SCM



世界中医药学会联合会 World Federation of Chinese Medicine Societies

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中药处方、调剂、给付与煎服要求 第2部分:调剂要求

Requirements for prescription, dispensing, delivery, decocting and taking of Chinese medicines

Part 2: Requirements for Dispensing of Chinese Medicines

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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。 本文件《中药处方、调剂、给付与煎服要求》分为4个部分:

- ——第1部分:中药处方要求;
- ——第2部分:中药调剂要求;
- ——第3部分:中药给付要求;
- 一一第4部分:中药煎服要求。

本文件为《中药处方、调剂、给付与煎服要求》的第2部分。

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引言

从病人就诊看医生开始,到医生服务病人,进行辩证论治,开具正确的中药处方,又到中药房和中药处方的管理,涉及中药人员如何审方,正确地调剂处方;在中医辩证论治的指导下,如何遣方用药,即:中药饮片的给付/配方,以及如何选购合格的中药饮片进行配方;又如何煎煮中药,用什么样的方法煎煮中药;病人又如何服用中药等医疗服务流程。以上的每一个环节和流程,呈现分散状态,没有形成有机结合,没有得到足够的重视,严重影响医疗与中药服务质量,中药的用药安全与有效,以及消费者切身权益。

本文件为第2部分,旨在整合中医药服务流程,建立、健全中医药标准服务体系与认证制度,规范行业行为和执业操守,营造中药种植、生产、流通、用药的安全与有效,促进贸易公平、公正、和谐和科学发展的良好氛围。因此,将分散的中药服务环节和流程,整合成为一个完整的中药服务体系,以标准形式固化下来,构建了一个质量可以追溯的中药服务流程,从而加强医生、中药与患者间的有效沟通,改善医患关系,减少医疗差错,杜绝医疗事故,提高医疗服务水平,保障人民用药安全与有效,维护消费者合法权益。

本文件将传统的中药饮片调剂流程分为审方和配方两个部分。中药审方部分着重是对中药处方进行审查的过程,以审查中药处方格式及书写要求,重点是"三查七对"为着力点。它与第1部分、第3部分和第4部分形成无缝对接,遵循医生辨证论治、理法方药的要求,将中医药的特色和优势传承下来,并且落实到实际工作的操作流程中,以减少调剂,遗方用药的差错,确保用药安全与有效,让世界各国人民共享中医药发展的成果,为全人类的健康作出应有的贡献。

中药处方、调剂、给付与煎煮要求 第2部分:调剂要求

1 范围

本文件规定了中药调剂人员的资格要求、调剂室的布局和设施、中药饮片斗谱编排、中药调剂操作流程以及特殊中药饮片的调剂管理等内容。

本文件适用于医疗机构和药品零售企业对中药的调剂服务。

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。

GB/T 7027 信息分类和编码的基本原则与方法

GB/T 7635.1 全国主要产品分类与代码 第1部分 可运输产品

GB 12904 商品条码 零售商品编码与条码表示

GB/T 17710 信息技术 安全技术 校验字符系统

GB/T 31773 中药方剂编码规则及编码

GB/T 31774 中药编码规则及编码

GB/T 31775 中药在供应链管理中的编码与表示

ISO 18662-1 中医药——术语——第1部分:中药材

ISO 18662-2 中医药——词汇——第2部分: 中药炮制

ISO 18668-1 中药编码系统——第1部分:中药编码规则

ISO 18668-2 中药编码系统——第2部分: 中药饮片的编码

ISO 18668-3 中药编码系统——第3部分: 中药材的编码

ISO 18668-4 中药编码系统——第4部分:中药配方颗粒的编码

ISO 20333 中药在供应链管理中的编码与表示

ISO 20334 中药方剂编码系统

3 术语和定义

下列术语和定义适用于本文件。

3. 1

中药饮片

中药材经过炮制后,直接用于中医临床或制剂生产的处方药品。 [来源: ISO 18668-1:2016,定义3.2]

3. 2

中药调剂

根据中药处方要求,将中药饮片调剂成可供患者使用的剂型的过程。

3.3

中药配方颗粒

由单味中药饮片按传统标准炮制后经提取浓缩制成的、供中医临床配方用的颗粒。又称为单味中药浓缩颗粒剂,商品名及民间称呼还有免煎中药饮片、新饮片、精制饮片、饮料型饮片、科学中药等。

