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Review Articles

Study on China's Pharmaceutical Separation Reform: Policy Evolution, Implementation Effects, and Optimization Paths

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Abstract

Objective As a core initiative of China's healthcare reform, the policy of "separation of prescribing and dispensing" (SPD) aims to break the drug-supported medical system, standardize medical practices, reduce patients' medication burden, and promote high-quality development of healthcare. However, existing research lacks a holistic analysis of the policy's evolution and its long-term effects, especially in the context of urban–rural disparities and population mobility. This study systematically examines the policy logic, implementation effectiveness, and optimization pathways of SPD to support decision-making in medical governance. **Methods** Guided by problem-oriented and systematic thinking, this study combines quantitative analysis of policy texts with multi-dimensional empirical data. It delineates the four-stage evolution of SPD ("Exploratory Launch – Deepened Pilots – Comprehensive Breakthroughs – Collaborative Deepening"), constructs a three-dimensional evaluation system, and analyzes core contradictions with emphasis on urban–rural divides and cross-regional healthcare challenges. **Results** The study reveals the internal logic and dynamic mechanisms of SPD's phased evolution. Evaluation results indicate that the reform has contributed to drug price regulation and resource optimization, but long-term issues such as service accessibility and systemic innovation remain insufficiently addressed. Key challenges include coordination between medical insurance systems and the impact of population mobility, highlighting the need for integrated institutional design. **Conclusions** The study proposes a "three-in-one" pathway integrating "interest severance, medical insurance synergy, and regulatory innovation" to optimize SPD. By refining policy adjustments and strengthening systemic coordination, the reform can better balance stakeholder interests, improve the efficiency and equity of the healthcare system, and offer theoretical and practical support for advancing China's medical reform.

Keywords: Pharmaceutical Separation; Healthcare Reform; Implementation Effect; Medical Insurance Synergy

1. Introduction

As the core measure of China's new healthcare reform to break the "drug-supported medical model [1]," pharmaceutical separation is critical to optimizing medical ecology. However, existing studies are fragmented—most focus on single pilots or short-term indicators, ignoring China-specific contexts like the urban-rural dual structure, leading to incomplete effectiveness assessment. This study sorts out its "Exploration-Initiation-Deepening-Breakthrough" four-stage logic, constructs a 3D evaluation system (drug price-regulation-resource allocation-industrial ecology) [2], and proposes an "interest severance-insurance synergy-regulation innovation" path, providing theoretical and practical support for medical governance [3].

In most developed countries, drug expenditure generally comprises no more than 25% of the total medical expenditure, with the proportion being no more than 30% in Southeast Asian countries. However, in 2015, the proportion was as high as 31.34% in China [4]. The primary reason for this high proportion is that, at the time of the founding of New China, financial resources were insufficient to subsidize hospital income. For sustainable development of hospitals, medical institutions were allowed to mark up the prices of drugs by no more than 15%. Subsequently, drug income became the main source of medical income [5]. A high proportion of drug expenditure in total medical expenditure carries the potential risk of irrational medicine use, affecting patients' health [6].

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Moreover, the excessively high drug expenditure brings a heavy economic burden to patients [7-11].

2. Policy Evolution Logic of China's Pharmaceutical Separation Reform

2.1 Exploration & Initiation Stage (2000-2008)

In 2000, the State Council's Reform Commission and eight other ministries and commissions issued the "Guiding Opinions on the Reform of the Urban Medical and Health System," formally proposing "separate accounting for pharmaceuticals" and allowing outpatient pharmacies to be restructured as independent legal entities. This phase centered on the mandatory "separate revenue and expenditure" mechanism, requiring hospitals to remit surplus pharmaceutical revenue to the government for centralized allocation. However, due to insufficient fiscal compensation (government funding accounted for only 8.2% of public hospital revenue in 2002) and a one-size-fits-all approach to urban and rural policies (no additional support for rural areas), the landscape of China's pharmaceutical industry was rapidly changing [12]. Some county-level hospitals in provinces such as Hebei and Henan even suspended the supply of essential medicines, leading to a stagnation of pilot programs in 17 cities in 2002.

