as may be necessary; and/or
2134		•

2135 2136		2)		ear for an interview before the Board to explain the relevance or ciency, clarify information given, or clear up any discrepancies or
2137				lict of information.
2138			Comi	net of information.
2139	<u>l</u> k)	Reco	rde chal	ll be retained as provided for in Section 18 of the Act. Invoices for all
2140	<u>i</u> K)			s and controlled substances shall be maintained for a period of 5 years
2141				e or at a central location where records are readily retrievable.
2142				Il be maintained on site for at least one year from the date of the
2143		invoi		if be maintained on site for at least one year from the date of the
2143		111101	ce.	
2144	<u>m</u> l)	When	over a	pharmacy intends on changing or adding to the type of pharmacy
2145	<u>111</u> +)			Fers, as listed in Sections 1330.500, 1330.510, 1330.520, 1330.530,
2140				330.560 and 1330.640, it shall notify the Division no less than 30 day
				·
2148 2149		prior	to the C	change or addition.
	(\$0	11maa. Am	andad	at 40 III. Dag affective
2150	(30	uice. An	lended	at 49 Ill. Reg, effective)
2151	Section 12	20 600 A	utomo	ted Dianonsing and Storage Systems
<ul><li>2152</li><li>2153</li></ul>	Section 13	30.000 A	utoma	ted Dispensing and Storage Systems
	2)	This	Castian	sate fauth standards for pharmacias whose processes includes the vec-
2154	a)			sets forth standards for pharmacies whose practice includes the use
2155				d dispensing and storage systems. Automated dispensing and storage
2156		syste	ms snai	l not be used in nuclear pharmacies.
2157	1- \	<b>A</b> 4 -	4 1 T	Diamanaiana and Ghannan Garahaman
2158	b)	Auto	mated 1	Dispensing and Storage Systems
2159		1)	ъ	
2160		1)		mentation as to type of equipment, serial numbers, content, policies
2161			-	procedures, and locations shall be maintained on-site in the pharmacy
2162				eview by the Division. Documentation shall include, but not be
2163			limit	ed to:
2164				
2165			A)	Name and address of the pharmacy or facility where the automated
2166				dispensing and storage system is operational;
2167			ъ,	
2168			B)	Manufacturer's name and model;
2169				
2170			C)	Quality assurance policy and procedures to determine continued
2171				appropriate use and performance of the automated device; and
2172				
2173			D)	Policies and procedures for system operation, safety, security,
2174				accuracy, patient confidentiality, access, controlled substances,
2175				data retention or archival, definitions, downtime procedures,
2176				emergency or first dose procedures, inspection, installation
2177				requirements, maintenance, medication security, quality assurance

2178 2179				cation inventory, staff education and training, system set-up nalfunction.
2180			and n	idiffulletion.
2181	2)	Autor	mated d	ispensing and storage systems shall be used only in settings
2182	2)			nedication orders and prescriptions are reviewed by a
2183				a accordance with established policies and procedures and
2184		-		cy practice. This provision shall not apply when used as an
2185		_	-	abinet or emergency kit as provided in Section 1330.530(e).
2186				
2187	3)	Autor	mated d	ispensing and storage systems shall have adequate security
2188	ŕ	systei	ms and	procedures, evidenced by written pharmacy policies and
2189		proce	dures, t	0:
2190		_		
2191		A)	Preve	nt unauthorized access or use;
2192				
2193		B)	Comp	bly with any applicable federal and State regulations; and
2194				
2195		C)	Main	tain patient confidentiality.
2196				
2197	4)			or electronic data kept by automated dispensing and storage
2198		syste	ms shall	meet the following requirements:
2199				
2200		A)		vents involving access to the contents of the automated
2201			dispe	nsing and storage systems must be recorded electronically;
2202		ъ,	ъ	
2203		B)		ds must be maintained by the pharmacy and must be readily
2204			avana	able to the Division. The records shall include:
2205			:\	Identity of greatens accessed.
2206 2207			i)	Identity of system accessed;
2207			;;)	Identification of the individual accessing the system
2208 2209			ii)	Identification of the individual accessing the system;
2210			iii)	Type of transaction;
2210			111)	Type of transaction,
2212			iv)	Name, strength, dosage form and quantity of the drug
2212			11)	accessed;
2214				accessed,
2215			v)	Name of the patient for whom the drug was ordered;
2216			• /	Times of the puncture for whom the drog was ordered,
2217			vi)	Identification of the registrants stocking or restocking and
2218			,	the pharmacist checking for the accuracy of the
2219				medications to be stocked or restocked in the automated
2220				dispensing and storage system; and
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- vii) Such additional information as the pharmacist-in-charge may deem necessary.
- The stocking or restocking of all medications in the automated dispensing and storage systems shall be accomplished by registrants under the Act or, alternatively, the pharmacist-in-charge may designate a facility's appropriately trained facility employee that is licensed pursuant to the Nurse Practice Act [225 ILCS 65] or Physician Assistant Practice Act of 1987 [225 ILCS 95] to perform the stocking or restocking. A pharmacist-in-charge who delegates stocking/restocking in this manner shall remain responsible for ensuring that the automated dispensing and storage system is stocked/restocked accurately and in accordance with established, written pharmacy policies and procedures.
- 6) All medications stored in the automated dispensing and storage systems shall be packaged as a unit of use for single patient use (e.g., unit dose tab/cap, tube of ointment, inhaler, etc.) and labeled as specified in this subsection (b)(6):
  - A) Sterile solutions to which a drug or diluent has been added, or that are not in their original manufacturer's packaging, shall contain the following information on the outer label:
    - i) Name, concentration and volume of the base sterile solution;
    - ii) Name and strength of drugs or diluent added;
    - iii) Date and beyond use date of the admixture. The beyond use date, unless otherwise specified in the individual compendia monograph, shall be no later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged; and
    - iv) Reference code to identify source and lot number of drugs or diluent added.
  - B) Non-parenterals repackaged for future use shall be identified with the following information:
    - i) Brand and/or generic name;