3.4

三查七对

操作前查、操作中查、操作后查,查对床号、查对姓名、查对药名、查对剂量、查对时间、查对浓度、查对用法。

注1: 三查七对就是要提醒医务人员在工作中认真核对,一直是护理工作的主要制度。延伸中药的三查七对。

注2:中药的三查七对。三查:一查,查医生是否获得当地卫生行政部门或行业管理列部门认可的处方权,具有开写处方资质;二查,处方书写格式和要求,是否符合当地卫生和行业管理政策法规的要求;三查,中药处方质量,医生辨证论治、理法方药、配伍禁忌(十八反十九畏,妊娠用药),以及《麻醉药品和精神药品管理条例》等有关。七对:一对,一般项目:包括医疗机构名称、费别、患者姓名、性别、年龄、门诊或住院病历号、科别或病区床位号等;二对,辨证论治,中医诊断,包括病名和证候,医嘱;三对,理法方药,药品名称、用量、用法,中成药还应标明剂型、规格;剂量使用公制单位,用阿拉伯数字书写,一般应以克(g)为单位;四对,检查处方的"君、臣、佐、使"的顺序排列;五对,对中药饮片的规格,生用或者制用,配伍禁忌,十八反十九畏;六对,医师签名或加盖专用签章、处方日期;七对,药品金额,审核、调配、核对、发药药师签名或者加盖专用签章。

3.5

理法方药

中医辨证论治完整体系的高度概括。理法是遣方用药的依据,方药是明理立法的体现。由于病人患病有外感内伤之别,病症表现有寒热虚实之分,兼之年龄、体质、方土、习俗等方面的个体差异,决定了中医组方用药,既有一定法度,又应灵活权变。

3. 6

医疗用毒性药品

根据中药处根据各国家和地区要求,列入"医疗用毒性药品目录"药品。 注1: 医疗用毒性药品简称毒性药品。

4 人员资格要求

- 4.1 调剂人员的资质应符合当地卫生、行业管理和 FDA 的要求。
- 4.2 调剂人员签名或者专用签章式样应在本机构留样备查。
- **4.3** 调剂人员应每年至少体检一次。凡患有精神病及可能影响药品质量的传染病、皮肤病在未治愈前,都不得参加中药调剂工作

5 调剂室布局与设施

5.1 布局要求

布局应满足工作需要,符合中药房基本设施相关要求。

5.2 设施要求

- 5.2.1 中药调剂室应有足够的面积和空间,室内墙面、地面、顶棚应光滑、无缝隙,不应有颗粒性物质脱落。墙面宜采用防水、防潮、防霉装修材料,可耐受擦洗。有空气调温、调湿等设施,有防潮、防霉、防火、防鼠、防水、防盗、遮阳等设施。
- 5.2.2 中药饮片调剂设备(器具)主要包括:药斗(架)、调剂台、称量用具(药戥、电子秤等)、粉碎用具(铜缸或小型粉碎机)、冷藏柜、新风除尘设备(可根据实际情况选配)、贵重药品柜、毒麻药品柜。

6 中药饮片斗谱编排

6.1 斗谱编排原则

斗谱编排的应满足以下要求:

- a) 有利于减轻劳动强度,方便调剂和加药。
- b) 有利于避免发生差错事故。
- c) 有利于记忆。
- d) 有利于中药饮片管理。
- e) 有利于人员分工合作。

6.2 屉斗标签

标签上应使用中药饮片标准名称。

7 调剂操作规程

7.1 审方

- 7.1.1 调剂人员在接到中药处方时,应进行三查七对。查处方,核对科别、姓名、年龄。核对药品,需核对药名、剂型、规格、数量等内容。
- 7.1.2 核查配伍禁忌、妊娠禁忌、医疗用毒性中药、含罂粟壳处方,配伍禁忌药和妊娠禁忌药可参见附录表A.1和附录表A.2。
- 7.1.3 核对药品性状、用法用量。核查用药合理性,核对临床诊断。 超出处方时效和剂量的对中药处方进行时效性调配。不规范的处方或者不能判定其合法性的处方,不应调剂。

