

中药药事服务规范

编制说明

立 项 单 位：世界中医药学会联合会

项目承担单位：北京中医药大学

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《中药药事服务规范》项目组

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世界中医药学会联合会国际组织标准

编制说明

Formulation Explanations

一、工作简况

（一）任务背景

随着现代临床药学服务的不断发展，全球多个国家药事服务内容规范进行了积极探索，美国、英国、日本、南非等已制定了明确的药事服务规范。药师全程化参与，指导患者合理用药是国际共识。

在全球化推动下，中医药以其独特的思想智慧、诊疗方法和养生理念，深受国际患者青睐。中药在海外目前主要以食品或膳食补充剂的身份进行流通，其合理使用依赖于从业人员的服务水平，但该方面的服务标准和技术规范尚为缺失，严重影响中药药事服务质量。因此，为提升中药在全球范围内用药的安全性和有效性，研制订中药全程化药事服务技术规范，有利于提升海内外中药药事服务水平。

（二）主要工作过程

2021年10月，由北京中医药大学中药调剂标准化研究中心启动SCM NP2021-0141《中药饮片药事服务规范》的研制工作。

2021年11月，成立标准起草小组，将现有标准汇总整理、申请立项并开始研制SCM NP2021-0141《中药饮片药事服务规范》标准草案。

2021年11~12月，进行多国专家访谈，了解各国中药饮片调剂、应用及药事服务现状。

2022年1~3月，召开2轮专家研讨会，对草案内容进行专家研讨。

2022年1月~2023年1月，根据专家意见对草案内容进行初步修改，开展文献研究，对中药饮片、药事服务相关文献进行分析，系统梳理中药饮片药事服务规范要素，并对所有要素进行分类。

2023年2月~2024年2月，补充国内多地实地调研及专家访谈，探究北京、南京、四川、广州等地中药药事服务内容及现状，了解中药饮片药事服务规范使用需求。

2024年2月~2024年10月，进行问卷调研，面向北京、杭州、南京、广州等多个地区药师开展调研，了解药师对中药饮片药事服务的认知情况以及需求程度，补充、完善中药饮片药事服务规范要素。

2024年11月，补充召开1轮专家研讨会，针对修订后的标准草案进行深入研讨，并听取了一线药师代表的意见建议。为提升标准在海外机构的应用性，与会专家经审议，一致同意扩大其适用范围，据此将标准名称由《中药饮片药事服务规范》调整为《中药药事服务规范》。此外，会议对相关条款表述进行了同步优化，切实增强规范的可操作性与适用范围。

2024年12月~2025年5月，根据专家意见对草案内容进行修改，补充、完善中药药事服务规范要素。

2025年6月，开展专家咨询，并对专家咨询的结果进行分析，进行小组讨论，形成中药药事服务规范框架。

2025年7月~11月，整理专家咨询结果，组织专家团队依据知识框架撰写中药药事服务规范草案。

（三）标准起草人及起草单位

主要起草单位：北京中医药大学、浙江中医药大学附属杭州市中医院、广东省中医院、中国-法国中医药中心。

参与起草单位：法国 KNP 集团、法国中医联盟（CFMTC）、美国 Dayou LLC 大有公司、日本名本株式会社、香港中医医院发展计划办事处、首都医科大学附属北京中医医院、北京中西医结合医院、中国中医科学院西苑医院、西南民族大学、南京市中医院、北京中医药大学第三附属医院、成都中医药大学附属医院、浙江省中医院、湖北省中医院、甘肃省中医院、上海市中医医院、山东省中医院、上海中医药大学附属岳阳中西医结合医院、北京大学第三医院、南方医科大学中西医结合医院、安徽中医药大学第一附属医院、北京科园信海医药经营有限公司、北京中医药学会、杭州唐古信息科技有限公司、上海同济堂药业有限公司、杭州方回春堂集团有限公司、浙江中医药大学中药饮片有限公司、浙江佐力百草中药饮片有限公司。

主要起草人：翟华强、陈红梅、杨浣菲、伍世恒、吴宛霖（法国）。

参与起草人：赵鑫（日本）、VBssBil Joëlle（法国）、陳穎莉（中国香港）、

周传利（美国）、冯世醒（法国）、刘仿尧、刘国秀、吴剑坤、陈占功、李培红、孔祥文、李红燕、刘莉、郑敏霞、陈树和、赵学龙、王红丽、张立超、马传江、林华、年华、杨毅恒、彭康、邓广海、张国豪、韩永鹏、李德荣、王春生、邵英俊、郇春锦、张忠全、韩永龙、李立华、王庸全、王倩、张方坤、管玲玲、魏娜敏、张囡、李丝雨、钟长鸣、李易轩、曾凤萍、俞辰倩、李斐玉、尚静、郭梦蕊、杨凡林、谭佳琦、刘朔、汤婉婷、刘若轩。

