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世界中医药学会联合会

World Federation of Chinese Medicine Societies

**SCM \*\*.20\*\***

# 中药药事服务规范

Specifications for TCM pharmaceutical services

(征求意见稿, CD)

世界中联国际组织标准

20\*\*-\*\*-\*\*发布实施

International Standard of WFCMS

Issued & implemented on \*\* \*\*, 20\*\*

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# 前 言

请注意本文件的某些内容可能涉及专利。本文件的发布机构不承担识别专利的责任。

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、广州医科大学附属中医医院、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。

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本文件的起草程序遵守了世界中医药学会联合会发布的 SCM1.1-2021 《标准化工作导则第 1 部分：标准制修订与发布》。

本文件由世界中医药学会联合会翻译专业委员会承担翻译，翻译人员为\*\*\*。若发生异议，以中文文本为准。

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# 引 言

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已成为国际共识。

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，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。

本文件对中国及世界各国（地区）的中药药事服务工作有一定的适用性，有利于提升医疗质量、促进中药的合理使用。本文件是依据现有的研究证据、特定的方法研制出的标准化文件，其应用优先遵循所在国的法律法规。

# 中药药事服务规范

## 1 范围

本文件规定了医院、中医诊所、零售药店等有中药零售业务的机构进行中药药事服务的工作流程、人员配置、基础设施、追溯性要求、制度建设和服务要求。

本文件适用于世界各国（地区）医院、中医诊所、零售药店等有中药零售业务（包括中药材、中药饮片、中药配方颗粒、中成药、中药提取物等）的机构从业人员。

## 2 规范性引用文件

下列文件中的内容通过文中的规范性引用而构成本文件必不可少的条款。其中，注日期的引用文件，仅该日期对应的版本适用于本文件；不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

SCM 53-2020 中药处方、调剂、给付与煎服要求 第 2 部分：调剂要求

SCM 55-2020 中药处方、调剂、给付与煎服要求 第 4 部分：中药煎服要求

SCM 74-2024 常用中药汤剂服用指南

GB/T 31774-2015 中药编码规则及编码

GB/T 42282-2022 煎药中心通用要求

T/CACM 1364-2021 中药饮片处方应付规范

T/CACM 1365-2021 中药饮片包装规范

T/CACM 1367-2021 中药饮片临方炮制规范

ISO 18668-1 中药编码系统——第 1 部分：中药编码规则

WHO international standard terminologies on traditional Chinese medicine

## 3 术语和定义

下列术语和定义适用于本文件。

### 3.1

#### 中药

在中医理论指导下用于医疗保健和疾病防治的药物。

注：包括中药材、中药饮片、中药配方颗粒、中成药和中药提取物。

[来源：根据 WHO international standard terminologies on traditional Chinese medicine,

3.3-2604, 增加注释]

### 3.2

#### 中药材

药用植物、动物、矿物经初步加工后的药用部位，可制成饮片、片剂、提取物或中成药的原料。

[来源：WHO international standard terminologies on traditional Chinese medicine, 3.3-2608, 有修改]

### 3.3

#### 中药饮片

在中医药和中药炮制方法指导下，直接用于中医临床或制剂生产使用的处方药品。

[来源：ISO 18668-1:2016, 定义 3.3]

### 3.4

#### 中药配方颗粒

单味饮片经提取、浓缩、干燥后制成的颗粒剂，是无需煎煮可直接用于调配冲服的饮片制剂。

[来源：ISO 18668-1:2016, 定义 3.4]

### 3.5

#### 中成药

在中医药理论指导下，以中药饮片为原料，按规定的处方和标准制成具有一定规格的剂型，可直接用于防治疾病的制剂。

### 3.6

#### 中药提取物

在中医药理论指导下，以中药材、中药饮片为原料，运用一定的规范的工艺或特定技术制得的具有药用活性成分的物质。

### 3.7

#### 药事服务

医药从业人员运用专业知识与实践技能，全程化保障患者合理使用药物的服务过程，其过程涵盖药品采购储存、处方审核、药品调配、用药指导与监测等环节。

### 3.8

#### 中药药事服务

中医药从业人员运用专业知识与实践技能，全程化保障患者合理使用中药的服务过程。

注：其内容包括进行中药采购验收及贮存养护，机构依据中医师或针灸医师开具的中药处方进行处方调剂，对于有需要的患者进行临方制剂加工，规范发药并进行发药交代，为咨询者进行用药咨询，有条件的机构依据实际所处地区特点进行用药监测，关注药物警戒，必要时为患者提供辅助服务等系列中药学技术服务过程。

## 4 总则

## 4.1 工作流程

中药药事服务应符合所在国家或地区卫生及安全相关规定，技术可分为基础性服务技术和个性化服务技术两方面。从业人员应按照本文件的技术内容开展中药相关药事服务，进行中药采购验收及贮存养护，为咨询者认真耐心进行用药咨询，机构依据中医师或针灸医师开具的中药处方进行处方调剂，对于有需要的患者进行临方制剂加工，规范发药并进行发药交代，有条件的机构依据实际所处地区特点进行用药监测，关注药物警戒，必要时为患者提供辅助服务等（见附录 A）。

## 4.2 人员配置

4.2.1 从事中药药事服务的人员应掌握中药学专业基础知识，取得相应中药学专业初级及以上技术职称资格，或遵照所在国家或地区卫生行政和行业主管部门对从业人员资格的要求。

4.2.2 负责采购验收和贮存养护服务的人员应具备一定中药材/中药饮片鉴别经验，宜具有2年以上的中药材/中药饮片鉴别经验。

4.2.3 负责中药临方制剂加工服务的人员应接受中药煎药等相关知识和技能培训，取得培训合格证后方可上岗。

4.2.4 进行处方调剂服务人员的签名或专用签章式样应在机构内留样备查。

4.2.5 应每年进行健康检查，患有传染病或者其他可能污染药品的疾病的，不得从事直接接触药品的工作。

4.2.6 应保护患者隐私，尊重患者的民族习惯和宗教信仰（如有的民族和宗教禁止使用动物基原的中药饮片，中药药事服务人员应对患者告知）。

4.2.7 宜定期接受工作相关内容的培训或继续教育，如无相关要求则可参照“SCM 72-2022”中相关内容进行学习。

## 4.3 基础设施

4.3.1 开展中药药事服务的机构应按相关规定配备所需的库房、药房、煎药房、调配器具、煎药机、临方制剂加工设备等场地和硬件设备，并依据所在国家或地区卫生行政和行业主管部门要求获取相应的服务资质。