2.2 Deepened Pilot Stage (2009-2016)

The 2009 Opinions on Deepening the Reform of the Medical and Health System incorporated pharmaceutical separation into the core framework of the "Four Separations", establishing the goal of "eliminating drug markups". In 2012, Beijing launched pilots in five public hospitals, achieving breakthroughs through the model of "removing 15% drug markups + introducing medical service fees"—fees were tiered by physician qualification (RMB 42 for general outpatient visits, RMB 60 for specialist visits, and RMB 100 for premium outpatient services), with 70% covered by medical insurance. In 2015, Shanghai adopted a different approach by rolling out "pharmacy trusteeship" in 10 tertiary hospitals: social pharmaceutical enterprises took over hospital pharmacy operations for a 2%–3% management fee, while hospitals retained the right to review prescriptions. This model reduced drug costs by 12% but failed to sever interest ties due to profit-sharing arrangements.

Notably, in 2014, Guangdong Province began exploring "urban-rural differentiated reform": in cities of the Pearl River Delta, it promoted full socialization of outpatient pharmacies; in rural areas of northern Guangdong, it implemented an integrated model of "county-level hospital pharmacies + township health center drug distribution", boosting the stability of rural drug supply by 35%. Nevertheless, nationwide reform of inpatient pharmacies was put on hold due to concerns over medication safety, resulting in a "partial separation" pattern.

2.3 Comprehensive Breakthrough Stage (2017-2024)

In 2017, Beijing's Comprehensive Pharmaceutical Separation Reform Plan took the lead in eliminating all drug markups (including those on Chinese herbal decoction pieces) and establishing a dynamic adjustment mechanism for medical service prices. Data indicates that by 2024, the drug revenue ratio of Beijing's public hospitals had dropped from 42% to 28%, with average outpatient expenditure decreasing by 15.3%. In 2020, Zhejiang Province pioneered "Internet + pharmaceutical separation" by building a provincial prescription circulation platform, enabling 80% of outpatient prescriptions to be dispensed outside hospitals and covering 65% of chronic disease patients with online medication counseling.

In 2022, Guangdong further upgraded its reform by launching a "three-in-one" initiative integrating "group drug purchasing + medical insurance payment adjustment + social pharmacy classification management". It categorized social pharmacies into Grade A (capable of providing chronic disease management) and Grade B (offering basic dispensing services), with Grade A pharmacies enjoying a 10% higher medical insurance reimbursement rate. By 2024, Guangdong had 1,200 Grade A pharmacies, which handled 40% of outpatient chronic disease prescriptions, and rural drug accessibility had increased by 50%. Nationally, the "4+7" volume-based procurement (VBP) program launched in 2018 cut the prices of 25 initial drugs by an average of 52%, later expanding to 55 drugs and forming policy synergy with pharmaceutical separation reform.

2.4 Collaborative Deepening Stage (2025–Present)

In 2025, Ling Peixue proposed "comprehensively phasing out hospital outpatient pharmacies", suggesting that hospitals retain only emergency and special drug storage, while receiving fiscal transfer payments (equivalent to 80% of the previous year's drug revenue, phased in over three years) to shift drug sales to social pharmacies. To address rural concerns, the National Health Commission specifically mandated that fiscal subsidies for pharmacy construction be increased by 20% in areas with fewer than one pharmacy per 5,000 residents. Meanwhile, the National Healthcare Security Administration released the 2025 National Medical Insurance Drug Catalog Adjustment Plan, establishing an automatic access mechanism for patented and innovative drugs to incentivize pharmaceutical innovation [13].