二、主要技术内容介绍

1 实地调研

1.1 调研方式

面向北京、江苏、四川、杭州、广州等地 6 家三级甲等中医医院、综合性医院中药房，1 家具有药品零售业务的中医诊所及 1 家中药饮片生产企业的 10 名主任药师、副主任药师及中医药从业人员进行实地调研。采用半结构式专家访谈法，制定中药师访谈提纲后，通过实地走访北京中医药大学第三附属医院、首都医科大学附属北京中医医院、杭州市中医院、广东省中医院、杭州方回春堂门诊部及浙江省中医药大学中药饮片有限公司，与 4 家医院的中药房主任、中医药从业人员，1 家中医诊所及 1 家中药饮片生产企业的中医药从业人员进行面对面的访谈；通过电话提问的形式，对南京市中医院、四川省中医院 2 家医院的 2 名主任药师、1 名副主任药师进行访谈。了解 6 家医院、1 家具有药品零售业务的中医诊所及 1 家中药饮片生产企业中药药事服务现状与相关需求。

1.2 调研结果

中药药事服务环节主要集中在企业向机构供应饮片、机构内部进行采购验收、贮存养护、处方调剂等方面。中药药事服务内容与西药药事服务流程的主要区别主要集中在临方炮制、处方应付、服药指导、饮片煎煮等方面的内容。不同类型的机构及不同级别医院的信息化程度各不相同，但均有机构内部的制度及重要节点的追溯性手段。对于中药药事服务从业人员要求主要集中在专业背景、学历、人员培训等方面的需求。

2 文献研究

2.1 检索策略

检索中国知网、万方数据知识服务平台、维普数据库、PubMed、Web of

Science、全国标准信息公共服务平台等大数据平台，以“药事服务”、“药事管理”、“药事服务规范”、“中药药事服务规范”、“药学服务”、“药学服务规范”等为关键词进行检索；检索《处方管理办法》《医院中药饮片管理规范》等相关法律法规。

2.2 纳入与排除标准

2.2.1 纳入标准：2010 年以后与中药药事服务相关的文献。

2.2.2 排除标准：2010 年以前的文献、二次文献、信息不全的文献、新闻资讯、重复发表、内容相似的文献。

2.3 文献筛选与信息提取

根据纳入和排除标准对文献条目进行筛选，剔除不合格的文献；根据合格文献整理中药药事服务规范相关要素，并对要素进行分类。

3 问卷调研

3.1 调研目标

面向北京市、杭州市、南京市等多个地区的药师进行调研，线上发放“问卷星”的形式，旨在明确中药药事服务的现状和规范需求。

3.2 问卷内容

问卷包含调研对象的基本信息，对中药药事服务规范认知程度，中药药事服务规范的需求度，内容涉及中药饮片、中药饮片相关法律法规及中药药事服务环节、中药药事服务规范相关需求等内容。

3.3 问卷回收

对填写时间过长或短、题目答案不完整、未答题数量超过总题数的 2/3、重复作答以及被调研对象个人信息填写不全的问卷进行剔除，共回收有效问卷 195 份。

3.4 结果分析

根据知识条目的需求度，调整中药药事服务规范知识条目，保留需求度超过 60%者，舍去需求度低于 60%者。结果显示对于中药药事服务相关环节应分为饮片企业向机构提供的药事服务（饮片供应）、机构内部提供的药事服务（采购验收、贮存养护）、机构向患者提供的药事服务（处方调剂、发药与用药交代、临方加工、临床药学服务）等各环节需求较大，均超过 60%；零售药店与中医诊所

向患者提供的其他药事服务环节需求度为 57.22%，低于 60%，但考虑到零售药店及中医诊所实际情况中存在与医疗机构不同的药事服务内容，因此暂时保留。部分从业人员认为应在患者用药指导、服务态度、流程追溯等方面进行重点规范。

4 专家咨询

4.1 专家遴选原则

(1) 遴选从事临床中药药事服务领域的专家，精通本学科业务，有一定的知名度，具有高级职称和长期临床工作经验，有兴趣和有毅力完成技术规范制定工作；

(2) 临床专家方面，遴选主任中药师并担任相关专业学会“委员”以上职务者，兼顾医院和地域代表性；

(3) 按照专家代表性、广泛性及权威性原则，同时结合相关专业领域及地域分布，兼顾本研究目的和主体；

(4) 从事临床中药相关工作 5 年以上、具有中级及以上职称的临床药师。

4.2 咨询表的制定和发放

根据前期研究形成的中药药事服务技术知识框架编制专家咨询表。专家征询问卷主要包含问卷说明，基本信息和问卷内容等三部分。问卷说明介绍了本研究的目的是填写说明，基本信息包含了征询的各位专家的姓名、年龄、性别、学历、地域、职称、工作年限、工作单位和研究方向等；问卷的主题内容包括专家权威程度自评表，中药药事服务技术内容和相关指标，专家对相关指标的重要性的和满意度进行打分，根据重要性将指标的重要程度进行赋值。

采用电子邮件或纸质问卷填写的方式发放和回收专家咨询问卷，征集北京市、杭州市、上海市、武汉市、广州市、宁夏回族自治区等多地三级甲等中医医院、三级甲等综合性医院、中医药高等院校的 20 名专家对于中药药事服务技术知识框架的意见和建议，并对中药药事服务技术知识条目的必要性进行评分。

4.3 结果分析

Delphi 专家咨询的问卷回收率为 100%，专家权威系数 $Cr=0.9$ （专家的判断系数 $Ca=0.99$ ，熟悉程度系数=0.81），专家的权威性和意见协调程度较好，其中，有 6 位专家对知识条目的必要性以及表述的规范性提出了修改意见。

