Illinois Department of Insurance

320 West Washington Street
Springfield, IL. 62767

Formulary Compliance Template

Company Name:

SERFF Tracking #:

Checklist Directions

- The checklist assists Companies with Prescription Drug Template Creation and ensures Fomulary Compliance in the State of Illinois

IMPORTANT NOTICE: This Checklist is not all-inclusive. Companies are responsible for reviewing applicable Illinois state statutes, rules and bulletins to ensure compliance with all requirements for Company policies and procedures.

SECTION A - GENERAL FORMULARY COMPLIANCE

Line	Review Requirement	Reference	Items required for Formulary Approval	Affirm (Initials/Date)
a.1	Formulary Accessibility	215 ILCS 5/155.37	Prescription drug formularies must be posted on the Company's website in a manner that is searchable and accessible to the general public without requiring an individual to create an account. Effective 10.1.25 (upload hyperlink)	
a.2	Formulary Tiering	215 ILCS 5/155.37	Prescription drug formularies must include information on cost sharing tiers along with information on what tier of the plan's drug formulary each medication is on.	
a.2a	Specialty Medication List*	215 ILCS 5/155.37	To ensure compliance and transparency related to prescription drug tiering and accessibility, provide the health plan's specialty medication list. (upload document)	
a.3	Utilization Management*	215 ILCS 5/155.37	Prescription drug benefits must include information on all utilization management controls, including but not limited to quantity limitations and/or prior authorizations, for each covered medication.	
a.4	Medication Coverage	215 ILCS 5/155.37	Prescription drug benefits must indicate which medications are covered, including both generic and brand name, along with which medications on the formulary are preferred over other medications on the formulary.	
a.5	Pharmacy Benefits vs. Medical Benefits	215 ILCS 5/155.37	Information must include the differences between medications adminstered and covered under a policy's medical benefit and medications covered under the pharmacy benefit, and how to obtain coverage information about medications that are not covered under the pharmacy benefit.	
a.6	Medical Exceptions	215 ILCS 5/155.37 215 ILCS 134/45.1	Prescription drug benefits must include information to educate members that policies providing drug benefits are required to have a method for enrollees to obtain drugs not listed in the formulary if they are deemed medically necessary by a clinician.	
a.7	Off-formulary Exception Requests	215 ILCS 134/45.1	Prescription drugs requiring off-formulary exception requests shall be approved if the formulary prescription drug is contraindicated, the patient has tried the formulary prescription drug under the current or previous plan and the provider submits evidence of failure or intolerance, or the patient is stable on the requested off-formulary medication. The approval duration must be 12 months.	