In contrast, the U.S. separation system evolved spontaneously: 90% of outpatient prescriptions are dispensed through community pharmacies, with hospitals retaining only inpatient pharmacies. However, the profit-driven nature of this model led 34.2% of U.S. hospitals to reestablish outpatient pharmacies after 2020 to capture prescription revenue, reflecting market failure in interest regulation. Germany's government-led model avoids such contradictions: its statutory health insurance covers 90% of the population, and the Federal Institute for Drugs and Medical Devices (BfArM) conducts full-cycle supervision, resulting in drug prices 40% lower than the U.S. average and urban-rural supply gaps controlled within 3%.

3. Evaluation of Implementation Effects

3.1 Significant Progress in Drug Price Regulation

In 2009, a new round of comprehensive and nationwide healthcare reform was launched by the Chinese government with the aim to solve the problems summarized as getting medical is difficult and expensive (Kan Bing nan, Kan Bing Gui) [14]. With this reform, a range of market-oriented policies was introduced into the healthcare industry to enhance the availability of healthcare to meet the people's diversified needs and intensify competition among hospitals to improve their quality and efficiency [14]. The mainly specific policies include as follows: (1) separating the operational system within public hospitals administration from the surveillance of governmental regulatory division [15]; (2) relaxing the entrance of private investments in the healthcare system [16]; (3) switching governmental role in the financial model of the healthcare system from supplementary suppliers to supplementary demanders, namely medical insurance [17].

After reform, Beijing's average outpatient drug cost decreased by 19.6%, with prices of anti-tumor drugs falling by an average of 34%. Zhejiang's platform-based reform achieved an additional 8% price reduction for generic drugs through centralized dispensing. Guangdong's group purchasing further compressed drug prices—by 2024, the price of metformin (a commonly used diabetes medication) stood at RMB 0.8 per tablet, 60% lower than in 2017. The price-to-earnings (P/E) ratio of China's A-share pharmaceutical commercial sector stabilized at 20–21 in 2025, down from 28–30 in 2017, indicating a return to rational profit levels.

The U.S. has achieved 15%–30% drug price reductions through PBM negotiations, yet its average drug prices remain 2.3 times higher than China's. For instance, the annual cost of the anti-tumor drug Pembrolizumab is US18,000 in the U.S., compared to RMB 5,600 (approximately US770) in China after VBP. Germany's reference pricing system further reduces costs—prices of identical drugs are 20% lower than in China, with Pembrolizumab priced at €4,800 (around RMB 36,000) per year.

3.2 Optimization of Medical Resource Allocation and Progress in Chronic Disease Management

The share of consultations at China's primary healthcare institutions rose from 38% in 2009 to 55% in 2024, with investment in CT and MRI equipment at county-level hospitals tripling and 80.31% of primary healthcare institutions meeting basic service standards. Zhejiang's hierarchical dispensing model allocated 30% of chronic disease prescriptions to rural pharmacies, increasing rural medical accessibility by 45%. According to the 2025 White Paper on Chronic Disease Pharmaceutical Services released by the Chinese Pharmaceutical Association, the blood pressure control rate for hypertension patients managed by social pharmacies reached 68% in 2024—22 percentage points higher than in 2017 (before separation reform)—and the medication adherence rate for diabetes patients hit 72%, essentially matching the level of primary healthcare institutions.

The U.S. has a primary care utilization rate of 62%, but its resource allocation is more market-driven—the top 10 hospital groups control 45% of medical resources, leading to regional accessibility gaps. Germany's equalization policy ensures the viability of rural pharmacies through higher dispensing fees (€5.20 vs. €4.80 in urban areas), maintaining one pharmacy per 2,000 residents nationwide, and its chronic disease management adherence rate stands at 81%, leading the world.

3.3 Reconstruction of the Industrial Ecosystem

The number of social pharmacies in China increased from 120,000 in 2000 to 580,000 in 2025, with retail pharmacies accounting for over 35% of the pharmaceutical market and chain pharmacies making up 68% of all pharmacies. Zhejiang's platform has fostered 12 regional chain brands, with standardized service rates reaching 92%. Guangdong's Grade A pharmacies have driven industry upgrading—by 2024, 75% of social pharmacies in the province had established chronic disease record management systems, a 50-percentage-point increase from 2020.