5 专家研讨

邀请国内中医药领域专家进行专家研讨，针对 Delphi 专家咨询问卷中的修改意见修订标准草案根据专家提出的修改意见进行标准草案的修订，最终确定“中药药事服务技术知识框架”包括一级知识条目 7 个，二级知识条目 38 个，三级知识条目 104 条，四级知识条目 78 条。

三、与相关法律、法规和强制性标准的关系

本项目组研究形成的《中药药事服务技术规范》与现行法律、法规和强制性标准没有冲突，并且在编制过程中严格遵循已有的国际、国内标准，使文本内容符合规范，言之有据。

四、重大意见的处理经过和依据

通过 1 次立项审定会，3 轮专家研讨，共处理专家意见 22 条，采纳 16 条，部分采纳 1 条，不采纳 5 条，汇总处理意见表见表 1。

表 1-标准研制阶段专家意见汇总处理表

序号 No.	标准 条文 号 Stan- dard Clau- se	意 见 内 容 Comments	提出单位/个人 Proposed Unit/ Individuals	处理意见 (由起草单位填写) Proposed Comments (Filled by Draft Unit)
1	全文	该规范内容只适宜国内中医院情况，且不够完善。若作为国际组织标准尚有一定差距。	专家 1	不采纳。本项目前期调研结果表明，国外对本标准的需求度较大。本项目将在项目执行过程中，加大国外中医医疗机构的调研，完善标准内容。
2	5.1.1	项目名称为中药药事服务规范，但草案内容涉及药品包括中成药等，有的地方照搬西药的相关描述，与中药饮片相关性不强，书写欠规范。	专家 1	采纳，文件中 5.1.1 引用世界中联标准《中药采购规范》的内容欠规范，已删除关于“药品”“中成药”等表述，并内容进行核对，使其符合中药饮片的特点。5.1.1 格式已调整。
3	引言	引言部分不需要提课题组的思路，提出目的意义重要性即可；	国家市场监督管理总局国家标准技术审评中心 高艳玲	采纳。引言部分已修改为“中药药事服务规范借鉴国内外药学领域的全程化药事服务理念，旨在规范中药调剂技术操作全过程……”
4	5	把第“5”点改成“调剂前药事服务”，第“6”点改为“调剂药事服务”，第“7”点改为“调剂后药事服务”；	国家市场监督管理总局国家标准技术审评中心 高艳玲	采纳。已将“5 全程化技术内容”标题删除，将内容更改为“5 调剂前药事服务”、“6 调剂药事服务”、“7 调剂后药事服务”。

5	3.1 3.2	针对术语“3.1”和“3.2”内容，需要考虑后面中医学概念跟它在不同的环节对应，如调剂前的“采购供应”是否需要纳入，该环节容易跟企业的采购供应混淆；	中国中医科学院 中药研究所 张华敏	采纳。已将采购供应、入库验收环节删除，参照 SCM XXXX-XXXX 中药采购规范
6	5.3.2	“处方点评”中，建议明确一下“违反十八反十九畏的处方”和“使用超量被双签字的处方”；	首都医科大学北京 中医医院药学部 吴剑坤	采纳。已修改至条目“7.2.2 点评用药不适宜处方”
7	5.3.2	“5.3.2.2”中“未标注”的原因是否需要了解，是否需要根据临床需要进行调整；	首都医科大学北京 中医医院药学部 吴剑坤	采纳。已修改至条目“7.2.1 点评书写不规范处方”
8	5.3.2	“5.3.2.3”中“滥用”的依据建议补充；e.清晰“临床炮制”的概念	首都医科大学北京 中医医院药学部 吴剑坤	采纳。已修改至条目“7.2.3 点评超常处方”
9	全文	制定标准要依据法律、法规、条例，语言表述需要规范化	北京中医药大学 乔延江	采纳。已修改部分语言，规范表述。
10	全文	整体结合调剂或调剂后的概念再斟酌，用词根据法律再规范，按照大法的词来写，例如“药厂”、“库房管理”、“顾客”，话术上更标准地统一；	首都医科大学北京 中医医院药学部 吴剑坤	采纳。“调剂前药事服务”已修改为“采购、贮存与养护服务”，“调剂后药事服务”已修改为“药物监测服务”。
11	3.1	对于“临床治疗药物监测”如何定义，中药饮片的药事服务定义如何与药事服务相对应	中国中医科学院 中药研究所 张华敏	采纳。仍需专家意见。
12	3.2	术语再斟酌，如“中药药事服务”正文中已提及，是否需要再定义；	国家市场监督管理总局 国家标准技术审评中心 高艳玲	不采纳。“中药药事服务”这一定义是经过国内以及海外众多专家几轮商讨最终定稿，不需要重新定义。
13	5.2.1	“5.2.1”内容中只重点写了“调配”相关内容，具体的内容是否需要添加	国家市场监督管理总局 国家标准技术审评中心 高艳玲	不采纳。其余相关内容 SCM 0053-2020 中均有提及，而本规范就调配应付药材给予补充。