4.3.2 开展中药药事服务的机构在开展中药饮片临床药事服务过程使用的设备、工具、材料及场地等应符合所在国家和地区的相关卫生标准和安全规定，应注意场所及设备的安全防火和清洁卫生工作。

4.3.3 零售药店、杂货店、食品店等经营机构所配备的场地及硬件设备应与经营规模相匹配。

4.3.4 宜依据实际情况设置提供用药咨询的专门区域。

## 4.4 追溯性要求

4.4.1 应实施适当的可追溯操作，宜记录采购环节、验收环节、贮存养护环节、处方调剂环节、临方制剂加工环节、发药与用药交代环节等关键参数，可根据实际情况建立用药监测环节、药物警戒环节及其余辅助服务环节等个性化服务环节关键参数，追溯记录和凭证保存期限宜不少于二年以上，确保中药药事服务全流程安全和质量。

4.4.2 可通过计算机信息系统辅助开展中药药事服务，做好服务对象的个人信息保护，对过程予以记录，确保相关记录真实、准确、完整、防篡改、可追溯。

#### 4.5 制度建设与信息维护

4.5.1 宜根据机构内实际情况，制定中药药事服务基础管理制度，包括采购验收制度、贮存养护制度、处方调剂制度、临方炮制加工制度、发药与用药交代制度等。可根据实际情况建立用药监测制度、药物警戒制度及其余辅助服务制度等个性化服务制度，并及时更新。

4.5.2 宜建立药事服务工作的质量控制、风险管理、质量评价、质量持续改进等方面的管理措施。

4.5.3 所在机构使用电子处方的宜根据饮片不同的炮制规格制定信息系统中饮片名称及处方用名规则，定期检查更新并维护信息系统中的饮片名称及处方用名。

### 5 中药药事服务技术要求

#### 5.1 基础性服务技术

##### 5.1.1 采购验收技术

5.1.1.1 应逐日检查中药各库房供应品种及数量情况，随时整理药品，对短缺品种及时登记并补充。

5.1.1.2 应选择证照齐全、药品质量可靠、供货及时、渠道规范的药品供应商采购中药，并签订药品购销合同。

5.1.1.3 应根据医疗诊疗或市场需要，按需制定采购计划，及时采购符合本机构需求的中药。

5.1.1.4 购进中药到库后，宜认真核对票、账（清）单、货三者相符性。验收过程中宜执行质量验收制度，做好质量验收记录，拒收文件不规范、质量不合格和近效期药品。验收内容包括但不限于：

——宜对中药材、中药饮片的品名、规格、数量、批准文号、生产批号、生产厂家、注册商标、保质期、小包装装量差异、外观包装情况进行验收，索要质检报告单，并遵照所在国家或地区药监部门对中药材、中药饮片外观质量的要求对中药材、中药饮片进行抽检；

——宜对中成药、配方颗粒、中药提取物的药品标签、说明书、批准文号、品名、规格、生产批号、有效期等进行验收，并对外观进行抽检。

5.1.1.5 宜定期对药品供应商的中药质量安全性和稳定性进行检查评估，并根据评估结果及时调整供应单位和供应方案。

##### 5.1.2 贮存养护技术

5.1.2.1 应掌握中药饮片的变异现象，包括虫蛀、发霉、泛油、变色、气味散失、风化、潮解溶化、粘连、挥发、腐烂等。

5.1.2.2 应定期对库房、调剂室的中药进行养护与质量检查，采取必要的冷藏、防冻、防潮、避光、通风、防火、防虫、防霉、防蛀、防走油、防变色、防鼠等措施，并做好记录。宜参照以下要求实施养护与检查措施：

——定期对中药库房进行清洁；

——按照包装或说明书中规定的储存温度、湿度对中成药、中药提取物进行贮存；

——保障中药材、中药饮片及配方颗粒库房通风、阴凉及干燥，避免日光直接照射，宜根据中药材、中药饮片的特点对中药材和中药饮片进行贮存；

5.1.2.3 应注意鲜药的养护与保管，定期检查保鲜冷柜的运行状态，检查鲜药是否变质损坏。

5.1.2.4 应定期检查中药的供应品种及数量情况，及时补充库房、调剂室及调剂室药斗内缺少的中药，并做好出入库记录。

### 5.1.3 用药咨询技术

5.1.3.1 应对咨询者生活习惯、病情、病史、用药情况等进行询问，应重点关注特殊人群（肝肾功能不全者、孕产妇、婴幼儿、老年患者等）、患有多种疾病及患有慢性病咨询者的用药情况，给予适当的指导，必要时采取口头指导及纸质指导单结合的模式。必要时应建议咨询者及时就医。

5.1.3.2 应以药品说明书、专业书籍等为依据进行用药咨询。

5.1.3.3 宜重点关注咨询者所咨询的各类中药、中药与西药之间联合用药是否存在重复用药、配伍禁忌等。

### 5.1.4 中药调剂技术

#### 5.1.4.1 中药处方审核技术

5.1.4.1.1 调剂人员在接到处方时，应进行四查十对，即查处方、查药品、查配伍禁忌、查用药合理性；核对患者信息应对科别、对姓名、对年龄，核对药品应对药名、对剂型、对规格、对数量、对药品性状、对用法用量、对临床诊断。

5.1.4.1.2 对于含有中成药的处方宜依照其说明书审核不良反应、禁忌、注意事项、特殊人群用药、警示语、中西药联合用药情况等是否合理。

#### 5.1.4.2 药品调配技术

5.1.4.2.1 中药处方调配全流程应符合 SCM 53-2020 中 7.2 的相关要求。

5.1.4.2.2 调配与复核宜由两人分别进行操作。

5.1.4.2.3 调配过程中，宜根据 ISO 18668-2 中“6 中药饮片编码”中的中药饮片名称或参照 T/CACM 1364-2021 中“9 常用中药饮片处方应付规则”项下要求进行中药饮片的处方应付。