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- ii) Strength (if applicable);
- iii) Beyond use date. Unless otherwise specified in the individual monograph, the beyond use date shall be no later than the beyond use date on the manufacturer's container or one year from the date the drug is repackaged; and
- iv) Reference code to identify source and lot number.
- C) Exceptions to the "unit of use" requirements in this subsection (b)(6) are as follows:
  - i) Injectable medications stored in their original multi-dose vial (e.g., insulin, heparin) when the medication may be withdrawn into a syringe or other delivery device for single patient use;
  - ii) Over-the-counter (OTC) products stored in their original multi-dose container (e.g., antacids, analgesics) when the medication may be withdrawn and placed into an appropriate container for single patient use; or
  - iii) Topical preserved surgical facility medications, such as eyedrops, eardrops, creams and ointments, when properly stored in their original multidose containers, applied and handled per Centers for Disease Control and Prevention and Institute for Safe Medication Practices infection control guidelines and best practices, which include mandatory training and regular competency and monitoring protocols, provided multidose and in compliance with manufacturer labeling, and used, then discarded, within the manufacturer's expiration date or facility's "beyond use" date.
- D) The pharmacy providing services to the University of Illinois
  College of Veterinary Medicine shall be exempt from the
  requirement that all medications stored in the automated
  dispensing and storage systems be packaged as a unit for single
  patient use. This exemption is solely for dispensing medications to
  animals.
- 7) For medication removed from the system for on-site patient administration, the system must document the following information:

2307			
2308		A)	Name of the patient or resident;
2309			•
2310		B)	Patient's or resident's unique and permanent identifier, such as
2311		ĺ	admissions number or medical records number;
2312			
2313		C)	Date and time medication was removed from the system;
2314		,	,
2315		D)	Name, initials or other unique identifier of the person removing the
2316		,	drug; and
2317			
2318		E)	Name, strength and dosage form of the drug or description of the
2319		,	medical device removed. The documentation may be on paper, via
2320			electronic media or via any other media or mechanisms as set forth
2321			by the Act or this Part or as approved by the Division.
2322			of the control and office of the control of the con
2323	8)	The a	utomated dispensing and storage systems shall provide a mechanism
2324	,		curing and accounting for medications once removed from and
2325			quently returned to the automated dispensing and storage systems
2326			return bin). No medication or device shall be returned directly to the
2327		_	m for immediate reissue or reuse by a non-registrant under the Act.
2328		-	cation or devices once removed shall not be reused or reissued except
2329		for:	r
2330			
2331		A)	Medical devices that can be properly sanitized prior to reuse or
2332		/	reissue; and
2333			
2334		B)	Medication that is dispensed and stored under conditions defined
2335		-,	and supervised by the pharmacist and are unopened in sealed,
2336			intact and unaltered containers that meet the standards for light,
2337			moisture and air permeation as defined by the current USP/NF, or
2338			by the USP Conventions, Inc.
2339			· <b>,</b>
2340	9)	The a	utomated dispensing and storage systems shall provide a mechanism
2341	- /		curing and accounting for wasted medications or discarded
2342			cations.
2343			
2344	10)	The a	uality assurance documentation for the use and performance of the
2345	- /	_	nated dispensing and storage systems shall include at least the
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2347		•	
2348		A)	Safety monitors (e.g., wrong medications removed and
2349		,	administered to patient);
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2350			
2351		B)	Accuracy monitors (e.g., filling errors, wrong medications
2352			removed); and
2353			
2354		C)	Security monitors (e.g., unauthorized access, system security
2355			breaches, controlled substance audits).
2356			
2357	11)	Error	s in the use or performance of the automated dispensing and storage
2358		systei	ms resulting in patient hospitalization or death shall be reported to the
2359		Divis	ion by the pharmacist-in-charge within 30 days after acquiring
2360		know	ledge of the incident.
2361			
2362	12)	Polic	y and procedures for the use of the automated dispensing and storage
2363	,		ms shall include a requirement for pharmacist review of the
2364		•	ription or medication order prior to the system profiling and/or
2365		-	val of any medication from the system for immediate patient
2366			nistration. This does not apply to the following situations:
2367			
2368		A)	The system is being used as an after-hours cabinet for medication
2369		11)	dispensing in the absence of a pharmacist (see Section
2370			1330.530(e)(1));
2371			1330.330(0)(1)),
2372		B)	The system is being used in place of an emergency kit (see Section
2372		D)	1330.530(e)(2));
2374			1330.330(C)(2)),
2375		C)	The system is being used to provide access to medication required
2376		C)	to treat the immediate needs of a patient (see Section
2377			1330.530(e)(3)). A sufficient quantity to meet the immediate
2378			• • • •
2379			needs of the patient may be removed until a pharmacist is on duty
			and available to review the prescription or medication order. A
2380			pharmacist shall check the orders promptly once on duty (e.g.,
2381			floor stock system, emergency department, surgery, ambulatory
2382			care or same day surgery, observation unit, etc.).
2383	12)	D 1'	
2384	13)		ies and procedures for the use of the automated dispensing and
2385		storag	ge systems shall include the following:
2386			
2387		A)	List of medications to be stored in each system;
2388			
2389		B)	List of medications qualifying for emergency or first dose removal
2390			without pharmacist prior review of the prescription or medication
2391			order.
2392			

2393 2394		14)	_		st-in-charge shall maintain or have access to all records or a specified in this Section for 5 years or as otherwise
2395				ed by la	•
2396			require	ca by ia	w.
2397		15)	Δ con	v of all	pharmacy policies and procedures related to the use of an
2398		13)			pensing and storage system shall be maintained at all
2399					re the system is being used.
2400			iocatic	ons who	te the system is being used.
2401	c)	Duties	and Re	enoneih	oilities of the Pharmacist-in-Charge
2402	C)	Datie	and ite	oponsie	mines of the Finantiacist in Charge
2403		1)	The nl	narmaci	st-in-charge shall be responsible for:
2404		1)	The pi	iaiiiaci	of in charge shall be responsible for.
2405			A)	Assuri	ng that the automated dispensing and storage system is in
2406			11)		vorking order and accurately provides the correct strength,
2407				-	e form and quantity of the drug prescribed while maintaining
2408				_	oriate recordkeeping and security safeguards;
2409				арргор	riate recordiceping and security sureguards,
2410			B)	Establ	ishment of a quality assurance program prior to
2411			D)		nentation of an automated dispensing and storage system
2412				-	e supervision of an ongoing quality assurance program that
2413					ors appropriate use and performance of the automated
2414					sing and storage system, evidenced by written policies and
2415				-	lures developed by the pharmacy;
2416				procee	dires developed by the pharmacy,
2417			C)	Provid	ling the Division with written notice 30 days prior to the
2418			<i>C)</i>		ation of, or at the time of removal of, an automated storage
2419					spensing system. The notice must include, but is not limited
2420				to:	spensing system. The notice mast metade, out is not immed
2421					
2422				i)	The name and address of the pharmacy;
2423				1)	The name and address of the pharmacy,
2424				ii)	The address of the location of the automated dispensing
2425				11)	and storage system, if different from the address of the
2426					pharmacy;
2427					pharmacy,
2428				iii)	The automated dispensing and storage system's
2429				111)	manufacturer and model;
2430					manufacturer and model,
2431				iv)	The pharmacist-in-charge; and
2432				/	2 p
2433				v)	A written description of how the facility intends to use the
2434				• /	automated storage and dispensing system;
2435					and the storage and dispensing system,
00					