14	附录	附录B中中药养护方法与实际应用有差距，参考意义不大，是否应修改与医院一致	中国中医科学院 广安门医院 金敏	不采纳，附录中养护方法为北京市调剂规范中传统养护方法，考虑到香港及海外地区有传统医学从业人员对中药饮片进行养护，因此暂时保留，待到后续专家研讨再次讨论确定
15	附录	附录B中中药养护方法所使用贮存器具是否需要参考2020版中国药典进行修改，现基本不用铁制容器	北京中医药大学 第三附属医院 孔祥文	采纳，2020版中国药典中中药饮片未明确要求贮存器具，因此参照北京市调剂规范对饮片贮存器具进行规范以供参考；已删除铁制容器
16	全文	中药制剂生产、配制、开发是否属于中药药事服务个性化服务技术中内容，比如临方制剂、个性化膏方等中药配制	武汉大学人民医院 李丹	不采纳，前期调研发现中药制剂的生产、配置、开发（包括中药煎药、个性化代加工等）操作实行机构较多，因此将其放在基础服务技术中
17	全文	建议增加规范中药调剂损耗的内容	安徽中医药大学 第二附属医院 蔡明	采纳，已添加相关条目
18	4.1.1	修改为“四查十对”	广州医科大学附属 中医医院 刘若轩	采纳
19	1.4	后续跟踪的信息比较难收集完整	宁夏医科大学总 医院 刘晨	采纳，已在标准相关条目中采用“宜、可”等表述，并将条目内容灵活规范为“可根据机构所处地区特点及实际情况逐步开展……用药监测”
20	3.2	在实际工作推进中存在一定的困难	宁夏医科大学总 医院 刘晨	采纳，已在标准相关条目中采用“宜、可”等表述，并在“5.2.3.2”中增加条目“逐步开展社区药事服务、居家药事服务等”进行灵活规范
21	全文	建议详细列出不同岗位的具体培训课程与学时要求	上海中医药大学 陈子君	部分采纳，由于各地要求不同，因此具体学时要求很难统一，具体培训课程已在4.2.7中增加相关条目：可参照“SCM 72-2022”中相关内容进行学习
22	全文	建议参与临床查房	陕西中医药大学 郭东艳	采纳，已增加条目“5.2.3.5 有条件的机构可进行临床查房，了解患者用药情况，提供药学支持。”

五、其他应予以说明的事项

本标准研制工作在国家重点研发计划项目《中医国际标准研制与评价研究》（2019YFC1712000）-课题《中医临床药学服务与调剂教育国际标准研制》（2019YFC1712002）经费支持下完成。

Specifications for TCM Pharmaceutical Services

Formulation Explanations

Initiating Organization: World Federation of Chinese Medicine Societies

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Project Team for 《Specifications for TCM Pharmaceutical Services》

November 2025

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International Organization Standard of the World Federation of

Chinese Medicine Societies

Formulation Explanations

Formulation Explanations

I. Work Overview

(1) Task Background

With the continuous advancement of modern clinical pharmacy services, numerous countries worldwide have actively explored standardizing pharmaceutical service content. The United States, United Kingdom, Japan, South Africa, and others have established clear pharmaceutical service standards. Pharmacist involvement throughout the patient journey to guide rational medication use represents an international consensus.

Driven by globalization, Traditional Chinese Medicine (TCM), with its unique philosophical wisdom, diagnostic and therapeutic methods, and health preservation concepts, has gained significant popularity among international patients. Currently, traditional Chinese medicines (TCM) circulate overseas primarily as food or dietary supplements. Their rational use relies on the service capabilities of practitioners, yet service standards and technical specifications in this area remain lacking, severely impacting the quality of TCM pharmaceutical services. Therefore, to enhance the safety and efficacy of TCM usage globally, developing technical specifications for comprehensive pharmaceutical services for TCM will elevate the standard of TCM pharmaceutical services both domestically and internationally.

(2) Primary Work Process

October 2021, Standardization Research Center of Traditional Chinese Medicine Dispensing at Beijing University of Chinese Medicine initiated the development of SCM NP2021-0141 《 Specifications for TCM decoction pieces Pharmaceutical Services》 .

November 2021, A drafting team was established to compile existing standards,

apply for project approval, and commence drafting SCM NP2021-0141 《Specifications for TCM decoction pieces Pharmaceutical Services》 standard.

November–December 2021,Conducted interviews with experts from multiple countries to understand the current status of TCM decoction pieces dispensing, application, and pharmaceutical services worldwide.

January–March 2022,Two rounds of expert workshops were convened to review the draft content.

January 2022–January 2023,Preliminary revisions to the draft based on expert feedback. Conducted literature research analyzing documents related to TCM decoction pieces and pharmaceutical services. Systematically organized the elements of the standard for pharmaceutical services for TCM decoction pieces and categorized all elements.

February 2023–February 2024,Conducted supplementary field research and expert interviews across multiple domestic locations to investigate the content and current status of TCM pharmaceutical services in Beijing, Nanjing, Sichuan, Guangzhou, and other regions, and to understand the practical needs for standardized TCM herbal slice pharmaceutical services.