5.1.4.2.4 调配中药饮片、中药材的人员应定期对调配器具进行检查及维护。

5.1.4.2.5 调配过程中宜检查中药性状、外观，如发现异常及时报损：

——检查中药材、中药饮片是否变质；

——检查中成药、配方颗粒、中药提取物是否有包装破损、药品颜色性状变化。

5.1.4.2.6 宜建立饮片调剂损耗台账，月损耗率可为不大于 1%。

#### 5.1.4.3 临方炮制技术

宜按照 T/CACM 1367-2021 第 6 章的要求和患者处方中实际治疗需求开展中药饮片临

方炮制工作，并填写中药饮片炮制加工记录。

#### 5.1.4.4 处方复核技术

5.1.4.4.1 应依据 SCM 53-2020 中“7.3 复核”项下要求进行中药处方复核。

5.1.4.4.2 应复核含有中成药的处方：

——复核处方的临床诊断与药品说明书的一致性，药品名称、规格、数量与处方开具的一致性；

——复核药品质量是否合格，包装无污损，无渗漏；

——复核药品批号，药品有效期。

5.1.4.4.3 复核含有中药配方颗粒处方中药品名称、规格、数量与处方开具的一致性，药品包装无破损。

5.1.4.4.4 复核后应对散装中药饮片进行包装，包装应符合 T/CACM 1365-2021“5 散装中药饮片”项下要求。

#### 5.1.5 临方制剂加工技术

5.1.5.1 宜参照 SCM 0055-2020 中“6 煎药操作方法”中中药饮片煎煮的相关要求进行中药饮片人工代煎或煎药机代煎操作。

5.1.5.2 将浸泡好的药物和浸泡水放入煎药机中时，宜再次评估加水量。

5.1.5.3 使用煎药机进行煎煮时宜参照 GB/T 42282-2022 中“5.4 煎药”项下要求进行煎药剂质量检查及煎煮过程中挤压的相关操作。

5.1.5.4 代煎操作各环节（收方、审方、调配、复核、煎煮、发药、邮寄）宜形成并存档清晰的记录，包括但不限于纸质记录、电子监控、照片等形式。

5.1.5.5 临方制剂加工为其他剂型的可根据机构内实际情况进行操作并遵循相关规定。

5.1.5.6 加工后应参照 5.1.6 项下要求进行发药与用药交代。

#### 5.1.6 发药与用药交代技术

5.1.6.1 发药前药师应进行以下核对，确保各项信息准确、合理：

——核对患者信息：包括姓名、科室、年龄等可识别其身份的信息；

——核对药品信息：包括药品名称、数量、规格、剂型、性状和效期；

——核对处方信息：包括药品适应症、禁忌症、单次剂量、用药频次、给药途径、相互作用等；

——核对用药指导材料：确认调配药师书写或打印的指导内容准确无误。

5.1.6.2 发药时宜进行用药告知：

——按照 SCM 0055-2020 中“6.1 一般中药饮片煎煮方法”中相关要求，详细告知患者中药饮片的浸泡及煎煮方法；

——根据中药饮片的不同特点和性质告知患者中药饮片的贮存方法及保质期；

——告知患者中药饮片、中药配方颗粒的服药温度、服药时间、服药次数、服药剂量、服药禁忌、药后护理、贮存方法，并进行日常生活的健康提示，如合理膳食、规律作息等。

宜参照“SCM 74-2024 常用中药汤剂服用指南”标准中的技术内容，指导患者中药饮片煎

煮完成后的汤剂服用方法（包括服药温度、服药时间、服药次数、服药剂量、服药禁忌、药后护理、贮存方法、特殊服药方法等）；

——告知患者中成药的用法用量、特殊贮存与禁忌症。避免发药交代使用药物计量单位，如 g, mg, mL 等，宜对处方计量单位换算为以片数、粒数、包数后告知患者；

——可参照中药饮片相关要求执行中药材、中药配方颗粒及中药提取物的用药告知。

5.1.6.3 遇特殊人群（肝肾功能不全者、孕产妇、婴幼儿、老年患者）需详细提示用药方法，宜避免使用专业词汇，适当给予生活方式指导、用药依从性建议，必要时予以纸质交代与口头交代结合的模式。

## 5.2 个性化服务技术

### 5.2.1 中药用药监测技术

5.2.1.1 获知或发现不良反应后，应及时分析上报并填写不良反应监测表。

5.2.1.2 宜建立本机构含有毒、麻成分的中药目录，并定期收集本机构含有毒、麻醉成分中药的临床报道及最新资料，补充或更新本机构含有毒、麻成分中药的不良反应及救治措施资料。

5.2.1.3 宜重点监测本机构含有毒、麻成分中药及已有明确依据表明可引起肝肾功能损伤中药的使用，及时进行中药不良反应的整理、分析、汇总，积累资料以备指导患者。

5.2.1.4 可根据机构所处地区特点及实际情况逐步开展特殊人群（肝肾功能不全者、孕产妇、婴幼儿、老年患者）、患有多种疾病及患有慢性病患者的用药监测，建立药历，跟踪其中药使用情况，药历内容包括但不限于基本资料、家族史、过敏史、购药历史、用药情况、联合用药、药效表现、不良反应等，发现异常时立即停药并采取救治措施，必要时及时送医。

### 5.2.2 中药药物警戒技术

5.2.2.1 宜警戒中药的使用情况，提出新信号：

——警戒各类型中药、中药与西药之间联合用药的相互作用情况；

——警戒特殊人群（肝肾功能不全者、孕产妇、婴幼儿、老年患者）、患有多种疾病及患有慢性病患者、用药疗程较长的用药异常情况。

5.2.2.2 宜警戒中药不良反应的动态和发生率，对中药的风险及效益进行定量评估和分析，及时将信息进行反馈与上报。

### 5.2.3 其他辅助服务技术

5.2.3.1 可根据专业书籍、所在国家或地区卫生行政和行业主管部门的中药相关要求等进行中药鉴别、中药打粉、中药熬胶等操作。

5.2.3.2 可根据实际各自所处地区特点，逐步开展社区药事服务、居家药事服务等：

——与患者的家庭医生、保健护士等人员进行配合开展用药咨询、用药监测等居家药事服务；

——通过包括发放用药宣传单、开展用药咨询日、举办健康教育讲座等多种形式定期开展中药相关的用药宣传和咨询；

——回收过有效期或废弃药品，并进行统一无害化处理。

5.2.3.3 可根据 5.1.3 项下要求进行网络用药咨询或电话用药咨询等网络药事服务。

5.2.3.4 可协助患者进行中药及成品制剂邮寄或送货上门：

——协助患者预约第三方物流配送；

——配送交付前认真核对药品及物流单上患者信息（包括姓名、性别、年龄、就诊日期、住址等）、包装情况（无破损、无漏液）、剂量、数量等，做好患者信息隐私保护措施并进行详细记录，对于有问题的药品应拒绝寄出；