7.2 调配

- 7. 2. 1 根据处方药物的不同体积和重量,选用适当的计量工具。如使用电子秤或天平,每次调配前要清零或调零。
- 7.2.2 对于一方多剂的处方应按"等量递减"的原则,每一剂的重量误差应控制在±原则以内。
- 7.2.3 调配时,应注意避免撒药及药斗之间掺混的现象。
- 7.2.4 为便于核对,要按处方药味所列的顺序调配,间隔平放,不可混放一堆。

- 7.2.5 按照中医师的处方要求进行调配。调配含有毒性中药饮片的处方,对处方未注明"生用"的,如有炮制品,应给付炮制品。注意不可生制不分,以生代制。
- 7.2.6 处方中如有鲜药,应洗净泥土,去掉非药用部分,切剪成段单包,以免干湿相混,发霉变质,影响疗效。
- 7.2.7 处方中有需要特殊处理的药品,如先煎、后下、包煎、冲服、烊化、另煎等,要单包成小包并注明用法。附录表A.3给出了常见需要特殊处理的药品。
- 7.2.8 矿物类、动物贝壳类、果实种子类等质地坚硬的药品,需要临时捣碎后再分剂量,以利于煎出有效成分。附录表A.4给出了需临时捣碎的常用中药饮片。
- 7.2.9 处方中有需要临时炮制加工的药品应按照相关规范,依法进行炮制。
- 7.2.10 小包装中药饮片调剂应遵循相关规定。
- 7.2.11 急诊处方应先调配,以免延误治疗。
- 7.2.12 调配完毕,经自查确认无误签名或者加盖专用签章后,再交由复核人员进行复核。

7.3 复核

- 7.3.1 审查调配好的药品是否与处方所开药味及剂数相符,有无错味、漏味、多味和掺杂异物。
- 7.3.2 审查称好的药品剂量是否与处方用量有差距,处方中各味药的剂量应准确,每剂药的剂量误差应控制在土查称以内。必要时需重新称量。
- 7.3.3 审查"十八反""十九畏"、妊娠禁忌、超过常用剂量等可能引起用药安全的问题,以及毒性中药、麻醉中药、贵细药品的调配是否得当。
- 7.3.4 审查需先煎、后下、包煎、烊化、另煎、冲服等特殊处理的药品是否单包并注明用法。
- 7.3.5 审查药品质量,有无虫蛀、发霉变质等。
- 7.3.6 审查有无乱代乱用等现象,有无生制不分或以生代制,以及应捣未捣等。
- 7.3.7 住院处方或代前药,还应复核前药瓶签与处方上的姓名、科室、送药日期、剂数。
- 7.3.8 复核人员检查无误后,应签名或者加盖专用签章,方可包装药品。

8 特殊中药饮片调剂要求

特殊中药饮片调剂要求应符合各国家和地区卫生管理部门的相关规定,也可参考附录A执行。

附录A

(资料性)

特殊中药饮片调剂要求

A. 1 特殊中药饮片的调剂管理

A. 1.1 医疗用毒性中药饮片调剂与管理

毒性中药需设毒剧药柜,实行专人、专帐、专柜加锁保管,并贴明标签。

医疗单位供应和调配毒性中药,应凭医生签名的处方。调配处方时,应认真负责,计量准确,按医嘱注明要求,并由配方人员及具有中药师以上技术职称的复核人员签名盖章后方可发出。对处方未注明"生用"的毒性中药,应付炮制品。如发现处方有疑问时,应经原处方医生重新审定后再行调配。

毒性中药应设立专帐卡,日清月结,做到帐物相符,并填写使用登记本,登记本上应写明 患者姓名、年龄、单位、联系方法、使用药品名称、数量及期限,处方医生姓名、调配人员姓 名。

处方一次有效,取药后处方及证明保存两年备查。

毒性中药管理品种范围及用法用量见SZJG 37.1-2011《中药处方与中药调剂标准 第1部分:中药处方标准》。

A. 1. 2 麻醉药品管理中药饮片调剂与管理

中药调剂人员应凭麻醉药品专用处方配药,对不合法、不合理处方,药学部门有权拒绝调配。

调剂麻醉药品处方应专册登记,登记内容包括:处方日期、科别、患者姓名、病历号、性别、年龄、诊断、罂粟壳用量、医师姓名、调剂人、核对人。

处方不得重复取药,取药后需由医疗机构保存三年备查。

A. 1. 3 贵重中药饮片调剂与管理

贵重中药品种见SZIG 37.1-2011《中药处方与中药调剂标准 第1部分:中药处方标准》。

凡属一类贵重药品,明细收支台帐的内容应包括: "日期""事件摘要""进、销、存数量""发药人""核对人"。发药处方逐张登记,集中存放,在"事件摘要"项下应登记病人姓名和处方号等。