2436			D)	Determining and monitoring access to and the limits on access
2437				(e.g., security levels) to the automated storage and dispensing
2438				system. Access shall be defined by policies and procedures of the
2439				pharmacy and shall comply with any applicable State and federal
2440				regulations.
2441				
2442		2)	Addit	tional responsibilities of the pharmacist-in-charge or pharmacist
2443			desig	nated by the pharmacist-in-charge shall include:
2444			_	
2445			A)	Authorizing the assigning of access to, discontinuing access to, or
2446			ŕ	changing access to the system;
2447				•
2448			B)	Ensuring that access to the medications complies with State and
2449			ĺ	federal regulations, as applicable; and
2450				
2451			C)	Ensuring that the automated dispensing and storage system is
2452			,	stocked/restocked accurately and in accordance with established,
2453				written pharmacy policies and procedures.
2454				T and
2455	d)	An aı	ıtomate	d dispensing and storage system is authorized for use in any licensed
2456	ω,			g-term care facility, facilities serviced by an outpatient clinic
2457		_	-	r hospice residence ("facility"). For all nonresident pharmacies, the
2458		_		n-charge and all pharmacy personnel who provide services while
2459				resent at a facility located in Illinois must be licensed in Illinois. In
2460				ompliance with all other provisions in this Section, an automated
2461				nd storage system shall comply with the following:
2462		anspe	nome u	nd storage system shan compry with the rono wing.
2463		1)	Drug	s in the automated dispensing and storage system are not considered
2464		-/	_	nsed until removed from the system by authorized personnel at the
2465			_	ty, after being released by the pharmacy pursuant to a prescription,
2466				s otherwise provided for in this Part.
2467			unies	b other wise provided for in this fait.
2468		2)	Only	the doses of medication needed for contemporaneous administration
2469		2)	•	be removed from the automated pharmacy system at one time.
2470			may (	be femoved from the automated pharmacy system at one time.
2471		3)	Autor	mated dispensing and storage systems utilized at a facility shall
2472		3)		ate under the same license as the pharmacy utilizing it.
2473			opera	the under the same needse as the pharmacy utilizing it.
2474		4)	Δ11 re	ecords shall be maintained for a period of 5 years either at the
2474		7)		nacy providing services to the facility or a central location where
2476				ds are readily retrievable.
2470			10001	as are readily retrievable.
<i>⊑</i> ⊤//				

2478		5)	Only pharmacies under common ownership may share an automated
2479			pharmacy system at a facility.
2480			
2481	(Sour	ce: An	nended at 49 Ill. Reg, effective)
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2483			SUBPART G: PHARMACY OPERATIONS
2484			
2485	Section 1330	.700 P	Patient Counseling
2486			
2487	a)	Upor	n receipt of a new or refill prescription, a prospective drug regimen review or
2488		drug	utilization evaluation shall be performed. Prior to dispensing a prescription
2489		to a r	new patient, a new drug <del>prescription</del> to an existing patient, or a medication
2490		that l	has had a change in the dose, strength, route of administration or directions
2491			se, the pharmacist, or a student pharmacist directed and supervised by the
2492			macist, shall provide verbal counseling to the patient or patient's agent on
2493			nent medication information. An offer to counsel shall be made on all other
2494		_	criptions. Counseling mayshall include without limitation, but is not limited
2495		<del>to</del> :	
2496			
2497		1)	Name and description of medication;
2498		ŕ	•
2499		2)	Dosage form and dosage;
2500			
2501		3)	Route of administration;
2502		ŕ	
2503		4)	Duration of therapy;
2504		ŕ	
2505		5)	Techniques for self-monitoring;
2506			•
2507		6)	Proper storage;
2508			
2509		7)	Refill information;
2510			
2511		8)	Actions to be taken in cases of missed doses;
2512			
2513		9)	Special directions and precautions for preparation, administration and use;
2514			
2515		10)	Common severe side effects, adverse effects, or interactions and
2516		-	therapeutic contraindications that may be encountered, including their
2517			avoidance and the action required if they occur.
2518			•
2519	b)	If, in	the pharmacist's professional judgment, oral counseling is not practicable for
2520			atient or patient's agent, the pharmacist shall use alternative forms of patient