——宜与物流公司签订时效性协议，明确规定各方责任，保证药品邮寄时效性及质量。

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。

附录 A  
(规范性)  
中药药事服务工作流程

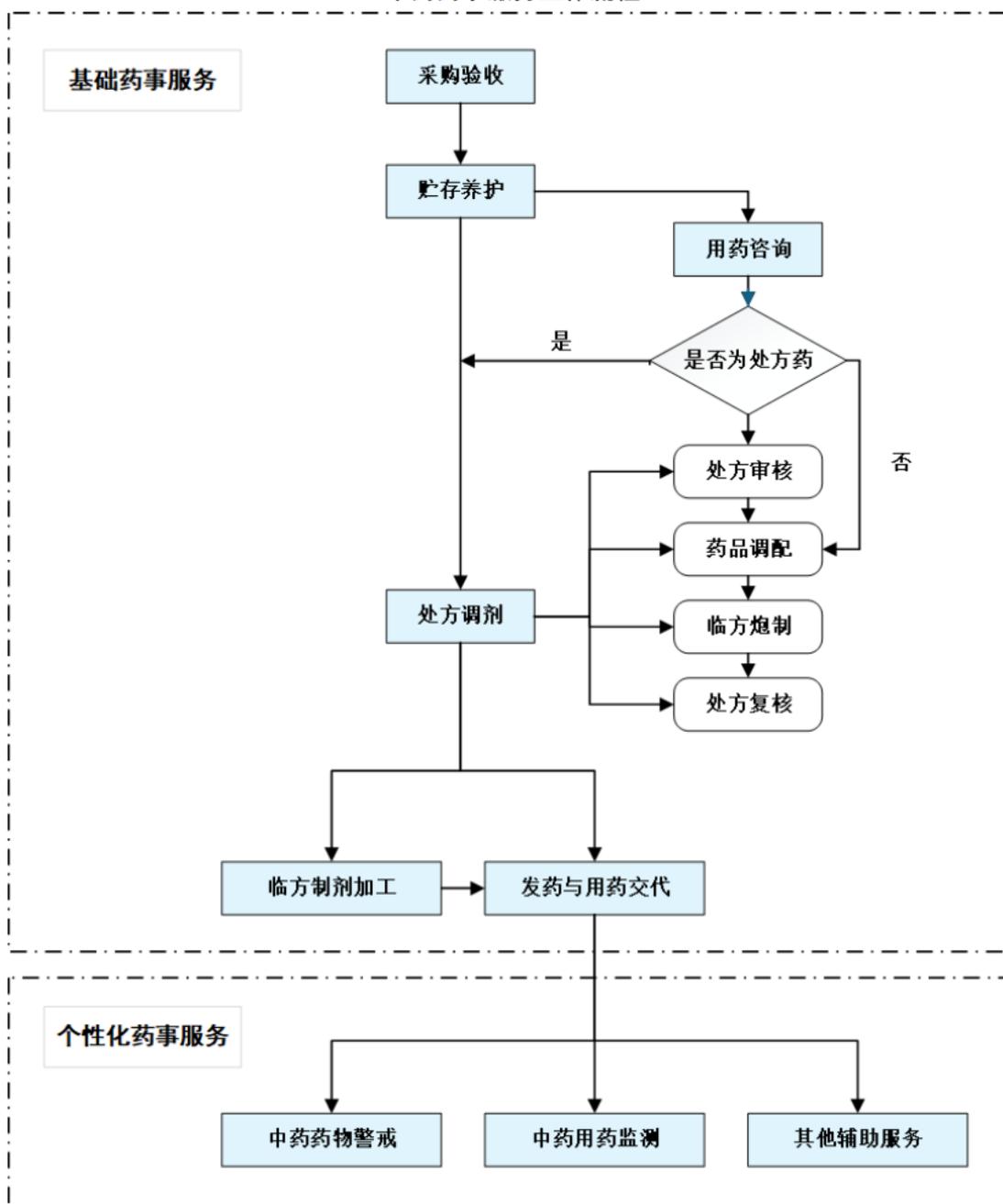


图 A.1 中药药事服务工作流程图

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## Foreword

Please note that certain aspects of this document may involve patents. The issuing body of this document assumes no responsibility for identifying patents.

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## **Introduction**

With the continuous development of modern clinical pharmacy services, numerous countries worldwide have actively explored the standardization of pharmaceutical services. The United States, the United Kingdom, Japan, South Africa, and others have established clear pharmaceutical service standards. The full-process involvement of pharmacists in guiding patients toward rational medication use has become 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, TCM (TCM) are primarily distributed overseas as food or dietary supplements. Their rational use relies on the service capabilities of practitioners, yet relevant service standards and technical specifications remain lacking, severely impacting the quality of TCM pharmaceutical services. Therefore, to enhance the safety and efficacy of TCM usage globally, establishing technical specifications for comprehensive pharmaceutical services for TCM will elevate the standard of TCM pharmaceutical services both domestically and internationally.

This document holds applicability for TCM pharmaceutical services in China and other countries (regions) worldwide, contributing to improved healthcare quality and promoting the rational use of TCM. Developed based on existing research evidence and specific methodologies, this standardized document prioritizes compliance with the laws and regulations of the country where it is applied.

# Specifications for TCM Pharmaceutical Services

## 1 Scope

This document specifies the workflow, staffing requirements, infrastructure, traceability requirements, institutional development, and service standards for TCM pharmaceutical services in institutions engaged in TCM retail operations, including hospitals, TCM clinics, and retail pharmacies.

This document applies to practitioners in hospitals, TCM clinics, retail pharmacies, and other institutions worldwide (including regions) that engage in TCM retail operations (including Raw Chinese medicines, TCM decoction pieces, TCM TCM granules form, Chinese patent medicines, and TCM extracts, etc.).

## 2 Normative References

The content of the following documents is indispensable to this document through normative references. For dated references, only the edition specified applies. For undated references, the latest edition (including all amendments) applies.