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Emily.Downs@illinois.gov

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a.8	Step Therapy Prohibited	215 ILCS 5/155.37	Prescription drug benefits may NOT establish any step therapy requirement(s) for the coverage of a medication on the formulary.	
a.9	Prior Authorizations for dosage changes prohibited	215 ILCS 200/60	Prescription drug benefits may not require a new prior authorization for a dosage change on a medication that was previously approved via the prior authorization process.	
a.10	Prior Authorization for treatment of chronic condition	215 ILCS 200/65	If prescription drug benefits require a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, the approval shall remain valid for the lesser of 12 months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment.	
a.13	Coverage during generic drug shortage	215 ILCS 5/356z.71	Prescription drug benefits must cover a brand name eligible prescription drug if the generic or therapeutic equivalent is unavailable due to a supply issue and the dosage cannot be adjusted. The brand name drug shall be covered until the supply of the generic drug or therapeutic equivalent is available.	
a.11	Continuity of Care	215 ILCS 200/75	Prescription drug benefits shall honor a prior authorization granted to a member from a previous health insurance issuer for at least the initial 90 days of coverage.	
a.12	Mental Health and Addiction Parity	45 CFR 156.110(a)(5) 45 CFR 147.160 215 ILCS 5/370c.1	Prescription drug benefit design and prospective utilization management techniques employ processes, strategies, evidentiary standards, and other factors that are comparable between mental health/substance use disorder benefits and medical surgical benefits.	
			SECTION B - SUBSTANCE USE DISORDER TREATMENT	
b.1	Prior Authorization Prohibited	215 ILCS 5/370c (b)(6.5)(A)	Prescription drug benefits must cover prescription medications approved by the the United States Food and Drug Administration (FDA) prescribed or administered for the treatment of substance use disorders WITHOUT any prior authorization requirements including limitations on dosage. *Since the American Society of Addiction Medicine (ASAM) has not established any limitations to date, quantity limit exceptions and non-formulary exceptions are also prohibited.	
b.2	Tiering and Accessibility	215ILCS 5/370c (b)(6.5)(C)	Prescription drug benefits must cover all FDA approved medications indicated for the treatment of substance use disorders on the lowest non-preventative tier of the drug formulary developed and maintained by the Company for brand AND generic medications.	
			FDA approved medications for the treatment of substance use disorders include the following: ***Suboxone, Zubsolv, buprenorphine/naloxone tablets/films, buprenorphine, naltrexone, Vivitrol, acamprosate, disulfiram, Lucemyra, Brixadi, Sublocade, Kloxxado, Zimhi, Narcan, naloxone, nicotine replacement therapy (NRT), varenicline, buproprion SR, and more *Note: this is not an exhaustive list.***	
b.3	Opioid Antagonist	215 ILCS 5/356z.23 215 ILCS 125/5-3(a)	Prescription drug benefits must cover at least one opioid antagonist including any refills without any cost-sharing requirements.	
			An "opioid antagonist" is a drug that binds to opioid receptors and blocks or inhibits the effect of opioids acting on those receptors, including, but not limited to, naloxone hydrochloride or any other similarly acting drug approved by the U.S. Food and Drug Administration.	
b.4	Opioid Medically Assisted Treatment (MAT)	Benchmark p. 21	Prescription drug benefits must cover buprenorphine products or brand equivalents without any prior authorization, dispensing limits, fail first policies, or lifetime limit requirements.	
b.5	Intranasal opioid reversal agent associated with opioid prescriptions	Benchmark p.32	Prescription drug benefits must cover at least one intranasal opioid reversal agent prescription for initial prescriptions of opioids with dosages of 50 MME or higher.	

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SECTION C - PREVENTATIVE HEALTH SERVICES				
c.1	Federal Preventative Services Rated A or B	42 USC 300gg-13(a)(1) 215 ILCS 5/356z.62(a)(1) 215 ILCS 125/5-3(a)	Prescription drug benefits must cover preventative services rated "A" or "B" in the current recommendations of the United States Preventative Services Task Force (USPSTF) without any cost-sharing requirements.	
c.1a	Aspirin	42 USC 300gg-13(a)(1) 215 ILCS 5/356z.62(a)(1) 215 ILCS 125/5-3(a)	Prescription drug benefits must cover low dose aspirin (81 mg/day) as a preventative medication in persons who are high risk for preeclampsia without any cost-sharing requirements.	
c.1b	Breast Cancer Risk Reduction	42 USC 300gg-13(a)(1) 215 ILCS 5/356z.62(a)(1) 215 ILCS 125/5-3(a)	Prescription drug benefits must cover risk-reducing medications such as tamoxifen, raloxifene, or aromatase inhibitors for women who are high risk for breast cancer and low risk for adverse medication effects, without any cost-sharing requirements.	
c.1c	Folic Acid Supplementation	42 USC 300gg-13(a)(1) 215 ILCS 5/356z.62(a)(1) 215 ILCS 125/5-3(a)	Prescription drug benefits must cover daily folic acid supplements (400 to 800mcg) for women who are planning to or could become pregnant without any cost-sharing requirements.	
c.1d	HIV Prevention Medication (PrEP)	45 CFR § 147.130 215 ILCS 5/356z.60 215 ILCS 5/356z.62(a)(1)	Prescription drug benefits must cover all medications for human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) approved by the United States Food and Drug Administration without any restrictions or delays, without any cost-sharing requirements.	
c.1e	HIV Prevention Medication (PEP)	215 ILCS 5/356z.60 215 ILCS 5/356z.62(a)(1)	Prescription drug benefits must cover all medications for human immunodeficiency virus (HIV) post-exposure prophylaxis (PEP) approved by the United States Food and Drug Administration without any restrictions or delays, without any cost-sharing requirements.	
c.1f	Oral Fluoride Supplementation	42 USC 300gg-13(a)(1) 215 ILCS 5/356z.62(a)(1) 215 ILCS 125/5-3(a)	Prescription drug benefits must cover oral fluoride supplementation for children whose water supply is deficient in fluoride without any cost-sharing requirements.	
c.1g	Smoking Cessation Medication	215 ILCS 5/356z.62(a)(1)	Prescription drug benefits must cover two 90-day regimens of all FDA approved tobacco cessation medications, including both prescription and over-the-counter medications, without any cost-sharing requirements.	
c.1h	Statins	215 ILCS 5/356z.62(a)(1)	Prescription drug benefits must cover statins for the primary prevention of Cardiovascular Disease (CVD) for adults aged 40 to 75 years who have 1 or more CVD risk factors (i.e. dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year risk of a cardiovascular event of 10% or greater, without any cost-sharing requirements.	
c.2	Immunizations	42 U.S.C. 300gg-13(a)(2) 215 ILCS 5/356z.62(a)(2) 215 ILCS 125/5-3(a) 215 ILCS 5/356z.71	Prescription drug benefits must cover the immunizations recommended by the Advisory Committee on Immunization Practices (ACIP) and the administration of these immunizations without any cost-sharing requirements.	
c.2a	Human Papillomavirus Vaccine (HPV)	215 ILCS 5/356z.9 215 ILCS 125/5-3(a) 215 ILCS 5/356z.71	Prescription drug benefits must cover without cost sharing a human papillomavirus vaccine (HPV) that is approved for marketing by the federal Food and Drug Administration.	