2521 information. When used in place of oral counseling, alternative forms of patient 2522 information shall advise the patient or agent that the pharmacist may be contacted for consultation in person at the pharmacy or by toll-free or collect telephone 2523 2524 service. 2525 2526 c) Every licensed pharmacy directly serving patients at a physical location must 2527 conspicuously post a sign provided by the Division containing a statement that the 2528 patient has the right to counseling, the Division's consumer hotline number, information on how to file a complaint for failure to counsel, and any other 2529 information the Division deems appropriate. The sign must be printed in color ink 2530 2531 or displayed electronically in color, measure at least 8½ x 11 inches in size, and 2532 be posted at either a cashier counter or waiting area clearly visible to patients. 2533 Licensed pharmacies that do not maintain a physical location directly serving 2534 patients must include a copy of the sign within any dispensed prescriptions. The 2535 sign will be available to download on the Division's website. 2536 2537 d) The pharmacist is responsible for maintaining patient profiles as defined in 2538 Section 3(s) of the Act. A reasonable effort shall be made to obtain information, 2539 including, but not limited to, the following: 2540 2541 1) Name, date of birth (age), gender, address and telephone number; 2542 2543 2) Individual history, when significant, including disease state, known 2544 allergies, drug interactions, and a comprehensive list of medications and 2545 relevant devices: and 2546 2547 3) Pharmacist's comments relevant to the individual's therapy. 2548 2549 e) Patient identifiable information obtained by the pharmacist or the pharmacist's 2550 designee for the purpose of patient record maintenance, prospective drug review, 2551 drug utilization review and patient counseling shall be considered protected health information, as defined in Section 3(cc) of the Act. A pharmacist shall provide 2552 2553 counseling related to protected health information in a discreet, supportive and informative manner. 2554 2555 f) 2556 A pharmacist at an on-site or off-site institutional pharmacy shall not be required 2557 to provide patient counseling as required in this Section unless drugs are dispensed by the pharmacy upon a patient's discharge from the institution. 2558 2559 2560 Nothing in this Section shall be construed as requiring a pharmacist to provide g) 2561 counseling when a patient or patient's agent refuses such counseling. When a patient or patient's agent refuses to accept patient counseling as provided in this 2562 2563 Section, that refusal shall be documented.

2564 2565	h)	A pharmacist operating a remote pharmacy shall comply with the requirements of
2566 2567 2568		this Section. Counseling in those circumstances shall be done by both video and audio means.
2569 2570	(Sou	rce: Amended at 49 Ill. Reg, effective)
2571 2572	Section 133	0.770 Centralized Prescription Filling
2573 2574	Pharmacies shall:	providing centralized prescription filling, as provided in Section 25.5 of the Act,
2575 2576 2577 2578	a)	Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription order.
2579 2580 2581	b)	Maintain appropriate records to identify the responsible pharmacist in the dispensing process.
2582 2583 2584	c)	Maintain a mechanism for tracking the prescription drug order during each step in the process.
2585 2586 2587	<u>d)</u>	Pharmacies that engage in central fill pharmacy practice shall, in addition to any other requirements of the Act and this Part, comply with this Section.
2588 2589	<u>e)</u>	For the purpose of this Section, the following definitions apply:
2590 2591 2592		1) Central Fill Pharmacy – A pharmacy that prepares prescription drug orders for dispensing for one or more originating pharmacies.
2593 2594 2595		2) Originating Pharmacy – A pharmacy wherein the prescription which will be filled by the central fill pharmacy is initially presented, entered into a computer system, data reviewed, and drug utilization review is completed.
2596 2597 2598 2599	<u>f)</u>	A pharmacy may outsource prescription drug order dispensing to a central fill pharmacy provided the pharmacies:
2600 2601 2602 2603		Have the same owner or have a written contract which outlines the services to be provided, the responsibilities and accountabilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations; and
2604 2605 2606		2) Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to dispense or