*SCM 53-2020 Requirements for Prescription, Dispensing, Administration, and Decoction of TCM Part 2: Dispensing Requirements*

*SCM 55-2020 Requirements for Prescribing, Dispensing, Administering, and Decoction of TCM Part 4: Requirements for Decoction of TCM*

*SCM 74-2024 Guidelines for Administration of Commonly Used TCM decoction pieces*

*GB/T 31774-2015 Coding Rules and Codes for TCM*

*GB/T 42282-2022 General Requirements for Decoction Centers*

*T/CACM 1364-2021 Specifications for Prescription of TCM Preparations*

*T/CACM 1365-2021 Packaging Specifications for Chinese Herbal Medicinal Materials*

*T/CACM 1367-2021 Specifications for Customized Processing of Chinese Herbal Medicinal Materials*

*ISO 18668-1 Traditional Chinese medicine—Coding system for Chinese medicines—Part 1: Coding rules for Chinese medicines*

*WHO international standard terminologies on traditional Chinese medicine*

## 3 Terms and Definitions

The following terms and definitions apply to this document.

### **3.1**

#### **Traditional Chinese medicine**

medicines to prevent, treat and diagnose diseases under the guidance of Chinese medical theories.

**Note:** Includes Raw Chinese medicines, TCM decoction pieces, TCM TCM granules form, Chinese patent medicines, and TCM extracts.

[Source: WHO international standard terminologies on traditional Chinese medicine, 3.3-2604, with annotation added]

### **3.2**

#### **Raw Chinese medicines**

raw materials include medicinal plants, animals and minerals that can be prepared into TCM decoction pieces, pieces, extracts or Chinese patent medicine.

[Source: Adapted from WHO international standard terminologies on traditional Chinese medicine, 3.3-2608, with modifications]

### **3.3**

#### **TCM decoction pieces**

prescription medicinal processed from Chinese Materia Medica under the guidance of TCM and processing methods for Chinese medicines.

[Source: ISO 18668-1:2016, Definition 3.3]

### **3.4**

#### **TCM Granules form of individual medicinal for prescriptions**

granular preparation processed from single decoction piece after extraction, concentration, and drying

[Source: ISO 18668-1:2016, Definition 3.4]

### **3.5**

#### **Chinese patent medicines**

Preparations manufactured under the guidance of traditional Chinese medicine theory, using crude TCM decoction pieces as raw ingredients, according to prescribed formulas and standards, in specific dosage forms, and intended for direct use in the prevention and treatment of diseases.

### **3.6**

#### **Chinese medicine extract**

substances containing medicinal active components, produced using standardized processes or specific technologies from raw Chinese medicines or Chinese medicine decoction pieces as raw materials, guided by Chinese medicine theory.

### **3.7**

#### **Pharmaceutical Services**

service process in which healthcare professionals utilize their specialized knowledge and practical skills to ensure the rational use of medications throughout the entire patient care journey. This process encompasses medication procurement and storage, prescription review, medication dispensing, medication counseling, and medication monitoring.

### **3.8**

#### **Traditional Chinese Medicine Pharmaceutical Services(TCMPS)**

Chinese medicine practitioners utilize their professional knowledge and practical skills to ensure the rational use of traditional Chinese medicine throughout the entire service process.

**Note:** This includes procuring, receiving, and storing TCM materials; dispensing TCM prescriptions based on prescriptions issued by TCM practitioners or acupuncturists; preparing compounded formulations for patients as needed; dispensing medications according to regulations and providing dispensing instructions; offering medication counseling to inquirers; conducting medication monitoring based on regional characteristics where feasible; monitoring pharmacological; and providing auxiliary services to patients when necessary.

## **4 General Provisions**

### **4.1 Workflow**

Traditional Chinese Medicine Pharmaceutical Services(TCMPS) must comply with relevant health and safety regulations of the country or region. Technically, these services can be categorized into foundational service techniques and personalized service techniques. Practitioners should conduct TCMPS in accordance with the technical content outlined in this document, including procurement, inspection, storage, and maintenance of TCM. They should provide thorough and patient medication consultations to clients. Institutions shall dispense prescriptions based on formulas prescribed by licensed Chinese medicine practitioners or acupuncturists, prepare bespoke formulations for patients requiring them, adhere to standardized dispensing procedures with

proper medication counseling, and where feasible, conduct medication monitoring tailored to regional characteristics, maintain pharmacovigilance, and provide supplementary services to patients as necessary (see Annex A).

## **4.2 Personnel Configuration**

**4.2.1** Personnel engaged in TCMPS shall possess specialized knowledge in TCM and hold a primary-level or higher professional technical title qualification in TCM, or meet the practitioner qualification requirements set by the health administration and industry authorities of their respective country or region.

**4.2.2** Personnel responsible for procurement, acceptance, and storage maintenance services should possess experience in identifying raw Chinese medicines/TCM decoction pieces, preferably with at least two years of such experience.

**4.2.3** Personnel responsible for processing TCM prescriptions shall receive training in relevant knowledge and skills, such as decoction preparation, and obtain a training qualification certificate before commencing work.

**4.2.4** Samples of the signature or official seal used by personnel performing prescription dispensing services shall be retained within the institution for reference.

**4.2.5** Annual health examinations shall be conducted. Personnel suffering from infectious diseases or other conditions that may contaminate medications shall not engage in work involving direct contact with medications.

**4.2.6** Patient privacy must be protected, and patients' ethnic customs and religious beliefs must be respected (e.g., if certain ethnic groups or religions prohibit the use of animal-derived TCM decoction pieces, pharmaceutical service personnel should inform patients accordingly).

**4.2.7** Personnel should undergo regular training or continuing education relevant to their duties. Where no specific requirements exist, they may refer to the relevant content in "SCM 72-2022" for learning.

## **4.3 Infrastructure**

**4.3.1** Institutions providing TCM pharmaceutical services shall equip themselves with required facilities and hardware, including storage rooms, pharmacies, decoction rooms, dispensing tools, decoction machines, and compounding equipment for preparing prescription formulations, in accordance with relevant regulations. They shall obtain corresponding service qualifications as required by the health administration and industry authorities of their country or region.

**4.3.2** Equipment, tools, materials, and premises used by institutions providing TCM pharmaceutical services during clinical TCM decoction piece services shall

comply with relevant health standards and safety regulations of the country or region. Attention shall be paid to fire safety and cleanliness of premises and equipment.

**4.3.3** The premises and hardware equipment provided by retail pharmacies, general stores, food stores, and other business entities shall be commensurate with their operational scale.