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c.2b	Shingles Vaccine (Herpes Zoster)	215 ILCS 5/356z.13 215 ILCS 125/5-3(a) 215 ILCS 5/356z.71 Benchmark p. 12 & 19	Prescription drug benefits must cover a shingles vaccine without cost share that is approved for marketing by the federal Food and Drug Administration if the vaccine is ordered by a practicing physician for a member who is 60 years of age or older.	
c.3	Contraceptives	215 ILCS 5/356z.4 215 ILCS 125/5-3(a)	Prescription drug benefits must cover at least one therapeutic equivalent of all contraceptive drugs, devices, and other products approved by the United States Food and Drug Administration without any cost-sharing requirements. *Male condoms must be covered with a prescription for female members as well.	
c.4	Gender Parity	215 ILCS 5/356z.62(j)	Prescription drug benefits may not deny or limit coverage on any recommendation or guideline specifically referring to men or women based upon a member's recorded sex or actual or perceived gender identity, or for the reason that the individual is gender nonconforming, intersex, transgender, or has undergone, or is in the process of undergoing, gender transition, if, notwithstanding the sex or gender assigned at birth, the covered individual meets the conditions for the recommendation or guideline at the time the item or service is furnished.	
			SECTION D - DIABETES TREATMENT	
d.1	Continuous Glucose Monitors	215 ILCS 5/356z.59 215 ILCS 125/5-3(a)	Prescription drug benefits must cover Continuous Glucose Monitor (CGMs) for all members who are diagnosed with diabetes mellitus without any cost-sharing requirements on a 30-day supply. The coverage must be provided as prescribed. Prior authorizations on CGMs are prohibited and the coverage must be continuous.	
d.2	Insulin Co-Pay	215 ILCS 5/356z.41 215 ILCS 125/5-3(a)	Prescription drug benefits must cover a 30-day supply of insulin at an amount not to exceed $35 regardless of type or quantity.	
d.3	Diabetic Equipment	215 ILCS 5/356w(d) 215 ILCS 125/5-3(a) 50 IAC 2019.40 Benchmark p. 31	Prescription drug benefits must cover the following equipment when medically necessary and prescribed by a licensed physician: (1) blood glucose monitors (2) blood glucose monitors for the legally blind (3) cartridges for the legally blind (4) lancets and lancing devices All are subject to the same deductible, copayment, and coinsurance provisions provided for other durable medical equipment.	
d.4	Diabetic pharmaceuticals & supplies	215 ILCS 5/356w(e) 215 ILCS 125/5-3(a) 50 IAC 2019.40 Benchmark p. 31	Prescription drug benefits must cover the following pharmaceuticals and supplies when medically necessary and prescribed by a licensed physician: (1) insulin (2) syringes and needles (3) test strips for glucose monitors (4) FDA approved oral agents used to control blood sugar (5) glucagon emergency kits.	
			SECTION E - ADDITIONAL MEDICATION AND TREATMENT COVERAGE REQUIREMENTS	
e.1	Estrogen	215 ILCS 5/356z.67 215 ILCS 125/5-3(a)	Prescription drug benefits must cover at least one therapeutic equivalent version of vaginal estrogen with cost-sharing requirements that are no more stringently applied to medications used for erectile dysfunction.	
e.2	Prescription Inhalants	215 ILCS 5/356z.5 215 ILCS 125/5-3(a)	Prescription drug benefits may not deny or limit coverage for prescription inhalants to enable persons to breathe when suffering from asthma or other life-threatening bronchial ailments based upon any restriction on the number of days before an inhaler refill may be obtained if, contrary to those restrictions, the inhalants have been ordered or prescribed by the treating physician and are medically appropriate.	