相关管理人员应每日根据门诊用药消耗数量,及时补充药品以保证临床用药,当日消耗的 贵重药品应及时登记入帐,并应帐物相符。

贵重药品应定期检查,严防过期霉变的现象发生,易变质的药品应存放于带锁的冷柜中。

A. 2 特殊中药饮片列表

A. 2.1 配伍禁忌药见表A. 1。

表 A. 1 配伍禁忌药

十八反	甘草反甘遂、大戟、芫花、海藻;乌头(川乌、草乌、附子)反贝母(川贝母、浙贝母、平贝母、伊贝母、湖北贝母)、瓜蒌(瓜蒌、瓜蒌子、瓜蒌皮、天花粉)、半夏、白蔹、白及;藜芦反人参、丹参、沙参、玄参、苦参、细辛、芍药(白芍、赤芍)
十九畏	硫黄畏朴硝,水银畏砒霜,狼毒畏密陀僧,巴豆畏牵牛,丁香畏郁金,川乌、草乌畏犀角,牙 硝畏三棱,官桂畏石脂,人参畏五灵脂。

A. 2. 2 妊娠禁忌药见表A. 2。

表 A. 2 妊娠禁忌药

	三棱、莪术、水蛭、虻虫、甘遂、京大戟、芫花、牵牛子、巴豆、千金子、商陆、轻粉、斑蝥、
禁用药	雄黄、麝香、猪牙皂、益母草、马钱子、附子、土鳖虫、川牛膝、玄明粉、芒硝、阿魏、闹羊
	花、蜈蚣等
慎用药	蟾酥、华山参、制天南星、干漆、急性子、硫黄、制川乌、制草乌、白附子、枳实、枳壳、大
	黄、番泻叶、肉桂、凌霄花、木鳖子、牛膝、红花、桃仁、三七 <mark>、</mark> 郁李仁、虎杖、卷柏、王不
	留行、禹州漏芦、漏芦、片姜黄、西红花、穿山甲、冰片、苏木、通草、常山、蒲黄、赭石、
	瞿麦等

A. 2. 3 需要特殊煎煮的中药饮片见表A. 3。

表 A. 3 需要特殊煎煮的中药饮片

	龟甲、鳖甲、赭石、石决明、牡蛎、 <mark>龙骨、磁石、石膏、紫石英、寒水石、自然铜、蛤壳、珍</mark>
先煎	│ 珠母、鹿角霜、瓦楞子、制川乌、制草乌、制附子、制白附子、商陆、生天南星、生半夏、石 │
	斛等
后下	薄荷、砂仁、豆蔻、沉香、苦杏仁、钩藤、大黄、番泻叶、徐长卿、青蒿、鱼腥草等
包煎	葶苈子、车前子、旋覆花、生蒲黄、六一散、黛蛤散、益元散、蛤粉、青黛、马勃、滑石粉、
世界	海金沙、儿茶等
冲服	牛黄、三七粉、珍珠、朱砂、麝香、熊胆、马宝、猴枣、羚羊角粉、沉香粉、琥珀粉、玳瑁粉、
7年70	川贝母、湖北 <mark>贝母、雷丸等</mark>
烊化	阿胶、鹿角胶、龟甲胶、蜂蜜、饴糖等
另煎	人参、天麻、羚羊角片、西洋参、西红花、冬虫夏草、鹿茸片等
溶化	芒硝、玄明粉等

A. 2. 4 需临时捣碎的常用中药饮片见表A. 4。

表 A. 4 需临时捣碎的常用中药饮片

果实和种子类	丁香、刀豆、大枣、川楝子、五味子、牛蒡子、白果、白扁豆、瓜蒌子、决明子、红
	豆蔻、豆蔻、芥子、诃子、青果、郁李仁、使君子、胡椒、荜茇、草豆蔻、草果、荔
	枝核、牵牛子、砂仁、桃仁、莱菔子、益智、预知子、猪牙皂、黑芝麻、榧子、酸枣
	仁、蔓荆子、蕤仁、橘核等
根和根茎类	山慈菇、平贝母、竹节参、华山参、珠子参、绵马贯众等
矿物类	白矾、自然铜等
动物类	海马、鹿角霜、穿山甲、鳖甲、龟甲等
其他药	儿茶、肉桂等

Foreword

Note that certain contents of this document may involve certain patents. The issuing authority of this document assumes no statutory duty to identify the patent.