**4.3.4** Dedicated areas for medication counseling should be established based on actual conditions.

#### **4.4 Traceability Requirements**

**4.4.1** Appropriate traceability procedures shall be implemented, Recording key parameters is recommended for procurement, acceptance, storage and maintenance, prescription dispensing, compounding of extemporaneous preparations, and medication dispensing with usage instructions. Additional parameters for personalized service segments such as medication monitoring, pharmacovigilance, and other auxiliary services may be established based on actual circumstances. Traceability records and supporting documentation should be retained for no less than two years to ensure the safety and quality of the entire traditional Chinese medicine pharmacy service process.

**4.4.2** Computer information systems may assist in conducting TCM pharmaceutical services. Personal information of service recipients must be protected, and processes must be documented to ensure records are authentic, accurate, complete, tamper-proof, and traceable.

#### **4.5 System Development and Information Maintenance**

**4.5.1** Institutions should establish foundational management systems for TCM pharmaceutical services based on their actual circumstances, including procurement and acceptance procedures, storage and maintenance protocols, prescription dispensing systems, on-site preparation and processing guidelines, and medication dispensing and usage instruction protocols. Additional customized service systems such as medication monitoring, pharmacovigilance, and other auxiliary service protocols may be developed as needed and updated promptly.

**4.5.2** Establish management measures for quality control, risk management, quality evaluation, and continuous quality improvement in pharmaceutical services.

**4.5.3** Institutions utilizing electronic prescriptions should establish naming conventions for herbal slices and prescription terms within their information systems based on different processing specifications. These naming conventions

should be regularly reviewed, updated, and maintained.

## **5 Technical Requirements for TCM Pharmaceutical Services**

### **5.1 Basic Service Technologies**

#### **5.1.1 Procurement and Acceptance Technical**

**5.1.1.1** Daily inspections should be conducted to verify the variety and quantity of supplies in each Chinese medicine warehouse. Medicines should be organized promptly, with shortages recorded and replenished in a timely manner.

**5.1.1.2** Procure TCMs from suppliers with complete licenses, reliable drug quality, timely delivery, and standardized channels, and sign drug purchase and sales contracts.

**5.1.1.3** Formulate procurement plans based on medical treatment needs or market demand, and promptly procure TCMs that meet the institution's requirements.

**5.1.1.4** Upon arrival of purchased TCMs in the warehouse, carefully verify the consistency between the invoice, inventory list, and actual goods. During acceptance, implement a quality inspection system, maintain quality inspection records, and reject items with non-compliant documentation, substandard quality, or nearing expiration. Acceptance checks shall include but are not limited to:

—It is advisable to inspect the product name, specifications, quantity, approval number, production batch number, manufacturer, registered trademark, shelf life, variations in unit packaging quantity, and appearance of packaging for raw Chinese medicines and TCM decoction pieces. Request quality inspection reports and conduct random sampling of raw Chinese medicines and TCM decoction pieces in accordance with the appearance quality requirements set by the pharmaceutical regulatory authorities of the respective country or region.

—It is advisable to inspect the labels, instructions, approval numbers, product names, specifications, production batch numbers, and expiration dates of Chinese patent medicines, TCM granules form, and TCM extracts, and conduct random inspections of their appearance.

**5.1.1.5** It is advisable to periodically inspect and evaluate the quality safety and stability of Chinese medicinal materials supplied by pharmaceutical suppliers, and adjust supply units and supply plans promptly based on evaluation results.

#### **5.1.2 Storage and Maintenance Techniques**

**5.1.2.1** Monitor variations in TCM decoction pieces, including insect infestation,

mold growth, oil seepage, discoloration, loss of aroma, weathering, deliquescence, agglomeration, volatilization, and decay.

**5.1.2.2** Regular maintenance and quality inspections should be conducted on TCMs in storage rooms and dispensing areas. Necessary measures for refrigeration, frost protection, moisture prevention, light avoidance, ventilation, fire prevention, insect control, mold prevention, insect damage prevention, oil seepage prevention, discoloration prevention, and rodent control should be implemented and documented. Maintenance and inspection measures should be carried out in accordance with the following requirements:

- Regularly clean the Chinese medicine storage area;
- Store Chinese patent medicines and TCM extracts according to the storage temperature and humidity specified on the packaging or instructions;
- Ensure ventilation, coolness, and dryness in storage areas for raw Chinese medicines, prepared TCM decoction pieces, and TCM granules form. Avoid direct sunlight exposure. Storage should be tailored to the characteristics of each type of raw Chinese medicines and prepared TCM decoction pieces;

**5.1.2.3** Pay attention to the maintenance and storage of fresh herbs. Regularly inspect the operational status of refrigerated cabinets and check for spoilage or damage to fresh herbs.

**5.1.2.4** Regularly inspect the variety and quantity of available Chinese medicinal products. Promptly replenish any shortages in storage areas, dispensing rooms, and dispensing room medicine drawers, maintaining accurate records of all entries and exits.

### **5.1.3 Medication Consultation Techniques**

**5.1.3.1** Inquire about the consultant's lifestyle habits, medical condition, medical history, and medication use. Pay particular attention to medication use among special populations (e.g., individuals with impaired liver or kidney function, pregnant women, infants, elderly patients), those with multiple conditions, and those with chronic diseases. Provide appropriate guidance, combining verbal instructions with written guidance sheets when necessary. Recommend timely medical consultation when appropriate.

**5.1.3.2** Medication counseling should be based on drug labels, professional literature, and other authoritative sources.

**5.1.3.3** Pay particular attention to potential drug duplication or contraindications when consulting on various TCMs or combinations of Chinese and Western medicines.

### **5.1.4 TCM Dispensing Techniques**

#### **5.1.4.1 TCM Prescription Review Techniques**

**5.1.4.1.1** Upon receiving a prescription, the dispensing staff shall conduct the "Four Checks and Ten Verifications": verify the prescription, verify the drugs, verify drug interactions, and verify the rationality of medication use. Patient information verification shall include: department, name, and age. Drug verification shall include: drug name, dosage form, specification, quantity, physical characteristics, administration method, dosage, and clinical diagnosis.

**5.1.4.1.2** For prescriptions containing Chinese patent medicines, review whether adverse reactions, contraindications, precautions, special populations, warnings, and combined use with Western medicines are appropriate according to the product instructions.

#### **5.1.4.2 Pharmaceutical Compounding Technology**

**5.1.4.2.1** The entire process of dispensing Chinese medicine prescriptions shall comply with the relevant requirements of Section 7.2 in SCM 53-2020.