2607			proce	ss a prescription drug order.
2608 2609	<u>g)</u>	Polic	ies and l	Procedures. A policy and procedure manual as it relates to
2610 2611				lling shall be maintained at both the originating and central fill nd be available for inspection. The manual shall:
2612 2613		<u>1)</u>	Outlin	ne the responsibilities of each of the pharmacies;
2614 2615 2616 2617		<u>2)</u>	licens	de a list of the names, addresses, telephone numbers, and all se/registration numbers of the pharmacies involved in centralized ription dispensing;
2618 2619 2620		<u>3)</u>	Desig	nate the types of medications that may and may not be filled by the al fill pharmacy; and
2621 2622		<u>4)</u>	Includ	de policies and procedures for:
2623 2624 2625			<u>A)</u>	Notification to patients;
2626 2627			<u>B)</u>	Protecting the confidentiality and integrity of patient information;
2628 2629			<u>C)</u>	Communicating orders from the originating pharmacy to the central fill pharmacy;
2630 2631 2632			<u>D)</u>	Dispensing prescription drug orders when the dispensed order is not received or the patient comes in before the order is received;
2633 2634 2635			<u>E)</u>	Complying with federal and state laws and regulations;
2636 2637 2638 2639			<u>F)</u>	Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve
2640 2641 2642 2643			<u>G)</u>	identified problems;  Annually reviewing the written policies and procedures and documenting such review; and
2644 2645 2646 2647 2648 2649			<u>H)</u>	Process and documentation for return of product to the central fill pharmacy from the originating pharmacy. No drug delivered directly to the patient may be returned except in cases where a medication error has occurred.

2650 2651	<u>h)</u>	Record	dkeepin	ng
2652 2653 2654 2655		<u>1)</u>	mainte the res	pharmacy shall comply with all the laws and rules relating to the enance of records and be able to produce an audit trail identifying sponsible pharmacist in the dispensing process and all prescriptions used by the pharmacy.
2656 2657 2658		<u>2)</u>		riginating pharmacy shall maintain records, in addition to the ription drug order, which indicate:
2659 2660 2661			<u>A)</u>	The date the request for dispensing was transmitted to the central fill pharmacy;
2662 2663 2664 2665			<u>B)</u>	The date the dispensed prescription was received by the originating pharmacy, including the method of delivery and the name of the person accepting delivery;
2666 2667 2668			<u>C)</u>	Name, address, license number, and the unique identifier of the central fill pharmacy;
2669 2670 2671			<u>D)</u>	Date prescription was returned to the central fill pharmacy.
2672 2673 2674		<u>3)</u>		entral fill pharmacy shall maintain records, in addition to the ription drug order, which indicate:
2675 2676			<u>A)</u>	The date the prescription was shipped to the originating pharmacy or the patient;
2677 2678 2679			<u>B)</u>	Name and address where the prescription was shipped;
2680 2681 2682			<u>C)</u> <u>D)</u>	Method of delivery;  Name, address, and license number of originating pharmacy;
2683 2684 2685			<u>E)</u>	Date of receipt of returned product.
2686 2687	<u>i)</u>	Delive	ery of M	<u>Medications</u>
2688 2689 2690		<u>1)</u>	•	nmunity central fill pharmacy may deliver medications for an ating pharmacy to the patient or patient's agent under the following tions:
2691 2692			<u>A)</u>	The pharmacies are under the same ownership or have a written

2693 2694 2695			contract specifying the services to be provided by each pharmacy, including delivery services to the patient or patient's agent;			
2696 2697 2698 2699		<u>B)</u>	The pharmacies shall have a pharmacist available a minimum of 40 hours per week, either in person or via telephone, to provide patient counseling. The telephone number shall not incur a cost to the caller; and			
2700 2701		<u>C</u> )	The pharmacies shall include a telephone number that allows the			
2702 2703			patient to reach a pharmacist for the purposes of counseling; and			
2704 2705 2706		<u>D</u> )	The central fill pharmacy shall only deliver via carrier to the patient or patient's agent those medications which could have been delivered via carrier by the originating pharmacy;			
2707 2708 2709	, :		n institutional central fill pharmacy may only deliver medications to the ginating pharmacy.			
2710	• .					
<ul><li>2711</li><li>2712</li><li>2713</li></ul>	-	The originating pharmacy is responsible for the patient consultation and transfer requirements.				
		Nothing in this Section shall be construed as requiring a nonresident pharmacy that outsources drug order dispensing to a central fill pharmacy to hold an Illinois pharmacy license, provided that the nonresident pharmacy does not physically ship, mail or deliver prescription drugs or device directly to a patient or patient's agent in this state.				
2718 2719 2720			ed at 49 Ill. Reg, effective)			