February 2024–October 2024,Conducted questionnaire surveys targeting pharmacists in multiple regions including Beijing, Hangzhou, Nanjing, and Guangzhou. This assessed pharmacists' awareness and demand levels for TCM decoction piece pharmaceutical services, supplementing and refining the regulatory elements for TCM decoction piece pharmaceutical services .

November 2024,an additional round of expert workshops was convened to conduct in-depth discussions on the revised draft standard and solicit feedback from front-line pharmacist representatives. To enhance the standard's applicability for overseas institutions, participating experts unanimously agreed to broaden its scope of application. Accordingly, the standard's title was adjusted from "Specifications for TCM decoction pieces Pharmaceutical Services" to "Specifications for TCM Pharmaceutical Services."Additionally, the meeting concurrently optimized the wording of relevant clauses to tangibly enhance the standard's operational feasibility

and applicability.

December 2024–May 2025, Draft content will be revised based on expert feedback, supplementing and refining the elements of the TCM Pharmaceutical Services standard.

June 2025, Expert consultations were conducted, with results analyzed through group discussions to establish the framework for the TCM Pharmaceutical Services standard.

July–November 2025, Compile expert consultation outcomes and organize an expert team to draft the TCM Pharmaceutical Services standard based on the knowledge framework.

(四) Standard Drafters and Drafting Units

Primary Drafting Organizations: Beijing University of Chinese Medicine, Hangzhou Hospital of Traditional Chinese Medicine Affiliated to Zhejiang University of Chinese Medicine, Guangdong Hospital of Chinese Medicine, China-France Center for Traditional Chinese Medicine.

Participating Drafting Units: KNP Group (France), French Alliance of Traditional Chinese Medicine (CFMTC), Dayou LLC (USA), Meihon Co., Ltd. (Japan), Hong Kong Chinese Medicine Hospital Development Project Office, Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University, Beijing Hospital of Integrated Traditional and Western Medicine, Xiyuan Hospital of China Academy of Chinese Medical Sciences, Southwest University for Nationalities, Nanjing Hospital of Traditional Chinese Medicine, Beijing University of Chinese Medicine Third Affiliated Hospital, Chengdu University of Traditional Chinese Medicine Affiliated Hospital, Zhejiang Provincial Hospital of Traditional Chinese Medicine, Hubei Provincial Hospital of Traditional Chinese Medicine, Gansu Provincial Hospital of Traditional Chinese Medicine, Shanghai Hospital of Traditional Chinese Medicine, Shandong Provincial Hospital of Traditional Chinese Medicine, Yueyang Hospital of Integrated Traditional and Western Medicine Affiliated to Shanghai University of Traditional Chinese Medicine, Peking University Third Hospital, Southern Medical University Hospital of Integrated Traditional and Western

Medicine, First Affiliated Hospital of Anhui University of Chinese Medicine, Beijing Keyuan Xinhai Pharmaceutical Trading Co., Ltd., Beijing Association of Traditional Chinese Medicine, Hangzhou Tanggu Information Technology Co., Ltd., Shanghai Tongjitang Pharmaceutical Co., Ltd., Hangzhou Fanghuichuntang Group Co., Ltd., Zhejiang University of Chinese Medicine TCM decoction pieces Co., Ltd., Zhejiang Zuoli Baicao TCM decoction pieces Co., Ltd.

Principal Drafters: Zhai Huaqiang, Chen Hongmei, Yang Huanfei, Wu Shiheng, Wu Wanlin (France).

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II. Introduction to Key Technical Content

1 Field Research

1.1 Survey Methodology

Field research was conducted with 10 chief pharmacists, deputy chief pharmacists, and TCM practitioners from six Grade III Class A TCM hospitals and comprehensive hospital TCM pharmacies in Beijing, Jiangsu, Sichuan, Hangzhou, and Guangzhou; one TCM clinic with retail pharmacy services; and one TCM decoction-ready medicines manufacturer. Employing a semi-structured expert interview approach, a standardized interview outline was developed. Field visits were conducted at the Third Affiliated Hospital of Beijing University of Chinese Medicine, Beijing Hospital of Traditional Chinese Medicine (affiliated with Capital Medical University), Hangzhou Hospital of Traditional Chinese Medicine, Guangdong

Hospital of Traditional Chinese Medicine, Hangzhou Fanghuichuntang Outpatient Department, and Zhejiang University of Chinese Medicine Chinese Herbal Medicine Slices Co., Ltd. Face-to-face interviews were conducted with the directors of Chinese medicine pharmacies and TCM practitioners from four hospitals, as well as practitioners from one TCM clinic and one Chinese herbal medicine slices manufacturer. Telephone interviews were conducted with two chief pharmacists and one deputy chief pharmacist from Nanjing Hospital of Traditional Chinese Medicine and Sichuan Provincial Hospital of Traditional Chinese Medicine. The study examined the current state and related needs of Chinese medicine pharmacy services at six hospitals, one TCM clinic with retail pharmacy operations, and one Chinese herbal medicine slice manufacturer.

1.2 Research Findings

Traditional Chinese medicine pharmacy services primarily encompass the supply of herbal slices from manufacturers to institutions, internal procurement and acceptance procedures, storage and maintenance, and prescription dispensing. Key differences between TCM pharmaceutical services and Western pharmaceutical service processes lie in areas such as prescription-specific processing, prescription dispensing, medication guidance, and decoction preparation. While the level of informatization varies across different types of institutions and hospital tiers, all possess internal institutional systems and traceability measures for critical stages. Requirements for TCM pharmaceutical service practitioners primarily revolve around professional background, educational qualifications, and training needs.