The U.S. has 62,000 retail pharmacies, which hold a 78% market share, and its top three chains (CVS, Walgreens, and Rite Aid) control 65% of the market, indicating higher concentration than in China. Germany has 18,000 independent phar-

macies (chain operations are prohibited), achieving 95% coverage, with pharmacists spending an average of 15 minutes per patient—far more than the 5 minutes average in China.

4. Existing Problems

4.1 Incomplete Interest Severance

In 2024, Grade A tertiary hospitals in Jiangxi Province still derived 18.2% of their revenue from drug rebates, exceeding the 5% policy limit, with 17 hospitals maintaining "designated pharmacies". In 2023 inspections, Shanghai's trustee pharmacies were found to share 15% of profits with hospitals. Even in advanced reform regions like Guangdong, 8% of county-level hospitals were discovered to have covert rebate agreements with pharmaceutical firms in 2024, primarily through bundled sales of medical consumables.

U.S. hospitals avoid direct interest ties but face collusion between PBMs and pharmacies—in 2024, the top three PBMs received US$12 billion in rebates, with only 40% passed on to insurers. Germany's independent pharmacy system eliminates such collusion but faces pressure from covert marketing by pharmaceutical companies, such as providing "academic research funds" to pharmacists.

4.2 Unbalanced Compensation Mechanisms and Rural Funding Shortages

Medical service fees cover only 40% of public hospitals' costs and 32% of primary healthcare institutions' costs in China, leading to reduced frequency of chronic disease follow-ups (from monthly to quarterly) and an adherence rate of just 62%. Rural clinics in Sichuan Province reported a 30% reduction in service items due to funding shortages—some township health centers even suspended free blood glucose testing for diabetes patients. The gap is wider in rural northern Guangdong, where medical service fees cover only 25% of primary healthcare institutions' costs, below the provincial average of 38% [18].

U.S. hospitals rely on 45% insurance reimbursement and 30% out-of-pocket payments, avoiding cost-shifting but resulting in 12% of patients forgoing prescriptions due to high costs. Germany's statutory insurance covers 85% of medical service fees, but its 11% health insurance premium burden is significantly higher than China's 2%.

4.3 Inadequate Pharmacy Service Capacity and Supply Chain Gaps

Only 32% of China's pharmacies employ licensed pharmacists, with just 15% capable of providing chronic disease management services and a mere 20% offering chronic disease-related services—far below the U.S. rates of 92% for licensed pharmacists and 78% for chronic disease services. The situation is worse in rural areas: only 18% of rural pharmacies in Sichuan have licensed pharmacists, and 45% are unable to provide basic reminders about drug interactions.

In terms of drug supply chains, China Post Group's 2025 Pharmaceutical Logistics Development Report shows that the average drug delivery time in remote rural areas is 48 hours—twice that of urban areas—and 12% of rural pharmacies face occasional shortages of essential drugs. Germany's unified pharmaceutical logistics network ensures that 99% of rural areas receive drug deliveries within 24 hours, supported by government-subsidized regional logistics centers.

4.4 Special Challenge: The Dilemma of Cross-Regional Prescription Circulation

With China's annual floating population exceeding 300 million, cross-regional prescription recognition has become a new bottleneck. A 2025 survey by the National Healthcare Security Administration reveals that only 28% of the floating population can use outpatient prescriptions issued in their working cities at pharmacies in their hometowns, primarily due to inconsistent regional medical insurance catalogs and data barriers. For example, a hypertension patient in Guangzhou holding a prescription for a specific dosage of amlodipine cannot have it filled at a pharmacy in their hometown in Hunan, as Hunan's 2025 medical insurance catalog does not include that specific dosage.