**5.1.4.2.2** Compounding and verification should be performed by two separate individuals.

**5.1.4.2.3** During dispensing, Chinese herbal slices should be prepared according to their names as specified in "6. Codes for decoction pieces" of ISO 18668-2 or in accordance with the requirements under "9. Rules for Preparing Common Chinese Herbal Slice Prescriptions" of T/CACM 1364-2021.

**5.1.4.2.4** Personnel handling Chinese herbal slices and raw Chinese medicines should regularly inspect and maintain dispensing equipment.

**5.1.4.2.5** During dispensing, inspect the properties and appearance of TCMs. Report any abnormalities promptly as losses:

- Check whether Chinese medicinal materials and TCM decoction pieces have deteriorated;

- Inspect whether finished Chinese patent medicines, TCM granules form, and extracts have damaged packaging or changes in color and appearance.

**5.1.4.2.6** Maintain a record of losses during decoction preparation, with a monthly loss rate not exceeding 1%.

#### **5.1.4.3 Prescription-Based Processing Techniques**

Processing of TCM decoction pieces slices for individual prescriptions should be conducted in accordance with the requirements of Chapter 6 of T/CACM 1367-2021 and the actual therapeutic needs specified in the patient's prescription. A record of the processing and preparation of TCM decoction pieces slices should be completed.

#### **5.1.4.4 Prescription Verification Techniques**

**5.1.4.4.1** TCM prescriptions should be reviewed in accordance with the requirements under "7.3 Reviewing" in SCM 53-2020.

**5.1.4.4.2** Prescriptions containing Chinese patent medicines shall be reviewed for:

— Verify consistency between the clinical diagnosis in the prescription and the drug label; ensure consistency in drug name, specification, and quantity with the prescription;

— Verify that the drug quality is qualified, packaging is free from contamination or damage, and there is no leakage;

— Verify the drug batch number and expiration date.

**5.1.4.4.3** Verify that the names, specifications, and quantities of TCM granules form in prescriptions match the prescribed details, and ensure packaging is undamaged.

**5.1.4.4.4** After verification, bulk TCM decoction pieces shall be packaged. Packaging shall comply with the requirements under Section 5 "Bulk TCM Decoction Pieces" of T/CACM 1365-2021.

#### **5.1.5 Processing Techniques for Custom-Formulated Preparations**

**5.1.5.1** Manual decoction or machine decoction of TCM decoction pieces should be performed in accordance with the relevant requirements for decocting Chinese herbal slices specified in "6. Decoction method of operation" of SCM 0055-2020.

**5.1.5.2** When placing soaked herbs and soaking water into the decoction machine, it is advisable to reassess the water volume.

**5.1.5.3** When using a decoction machine, quality inspection of the decoction and related squeezing operations during the decoction process should be conducted in accordance with the requirements under "5.4 Decoction" in GB/T 42282-2022.

**5.1.5.4** Clear records should be established and archived for each step of the decoction service (prescription collection, prescription review, dispensing, verification, decoction, dispensing, and mailing), including but not limited to paper records, electronic monitoring, photographs, etc.

**5.1.5.5** Processing of freshly prescribed preparations into other dosage forms may be conducted according to the institution's actual circumstances while adhering to relevant regulations.

**5.1.5.6** Post-processing, dispensing and medication instructions shall be provided in accordance with the requirements under Section 5.1.6.

#### **5.1.6 Dispensing and Medication Instructions**

**5.1.6.1** Prior to dispensing, pharmacists shall perform the following verifications to ensure all information is accurate and appropriate:

- Verify patient information: including name, department, age, and other identifying details;

- Verify medication information: including drug name, quantity, strength, dosage form, physical characteristics, and expiration date;

- Verify prescription information: including indications, contraindications, single dose, frequency of administration, route of administration, and drug interactions;

- Verify medication guidance materials: Confirm the accuracy of written or printed guidance provided by the dispensing pharmacist.

**5.1.6.2** Medication counseling should be provided during dispensing:

- Provide detailed instructions to patients on soaking and decocting TCM decoction pieces according to the relevant requirements in "6.1 General decocting method of Chinese herbal medicine" of SCM 0055-2020;

- Advise patients on storage methods and shelf life based on the distinct characteristics and properties of each TCM decoction pieces;

- Inform patients about the appropriate temperature, timing, frequency, dosage, contraindications, post-administration care, and storage methods for TCM decoction pieces and granules form. Provide daily health guidance, such as balanced diet and regular sleep patterns. Refer to the technical content in the "SCM 74-2024 Guidelines for Taking commonly-used Chinese medicine decoctions" standard to instruct patients on how to take the decoction after preparation (including temperature, timing, frequency, dosage, contraindications, post-medication care, storage methods, and special administration methods);

- Inform patients about the dosage, special storage requirements, and contraindications for Chinese patent medicines. Avoid using measurement units like g, mg, or mL when dispensing instructions; instead, convert prescription units to tablets, capsules, or packets before communicating with patients.

- For raw Chinese medicines, herbal TCM granules form, and extracts, follow relevant guidelines for medication instructions.

**5.1.6.3** For special populations (patients with hepatic or renal impairment, pregnant women, infants, elderly patients), provide detailed instructions on medication administration. Avoid using technical jargon, offer appropriate lifestyle guidance and medication adherence advice, and when necessary, combine written instructions with verbal explanations.

## **5.2 Personalized Service Technologies**

### **5.2.1 TCM Monitoring Technology**

**5.2.1.1** Upon learning of or discovering an adverse reaction, promptly analyze and report it, completing the adverse reaction monitoring form.

**5.2.1.2** Establish an institutional inventory of TCM containing toxic or narcotic components. Regularly collect clinical reports and updated information on such TCM within the institution to supplement or update records of adverse reactions and treatment measures.

**5.2.1.3** Prioritize monitoring the use of TCMs containing toxic or narcotic components within the institution, as well as TCMs with established evidence of causing hepatic or renal impairment. Timely collate, analyze, and summarize adverse reactions to TCMs, accumulating data to guide patient care.

**5.2.1.4** Based on regional characteristics and practical circumstances, gradually implement monitoring for special populations (patients with hepatic or renal impairment, pregnant women, infants, elderly patients), patients with multiple conditions or chronic diseases. Establish medication histories to track TCM usage, including but not limited to: basic information, family history, allergy history, medication purchase history, usage patterns, drug interactions, therapeutic effects, and adverse reactions. Immediately discontinue medication and implement rescue measures upon detecting abnormalities; seek medical attention promptly when necessary.