The series of standards of Medication service process of Chinese medicines consists of 4 parts.

- Part 1: Requirements for Prescription of Chinese medicines
- Part 2: Requirements for Dispensing of Chinese medicines
- Part 3: Requirements for Delivery of Chinese medicines
- Part4: Requirements for Decocting and Taking of Chinese medicines

This document is the second part: Requirements for Dispensing of Chinese medicine.

The main drafting organizations of this document are: Jiangxi University of Chinese Medicine, Hong Kong Baptist University, Jiangxi Administration of Traditional Chinese Medicine, Shenzhen Health Development Research and Data Management Center, Macau University of Science and Technology, Shenzhen Municipal Health Commission, Shenzhen Traditional Chinese medicine Hospital, Shenzhen Luohu District Hospital of Traditional Chinese Medicine, Shenzhen People's Hospital, Shenzhen institute of standards and technology, Shenzhen Technology University, Beijing 302 Hospital, Shenzhen Unified Standard Technology Co., Ltd, Institute of Information on Traditional Chinese Medicine, China Academy of Chinese Medical Sciences, China Traditional Chinese Medicine Holdings Co., Ltd., Inspection Office of Traditional Chinese Medicine of National Institute for Food and Drug Control, USA Hingli Health and Technology Co.,ltd., Federation of Chinese Medicine and Acupuncture Societies of Australia (FCMA), Australian Austro-Central China Medical Association, Chinese Medicine & Acupuncture Society of Australia and USA Hingli Health and Technology LLC.

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HanseMerkur Center for Traditional Chinese Medicine at the University Medical Center Hamburg-Eppendorf GmbH in Germany, Health Center of Xi'nan Chenghai Shantou, Health Commission of Jiangxi Province, Hong Kong Baptist University, Inspection Office of Traditional Chinese Medicine of National Institute for Food and Drug Control, Institute of Information on Traditional Chinese Medicine, China Academy of Chinese Medical Sciences, Jiangxi Institute for Drug Control, Jiangxi Jiangzhong TCM Decotion Pieces Co., Ltd., Jiangxi University of Traditional Chinese Medicine, Korea KyungHee University, New South Wales Association of Chinese Medicine Inc. Australia New York College of Traditional Chinese Medicine, People's Hospital of Chenghai Shantou, Shanghai University of Traditional Chinese Medicine, Shantou Central Hospital, Shantou Hospital of Traditional Chinese Medicine, Shenzhen Hospital of Southern Medical University, Shenzhen Hospital of Traditional Chinese Medicine, Shenzhen Huahui Pharmaceutical Co., Ltd., Shenzhen Institute for Drug Control, Shenzhen institute of standards and technology, Shenzhen Luohu District Hospital of Traditional Chinese Medicine, Shenzhen Municipal Health Commission Shenzhen People's Hospital, Shenzhen Society of Traditional Chinese Medicine, Shenzhen Standards Alliance for Traditional Chinese Medicine Enterprises, Shenzhen Unified Standard Technology Co., Ltd., Suzhou Xinheng Automation Technology Co., Ltd, The Fifth Medical Center of the General Hospital of the Chinese People's Liberation Army, The Second Affiliated Hospital of Shantou University Medical College, USA Hingli Health and Technology Co., ltd., USA Kamwo Meridian Herbs, Xiayuan Community Health Service Station of Suidong Huangpu Guangzhou and Zhongshan Hospital of Traditional Chinese Medicine.

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The drafting procedure of This document complies with the Standard Management Measures for International Organizations of the World Federation of Chinese Medicine Societies and SCM 0001-2009 Standards Development and Publication Work Specification issued by WFCMS.