2 Literature Review

2.1 Search Strategy

Major databases including CNKI, Wanfang Data, VIP Database, PubMed, Web of Science, and the National Standard Information Public Service Platform were searched using keywords such as "pharmaceutical services," "pharmaceutical management," "pharmaceutical service standards," "traditional Chinese medicine pharmaceutical service standards," "pharmaceutical services," and "pharmaceutical service norms." Relevant laws and regulations, including the "Prescription

Management Measures" and "Hospital TCM Decoction-ready medicines Management Standards," were also reviewed.

2.2 Inclusion and Exclusion Criteria

2.2.1 Inclusion Criteria: Literature related to Chinese herbal medicine pharmacy services published after 2010.

2.2.2 Exclusion Criteria: Literature published before 2010, secondary literature, incomplete literature, news reports, duplicate publications, and literature with similar content.

2.3 Literature Screening and Information Extraction

Literature entries were screened based on inclusion and exclusion criteria, with non-compliant literature excluded. Qualified literature was used to organize elements related to Chinese herbal medicine pharmacy service standards, which were then categorized.

3 Questionnaire Survey

3.1 Survey Objectives

Conducted online via "Questionnaire Star" targeting pharmacists in multiple regions including Beijing, Hangzhou, and Nanjing, aiming to clarify the current status and standardization needs of Chinese herbal medicine pharmacy services.

3.2 Questionnaire Content

The questionnaire included respondents' basic information, their level of awareness regarding TCM pharmaceutical service standards, and their demand for such standards. Content covered TCM decoction-ready medicines, relevant laws and regulations, TCM pharmaceutical service processes, and related standardization needs.

3.3 Questionnaire Screening

Questionnaires were excluded if completion time was excessively long or short, answers were incomplete, more than two-thirds of questions remained unanswered, responses were duplicated, or personal information was incomplete. A total of 195 valid questionnaires were collected.

3.4 Results Analysis

Based on the demand levels of knowledge items, the knowledge items for Chinese herbal medicine pharmaceutical service standards were adjusted. Items with demand levels exceeding 60% were retained, while those below 60% were discarded. Results indicate significant demand (all exceeding 60%) for the following TCM pharmaceutical service segments: Other pharmaceutical services provided by retail pharmacies and TCM clinics to patients registered a demand level of 57.22%, below 60%. However, considering the distinct pharmaceutical service content offered by retail pharmacies and TCM clinics compared to medical institutions, these services are temporarily retained. Some practitioners suggest prioritizing standardization in patient medication guidance, service attitude, and process traceability.

4 Expert Consultation

4.1 Expert Selection Principles

(1) Select experts specializing in clinical Chinese medicine pharmacy services who demonstrate proficiency in their discipline, possess a certain level of recognition, hold senior professional titles, have extensive clinical experience, and exhibit both interest and perseverance in completing the technical specification development process;

(2) For clinical experts, select chief Chinese medicine pharmacists holding positions at or above "committee member" in relevant professional societies, ensuring representation from both hospitals and diverse geographic regions;

(3) Experts shall be selected based on principles of representativeness, breadth, and authority, while considering relevant professional fields and geographic distribution, and aligning with the objectives and primary focus of this study.

(4) Clinical pharmacists with over 5 years of experience in clinical Chinese medicine-related work and holding an intermediate-level or higher professional title.

4.2 Development and Distribution of the Expert Consultation Form

The expert consultation form was developed based on the technical knowledge framework for Chinese herbal medicine pharmacy services established in preliminary research. The expert survey questionnaire primarily consists of three sections: questionnaire instructions, basic information, and questionnaire content. The

questionnaire instructions outlined the study objectives and completion guidelines. Basic information included the experts' names, age, gender, educational background, region, professional title, years of experience, workplace, and research focus. The core content comprised an expert self-assessment of authority, technical aspects of Chinese herbal medicine pharmacy services, and related indicators. Experts rated the importance and satisfaction levels of these indicators, with importance levels assigned based on their significance.

The expert consultation questionnaire was distributed and collected via email or paper copies. Opinions and suggestions on the technical knowledge framework for Chinese herbal medicine pharmacy services were solicited from 20 experts at tertiary Class A traditional Chinese medicine hospitals, tertiary Class A general hospitals, and higher education institutions specializing in traditional Chinese medicine in multiple locations including Beijing, Hangzhou, Shanghai, Wuhan, Guangzhou, and the Ningxia Hui Autonomous Region. Experts also rated the necessity of each knowledge item within the technical framework.

4.3 Results Analysis

The Delphi expert consultation achieved a 100% questionnaire return rate. The expert authority coefficient $Cr = 0.9$ (expert judgment coefficient $Ca = 0.99$, familiarity coefficient = 0.81), indicating good expert authority and opinion coordination. Six experts provided revision suggestions regarding the necessity and normative expression of knowledge items.