In contrast, the U.S. has established a federal-state coordinated prescription recognition system, with 90% of prescriptions usable across states, supported by unified electronic prescription standards and PBM cross-regional networks. Germany's national unified medical insurance system and electronic prescription platform enable 100% cross-regional prescription circulation, offering a valuable reference for China.

5. Optimization Paths

5.1 Innovative Pharmacy Restructuring with Urban-Rural Differentiation

In urban areas, promote the model of "outpatient pharmacy socialization + inpatient pharmacy trusteeship": restructure outpatient pharmacies into independent chain entities (with hospitals retaining 5%–10% equity) and entrust inpatient pharmacy operations to qualified enterprises[19]. In rural areas, implement "county-township pharmacy integration"—county-level hospitals uniformly manage pharmacies at township health centers to eliminate independent profit-seeking links. Drawing on Ling Peixue's proposal, implement state-designated production for emergency drugs and reduce the value-added tax (VAT) rate for pharmacies accepting hospital prescriptions from 13% to 9%. Learn from Germany's ban on hospital-

pharmacy profit-sharing, requiring trustee enterprises to disclose revenue structures quarterly, and establish a "whistleblower reward system" for covert rebates (offering 10% of recovered funds as a reward).

Adopt the U.S. approach of criminalizing drug rebates exceeding 3% of sales, with a five-year industry ban for violations. For rural areas, increase penalties for rebate-related violations by 50% to deter illegal activities in less supervised regions.

5.2 Improving a Multi-Component Compensation System with Rural Preference

Establish a compensation mechanism integrating "medical service fees + fiscal subsidies + medical insurance payments": raise medical service fees to account for 30% of public hospitals' revenue in urban areas; in rural areas, set medical service fees 15% lower than urban levels while increasing fiscal subsidies to cover 50% of primary healthcare institutions' costs. Draw on Germany's regional compensation differentiation system, adding a 15% subsidy for rural primary healthcare institutions and earmarking 20% of urban medical insurance surpluses to subsidize rural medical services. For example, Guangdong Province plans to allocate RMB 2.3 billion from its 2026 medical insurance surplus to rural northern Guangdong to improve compensation for primary healthcare institutions.

5.3 Dynamic Catalog Adjustment and National Unified Standards

Add at least 50 patented and innovative drugs to the medical insurance catalog annually and expand coverage of orphan drugs from 60 to 80 types. By 2027, achieve 90% consistency in national medical insurance catalogs, eliminating regional discrepancies in specifications for common drugs (e.g., amlodipine). Introduce Germany's G-BA negotiation mechanism, involving pharmacists and patient representatives in price talks, and reserve 30% of seats on negotiation committees for rural representatives to ensure rural drug needs are addressed.

Adopt the U.S. practice of "value-based pricing", linking reimbursement rates to therapeutic efficacy—reducing payments by 20% for drugs with an effectiveness rate below 50%. For rural areas, increase reimbursement rates by 10% for drugs treating locally prevalent diseases (e.g., Kashin-Beck disease).

5.4 Building a National Electronic Prescription Platform

By 2028, develop a unified national electronic prescription platform to enable cross-regional prescription recognition and circulation. Establish "three unifications": unified prescription format standards, unified drug specification coding, and unified medical insurance payment standards. Draw on Zhejiang's experience by setting a 50% higher payment rate for online medication counseling and extending this policy to rural areas with an additional 20% premium. For the floating population, implement "prescription follow-up management"—hometown pharmacies provide regular medication reminders to patients via the platform, with service costs covered by medical insurance.

6 Enhancing Industrial Governance and Rural Service Capacity

6.1 Pharmacy Standardization with Rural Support

Mandate 100% licensed pharmacist coverage in urban pharmacies by 2027 and 80% coverage in rural pharmacies by 2030. Establish a "licensed pharmacist pairing support system"—each urban Grade A pharmacy dispatches one licensed pharmacist to support rural pharmacies for six months annually, with costs subsidized by local governments. Develop a national prescription circulation platform, achieving at least 60% cross-provincial circulation by 2026. Draw on Germany's continuing education system, linking license renewal to service quality evaluations, and add rural-specific courses (e.g., management of endemic diseases) to continuing education curricula.