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Introduction

In order to implement the plan of the World Federation of Chinese Medicine Societies (WFCMS) regarding the formulation of standards for traditional Chinese medicine, Jiangxi University of Chinese Medicine, Hong Kong Baptist University, Jiangxi Administration of Traditional Chinese Medicine, Shenzhen Health Development Research and Data Management Center, Macau University of Science and Technology, Shenzhen Municipal Health Commission, Shenzhen Traditional Chinese Medicine Hospital, Shenzhen Luohu District Hospital of Traditional Chinese Medicine, Shenzhen People's Hospital, Shenzhen institute of standards and technology, Shenzhen Technology University, Beijing 302 Hospital, Shenzhen Unified Standard Technology Co., Ltd, Institute of Information on Traditional Chinese Medicine, China Academy of Chinese Medical Sciences, China Traditional Chinese Medicine Holdings Co., Ltd., Inspection Office of Traditional Chinese Medicine of National Institute for Food and Drug Control, USA Hingli Health and Technology Co.,ltd., Federation of Chinese Medicine and Acupuncture Societies of Australia (FCMA), Australian Austro-Central China Medical Association, Chinese Medicine & Acupuncture Society of Australia and USA Hingli Health and Technology LLC and other units, in conjunction with 37 institutions, research institutions, medical institutions, Chinese medicine pharmaceutical enterprises and other well-known institutions at home and abroad, including China, the United States, Germany, Canada, Australia and South Korea, and 87 drafters, over a period of 3 years, they jointly drafted the series of standard of Medication service requirements for prescription, dispensing, decocting and taking of Chinese medicines.

Medication service process of Chinese medicines mainly consists of 4 parts, including, requirements for prescription, dispensing, delivery, decocting and taking of Chinese medicines. It covers the overall process of medicinal service from a patient seeking medical service to the doctor providing him diagnosis, to conducting dialectical treatment, and to writing him prescription, as well as then from administration of hospital pharmacy and prescription, involving pharmacist's reviewing and dispensing of prescription, namely, filling the prescription with proper decoction pieces under the theoretical guidance of TCM dialectical treatment, and last, to patient's decocting and taking of the medicines. Each of the above service processes is yet fragmented and unsystematic, has not formed an organic entirety, and hasn't got enough attention, seriously affecting the quality of medical care and services, as well as medication safety and effectiveness of traditional Chinese medicine, and the vital rights of consumers.

Therefore, integrating the scattered medication service segments into a united systematic medication service series of Chinese medicines, solidifying in form of

standards, establishing a traceable international standard series of medication service process of Chinese medicines. This is conducive to strengthening effective communication among doctors, pharmacist and patients, improving relationship between doctors and patients, improving level of medical service, eradicating medical errors and accidents, ensuring the safety and effectiveness of people's medication, safeguarding the legitimate rights and interests of consumers, making due contributions to human health.

The series of *Standards for Medication Service of Chinese Medicines* consists for parts of requirements 4 prescription, dispensing, delivery, decocting and taking of Chinese medicines:

Part 1: Prescription of Chinese medicines.

Part 2: Dispensing of Chinese medicines.

Part 3: Delivery of Chinese medicines.

Part 4: Decocting and taking of Chinese medicines.

This document is part 2. Dispensing of Chinese medicines consists of two sections: prescription reviewing and prescription filling. Prescription reviewing mainly focuses on the procedure of prescription checking strictly in accordance with principles of "three reviews and seven checks". This part is consistent with Part I: Prescription of Chinese medicines, abiding by syndrome differentiation and treatment as well as requirements of principle-method-recipe-medicines to inherit the characteristics and advantages of TCM, and put them into specific operation processes of medical practice, aiming to reducing mistakes and errors in prescription dispensing and filling, ensuring medication safety and effectiveness, and safeguarding the vital interests of consumers.

This document is consistent with ISO 20334 Coding system of formulae, ISO 18668-2 "Coding System for Chinese Medicines- Part 2: Codes for decoction Pieces", ISO 18668-4 Coding system for Chinese medicines -- Part 4: Codes for granule forms of individual medicinal for prescriptions, ISO 20333 Coding rules for Chinese medicines in supply chain management and other relevant international standards.

This series of standards are aimed to establish and improve the standard of Chinese medicines service system and certification system, regulating the behavior of the industry and professional ethics, integrating traditional Chinese medicine service process, ensuring safety and effectiveness of Chinese medicine planting, producing, circulating, and medicating, promoting good atmosphere of trade fair, justice, harmony and scientific development, making people all over the world share the fruits of development of traditional Chinese medicine, to make due contribution to the health of mankind.