5. Expert Workshop

Domestic experts in traditional Chinese medicine were invited to participate in an expert workshop. The draft standard was revised based on the modification suggestions from the Delphi expert consultation questionnaire and the expert workshop. The final "Technical Knowledge Framework for Pharmaceutical Services in Traditional Chinese Medicine" comprises 7 Level 1 knowledge items, 38 Level 2 knowledge items, 104 Level 3 knowledge items, and 78 Level 4 knowledge items.

III. Relationship with Relevant Laws, Regulations, and Mandatory Standards

The "Technical Specifications for Chinese Medicine Pharmaceutical Services"

developed by this project team does not conflict with existing laws, regulations, or mandatory standards. The drafting process strictly adhered to established international and domestic standards, ensuring the text is well-founded and compliant with regulations.

五、 Process and Basis for Addressing Major Comments

Through one project approval meeting and three rounds of expert discussions, a total of 22 expert opinions were processed: 16 were adopted, 1 was partially adopted, and 5 were rejected. The summary of processed opinions is shown in Table 1.

Table 1 - Summary of Expert Opinions During Standard Development Phase

No.	Standard Clause Number Standard Clause	Comment Content Comments	Proposing Unit/Individuals	Handling Opinion (Filled by Drafting Unit) (Filled by Drafting Unit)
1	Full Text	The content of this specification is only suitable for domestic traditional Chinese medicine hospitals and is not sufficiently comprehensive. It falls short of meeting the standards required for international organizations.	Expert 1	Not adopted. Preliminary research for this project indicates significant demand for this standard internationally. During project implementation, we will intensify research on overseas TCM medical institutions to refine the standard's content.

2	5.1.1	<p>The project title is "Chinese Medicine Pharmaceutical Services Standard," yet the draft content covers pharmaceuticals including proprietary Chinese medicines. Some sections directly replicate descriptions relevant to Western medicines, showing weak relevance to Chinese herbal decoction pieces and exhibiting non-standardized writing.</p>	Expert 1	<p>Accepted. The content referenced in Section 5.1.1 from the World Federation of Chinese Medicine Societies' "Chinese Medicine Procurement Specifications" was non-standard. References to "medicines" and "Chinese patent medicines" have been removed, and the content has been revised to align with the characteristics of Chinese herbal slices. The format of Section 5.1.1 has been adjusted.</p>
3	Introduction	<p>The introduction need not elaborate on the research team's rationale; it suffices to state the purpose, significance, and importance.</p>	<p>Gao Yanling, National Standard Technical Review Center, State Administration for Market Regulation</p>	<p>Adopted. The introduction has been revised to: "The Chinese Herbal Medicine Pharmacy Service Specifications draw upon the concept of comprehensive pharmacy services from domestic and international pharmaceutical fields, aiming to standardize the entire process of Chinese herbal medicine dispensing technical operations..."</p>
4	5	<p>Reword point "5" as "Pre-dispensing Pharmaceutical Services," point "6" as "Dispensing Pharmaceutical Services," and point "7" as "Post-dispensing Pharmaceutical Services";</p>	<p>National Standard Technical Review Center, State Administration for Market Regulation Gao Yanling</p>	<p>Adopted. The heading "5 Comprehensive Technical Content" has been removed, and the content has been revised to "5 Pre-dispensing Pharmaceutical Services," "6 Dispensing Pharmaceutical Services," and "7 Post-dispensing Pharmaceutical Services."</p>

5	3.1 3.2	Regarding the terminology in sections "3.1" and "3.2," consideration should be given to aligning subsequent Traditional Chinese Medicine concepts with their corresponding stages. For instance, whether "procurement and supply" should be included in the pre-dispensing stage—as this stage may be easily confused with corporate procurement and supply processes.	Zhang Huamin, Institute of Chinese Materia Medica, China Academy of Chinese Medical Sciences	Adopted. Procurement and supply, as well as warehouse acceptance stages, have been removed. Refer to SCM XXXX-XXXX Chinese Medicine Procurement Specifications.
6	5.3.2	In "Prescription Review," it is recommended to clarify the definitions of "prescriptions violating the Eighteen Contraindications and Nineteen Fears" and "prescriptions using excessive quantities that require dual signatures."	Wu Jiankun, Department of Pharmacy, Beijing Hospital of Traditional Chinese Medicine, Capital Medical University	Adopted. Revised to section "7.2.2 Reviewing Inappropriate Prescriptions."
7	5.3.2	In "5.3.2.2," is it necessary to understand the reasons for "unlabeled" prescriptions? Should adjustments be made based on clinical needs?	Wu Jiankun, Department of Pharmacy, Beijing Hospital of Traditional Chinese Medicine, Capital Medical University	Adopted. Revised to section "7.2.1 Reviewing Prescriptions with Non-Standard Writing".
8	5.3.2	Recommendation to supplement the basis for "abuse" in section 5.3.2.3; e. Clarify the concept of "clinical preparation"	Wu Jiankun, Department of Pharmacy, Beijing Hospital of Traditional Chinese Medicine, Capital Medical University	Adopted. Revised to section "7.2.3 Reviewing Non-Standard Prescriptions"