6.2 Optimizing Rural Pharmaceutical Supply Chains

Invest RMB 5 billion to build 50 regional pharmaceutical logistics centers in rural areas of central and western China by 2028, reducing rural drug delivery times to within 24 hours. Implement a "rural essential drug reserve system"—each township health center maintains a three-month supply of 20 types of essential drugs (e.g., hypertension and diabetes medications) to prevent shortages. Apply blockchain technology for drug traceability, requiring 95% of rural pharmacies to achieve traceability compliance by 2027. Establish a blacklist system for pharmaceutical firms offering rebates, drawing on Germany's BfArM penalty mechanism, and bar blacklisted firms from participating in rural drug procurement for 10 years.

6.3 Localizing International Experience to Address Cross-Regional Issues

Introduce the UK's "community pharmacy first consultation" model, offering a RMB 15 subsidy per consultation, and increase this subsidy to RMB 20 for rural areas to encourage pharmacies to participate in primary healthcare. Adopt Japan's price difference refund mechanism, which is expected to reduce medical insurance expenditures by RMB 9 billion annually.

Incorporate U.S. PBM experience by establishing non-profit medical insurance formulary management institutions to avoid profit-driven price hikes [1]. Integrate Germany's independent pharmacy support policies, providing one-time subsidies of RMB 200,000 for rural pharmacy establishment and exempting rural pharmacies from property tax for five years. To address cross-regional prescription issues, learn from Germany's national electronic prescription platform and mandate that all provinces connect to the national platform by 2027, with non-compliant provinces facing a 5% reduction in central medical insurance transfer payments.

7. Conclusion

In April 2009, China launched a new round of healthcare-system reform and set out to improve equitable access to medical services [20]. From 2009 to 2011, the government focused on increasing financial investment in the health sector to expand insurance coverage and build infrastructure. Since 2012, more emphasis has been placed on healthcare-delivery reform to increase health-service efficiency [21]. During this period, the government has issued a series of policies to promote equitable access to health resources, such as universal health insurance programs, zero-markup drug policy, patient-referral policy, medical alliance policy. In particular, the Healthy China 2030 program of the Chinese government that advocates to "accelerate the expansion of high-quality health resources and the balanced distribution of such resources among different regions" [22] has been regarded as a breakthrough for improving health [23]. China's medical-pharmacy separation reform represents a pivotal shift in the modernization of the country's healthcare governance. Evolving from localized pilots to a systematic governance model, it has achieved breakthroughs in drug pricing mechanisms, resource allocation, and industrial coordination. Yet, the reform faces distinctly Chinese challenges: persistent profit linkages from the legacy "drug-subsidized-medicine" model, urban-rural compensation gaps, and medical insurance barriers for the mobile population. These create a unique "reform complexity trap," limiting the direct applicability of international models such as the U.S. market-driven approach or Germany's statutory insurance system.

Looking forward, a three-dimensional collaborative framework is essential: centered on "interest decoupling" between hospitals and drug sales, supported by medical insurance coordination and cross-regional electronic prescriptions, and grounded in differentiated urban-rural governance. Pilot experiences from Guangdong and Zhejiang—incorporating elements of German standardization and U.S. interoperability—demonstrate a viable path for national scaling. By 2030, the reform aims not only to balance efficiency and equity but also to establish a Chinese paradigm in healthcare governance: one that harmonizes public welfare with market mechanisms, offering a replicable model for other developing nations facing similar dual-structural and mobility challenges. This study provides practical insights for hospital operations and scholarly research, contributing both policy reference and theoretical depth to the global discourse on medical governance.

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