## **5.2.2 TCM Pharmacovigilance Techniques**

**5.2.2.1** Monitor the use of TCM subject to pharmacovigilance and identify new signals:

- Monitor interactions between various types of TCM and between TCM and Western medications;

- Monitor medication anomalies in special populations (patients with hepatic or renal impairment, pregnant women, infants, elderly patients), those with multiple or chronic conditions, and those undergoing prolonged treatment regimens.

**5.2.2.2** Monitor trends and incidence rates of adverse reactions to TCM, conduct quantitative risk-benefit assessments and analyses, and promptly report findings.

## **5.2.3 Other Auxiliary Service Technologies**

**5.2.3.1** Perform operations such as TCM identification, powdering, and decoction into gelatinous extracts based on professional literature and relevant requirements from national or regional health administrative and industry authorities.

**5.2.3.2** Based on local characteristics, gradually develop community pharmacy

services and home-based pharmacy services:

- Collaborate with patients' family doctors, public health nurses, and other personnel to provide home-based pharmaceutical services such as medication counseling and medication monitoring;

- Regularly conduct TCM-related medication promotion and consultation through various methods, including distributing medication leaflets, organizing medication consultation days, and hosting health education lectures;

- Collect expired or discarded medications for centralized, environmentally safe disposal.

**5.2.3.3** Provide online pharmaceutical services such as online medication consultations or telephone medication consultations in accordance with the requirements under Section 5.1.3.

**5.2.3.4** Assist patients with mail-order or door-to-door delivery of TCM and finished preparations:

- Assist patients in scheduling third-party logistics delivery;

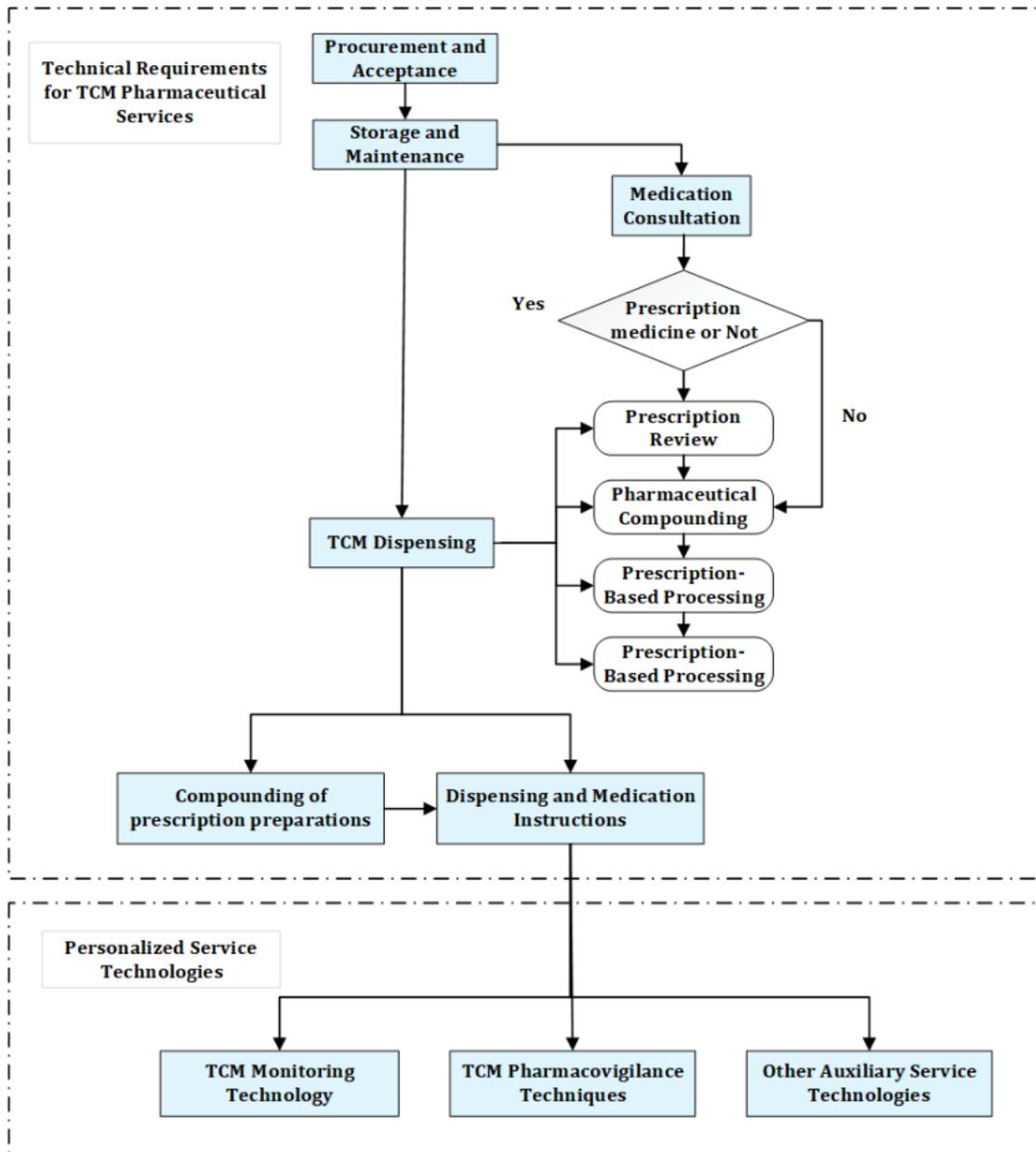
- Before delivery, meticulously verify patient information (including name, gender, age, date of visit, address, etc.) on both the medication and shipping documents, inspect packaging (for damage or leakage), confirm dosage and quantity, implement patient privacy protection measures, and maintain detailed records; refuse shipment of any problematic medications;

- Establish timeliness agreements with logistics companies, clearly defining responsibilities to ensure delivery efficiency and medication quality.

**5.2.3.5** Institutions with the capacity may conduct clinical rounds to assess medication adherence and provide pharmaceutical support.

**Annex A  
(Normative)**

**Workflow for Chinese Medicine Pharmaceutical Services**



**Figure A.1 Workflow Diagram for Traditional Chinese Medicine Pharmaceutical Services**

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