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e.2a	Prescription Inhalants	215 ILCS 5/356z.5(c)	Prescription drug benefits must provide coverage for prescription inhalants at a cost no greater than $25 per 30 day supply. HDHP with HSA exempt from no cost-sharing requirement until the minimal deductible under 26 U.S.C. § 223 has been met.	
e.3	Epinephrine Injectors	215 ILCS 125/5-3(a) 215 ILCS 5/356z.33 P.A. 103-0454	Prescription drug benefits must cover medically necessary epinephrine injectors for members 18 years of age and younger. The amount that the insured is required to pay for a twin-pack of medically necessary epinephrine injectors may not exceed $60.	
e.4	Tick-Borne Disease	215 ILCS 5/356z.35 215 ILCS 125/5-3(a)	Prescription drug benefits must cover long-term antibiotic therapy for any members who are diagnosed with a tick-borne disease when determined to be medically necessary by a physician. This includes experimental drugs. The requested drug may be used off-label if it has been approved by the FDA.	
e.5	Hormonal and Non-Hormonal Therapy to treat menopause	215 ILCS 5/356z.56 215 ILCS 125/5-3(a)	Prescription drug benefits must cover medically necessary hormonal and non-hormonal therapy treatment to treat menopause that has been induced by a hysterectomy and is recommended qualified health care provider.	
e.6	Hereditary Bleeding Disorders	215 ILCS 200/77	A health insurance issuer or a contracted utilization review organization may not require a prior authorization for drug therapies approved by the U.S. Food and Drug Administration for the treatment of hereditary bleeding disorders any more frequently than 6 months or the length of time the prescription for that dosage remains valid, whichever period is shorter.	
e.7	Breast Cancer Pain Medication and Therapy	215 ILCS 5/356g.5-1 215 ILCS 125/5-3(a) Benchmark p. 12 & 32	Prescription drug benefits must cover medically necessary pain medication related to breast cancer on the same terms and conditions that are generally applicable to coverage for other conditions.	
e.8	Abortifacients	215 ILCS 5/356z.60 215 ILCS 5/356z.4(a) 215 ILCS 125/5-3(a)	Prescription drug benefits must cover at least one therapeutic equivalent of all abortifacients approved by the United States Food and Drug Administration without any cost-sharing requirements. Off-label abortifacients must also be covered without any cost-sharing requirements when medically necessary.	
			Examples of abortifacients include: Carboprost tromethamine, Methotrexate, Mifepristone, Misoprostol, Trilostane, Dinoprost tromethamine, Gemeprost, Fenprostalene, Sulprostone, Dinoprost, Cloprostenol, Fluprostenol, Carboprost	
e.9	Hormonal Therapy for Gender Dysphoria	215 ILCS 5/356z.60 215 ILCS 125/5-3(a)	Prescription drug benefits must cover all hormonal therapy medications administered to treat gender dysphoria that are approved by the United States Food and Drug Administration without any cost-sharing requirements. This includes those that are prescribed or ordered for off label use. HDHP with HSA exempt from no cost-sharing requirement until the minimal deductible under 26 U.S.C. § 223 has been met.	
e.10	Prenatal Vitamins	215 ILCS 5/356z.58 215 ILCS 125/5-3(a) P.A. 103-0426	Prescription drug benefits must cover prenatal vitamins when prescribed by a licensed physician or advanced practice nurse.	
e.11	Topical Anti-Inflammatory acute and chronic pain medication	Benchmark p. 32	Prescription drug benefits must cover topical anti-inflammatory medication including, but not limited to, Ketoprofen, Diclofenac, or another brand equivalent approved by the FDA for acute and chronic pain.	
e.12	Short-term opioid prescription limitations	Benchmark p. 31	Prescription drug benefits must limit short-term opioid prescriptions to no more than a 7-day supply.	

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