9	Full Text	Standards formulation must be based on laws, regulations, and ordinances; language expression requires standardization	Qiao Yanjing, Beijing University of Chinese Medicine	Adopted. Partial language revised for standardized expression.
10	Full Text	Reconsider the concept of overall integration or adjustment, standardize terminology according to legal requirements, and use terms consistent with the Basic Law, such as "pharmaceutical factory," "warehouse management," and "customer." Ensure greater consistency and standardization in phrasing.	Wu Jiankun, Department of Pharmacy, Beijing Hospital of Traditional Chinese Medicine, Capital Medical University	Adopted. "Pre-dispensing pharmaceutical services" has been revised to "procurement, storage, and maintenance services," and "post-dispensing pharmaceutical services" has been revised to "drug monitoring services."
11	3.1	Regarding the definition of "clinical therapeutic drug monitoring," how does the definition of pharmaceutical services for Chinese herbal decoction pieces correspond to pharmaceutical services?	Zhang Huamin, Institute of Chinese Materia Medica, China Academy of Chinese Medical Sciences	Adopted. Expert opinion still required.
12	3.2	Reconsider terminology. For example, since "pharmaceutical services for traditional Chinese medicine" has already been mentioned in the main text, is it necessary to define it again?	Gao Yanling, National Center for Technical Review of Standards, State Administration for Market Regulation	Not adopted. The definition of "traditional Chinese medicine pharmaceutical services" was finalized after multiple rounds of discussions among numerous domestic and international experts and does not require redefinition.
13	5.2.1	The content under "5.2.1" focuses only on "dispensing." Should specific details be added?	National Standard Technical Review Center, State Administration for Market Regulation Gao Yanling	Not adopted. All other relevant content is covered in SCM 0053-2020, while this specification supplements provisions regarding dispensing and handling of medicinal materials.

14	Appendix	Appendix B's herbal medicine maintenance methods differ from actual practice and offer limited reference value. Should it be revised to align with hospital protocols?	Guang'anmen Hospital, China Academy of Chinese Medical Sciences Jin Min	Not adopted. The preservation methods in the appendix are traditional methods specified in Beijing's dispensing standards. Considering that traditional medicine practitioners in Hong Kong and overseas regions also preserve Chinese herbal slices, they are temporarily retained. Further discussion will be held during subsequent expert workshops to determine their status.
15	Appendix	Should the storage containers used in the Chinese herbal medicine maintenance methods in Appendix B be modified to comply with the 2020 edition of the Chinese Pharmacopoeia? Currently, iron containers are rarely used.	The Third Affiliated Hospital of Beijing University of Chinese Medicine Kong Xiangwen	Adopted. The 2020 edition of the Chinese Pharmacopoeia does not explicitly specify storage containers for Chinese herbal medicine slices. Therefore, storage containers for herbal slices are standardized according to Beijing's dispensing regulations for reference; iron containers have been removed.
16	Full Text	Whether the production, compounding, and development of Chinese herbal preparations fall under the scope of personalized pharmaceutical services for traditional Chinese medicine, such as custom-formulated preparations and personalized herbal paste formulations.	Wuhan University People's Hospital Li Dan	Not adopted. Preliminary research indicates that the production, compounding, and development of traditional Chinese medicine preparations (including decoction processing and personalized contract manufacturing) are carried out by numerous institutions. Therefore, these activities are categorized under foundational service technologies.
17	Full Text	Recommendation to add provisions regulating dispensing losses in traditional Chinese medicine	The Second Affiliated Hospital of Anhui University of Chinese Medicine Cai Ming	Adopted; relevant entries added
18	4.1.1	Revised to "Four Checks and Ten Verifications"	Guangzhou Medical University Affiliated Hospital of Traditional Chinese Medicine Liu Ruoxuan	Adopted

19	1.4	Follow-up information is difficult to collect comprehensively	Ningxia Medical University General Hospital Liu Chen	Adopted. The terms "should" and "may" have been incorporated into relevant standard entries, and the content has been flexibly standardized as "may be gradually implemented based on the regional characteristics and actual circumstances of the institution... for medication monitoring."
20	3.2	Certain difficulties exist in the practical implementation of this work.	Ningxia Medical University General Hospital Liu Chen	Adopted. The terms "should" and "may" have been incorporated into relevant standard entries. Additionally, the entry "Gradually develop community pharmacy services, home-based pharmacy services, etc." has been added to Section 5.2.3.2 to provide flexible guidance.
21	Full Text	Recommendation: Detail specific training courses and credit hour requirements for different positions.	Shanghai University of Traditional Chinese Medicine Chen Zijun	Partially adopted. Due to varying regional requirements, it is difficult to standardize specific credit hour requirements. Relevant training courses have been added in Section 4.2.7: Refer to the corresponding content in "SCM 72-2022" for study.
22	Full Text	Recommend participation in clinical rounds	Shaanxi University of Chinese Medicine Guo Dongyan	Adopted, entry added "5.2.3.5 Institutions with the capacity may conduct clinical rounds to understand patients' medication use and provide pharmaceutical support."

V. Other Matters Requiring Clarification

This standard was developed with funding support from the National Key R&D Program project "Research on the Development and Evaluation of International Standards for Traditional Chinese Medicine" (2019YFC1712000) – Subproject "Development of International Standards for Clinical Pharmacy Services and Dispensing Education in Traditional Chinese Medicine" (2019YFC1712002).