1 Scope

This document specifies the regulations for the qualifications of Chinese medicine dispensing, arrangement and facilities of dispensing rooms, the index of decoction pieces and Chinese patent medicine in the medicine cupboard, the dispensing process, as well as dispensing management for the special medicines.

This document is applicable to carry out Chinese medicine dispensing services of medical institutions and drug retail enterprises.

2 Normative reference

The following documents are indispensable for the application of this document. As for the dated references, only the dated versions apply to this document. As for the undated references, the latest edition (including all amendments) are applicable to this document.

ISO 18668-2:2017 Coding system for Chinese medicines -- Part 2: Codes for decoction pieces

ISO 18668-3:2017 Coding system for Chi<mark>nese medicine</mark>s -- Part 3: Codes for Chinese Materia Medica

ISO 18668-4:2017 Coding system for Chinese medicines -- Part 4: Codes for granule forms of individual medicinals for prescriptions

ISO 20333:2017 Coding rules for Chinese medicines in supply chain management ISO 20334:2018 Coding system of formulae

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

Decoction pieces

the processed and prescripted medicines which are directly used in clinical or pharmacy producing.

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

3.2

Dispensing of Chinese Medicine decoction pieces

the process of dispensing the medicine pieces into the suitable dosages for patients' use in accordance with the requirements of Chinese medicine prescription.

3.3

Chinese Medicine Formula Granules

Granules made from single herbal pieces processed according to traditional standards and then extracted and concentrated for the clinical formulation of Chinese medicine, which is also called single Chinese medicine concentrated granules, the trade name and folk name include decoction-free pieces, new pieces, refined pieces, beverage-type pieces, scientific Chinese medicine, etc.

3.4

Three reviews and seven checks

Three reviews refer to prescription reviewing before, in during and after of its dispensing; seven checks refer to check of patientinical formulation of Chinese medicine, which is also called single Chinese medicine concentr

Notes 1 to entry: The purpose of three reviews and seven checks is to remind medical staff to check carefully at work, which has always been the major system of nursing work.

Extension to Chinese medicine has another meaning.

Notes 2 to entry: three reviews and seven checks in Chinese medicines. Three reviews: First, inquiry into whether the doctor has the prescribing authority recognized by the local health administrative department or industry management department to prescribe; Second, inquiry into whether the prescription writing format and requirements comply with local health and industry management policies and regulations; Third, inquiry into the quality of Chinese medicine prescriptions, the doctor's treatment based on syndrome differentiation, the rationale for prescriptions, the contraindications (eighteen incompatibilities and nineteen antagonisms, pregnancy medication), and the "Regulations on the Administration of Narcotic Drugs and Psychotropic Substances", etc.Seven checks: 1. General items: including medical institution name, fee, patient name, gender, age, outpatient or inpatient medical record number, department or ward bed number, etc; 2. Treatment based on syndrome differentiation, diagnosis, including disease name and syndrome, doctor's advice; 3. For prescription medicines, the name, dosage and usage of the medicine, the dosage form and specification of the Chinese patent medicine shall also be indicated; the dosage shall be written in metric units and written in Arabic numerals, generally in grams (g); 4. Check the order of "monarch, minister, assistant, envoy" (also known as based on syndrome d -assitant-courier) of the prescription; 5. Specifications of decoction pieces, for raw or prepared use, incompatibility, eighteen incompatibilities and nineteen antagonisms; 6. Physician's signature or special seal, prescription date; 7. The amount of the drug, audited, dispensed, checked, signed by the pharmacist issuing the drug or stamped with a special seal.

3.5

Principle-method-recipe-medicines

It is a high-level summary of the complete system of TCM syndrome differentiation and treatment. Method refers to the basis for prescription medication, prescription is the embodiment of using TCM theories. The patient's illness is different from exogenous diseases and internal impairment, the symptoms of the disease are divided into cold and heat, deficiency and excess, and in addition

individual differences in age, physique, recipe, customs, etc., it determines the prescription of Chinese medicine and has certain principles and flexibility.

3.6

Toxic medicine

medicines listed in the "List of Toxic Drugs for Medical Use" according to the requirements of various countries and regions.

4 Qualifications of dispensing stuff

- **4.1** Qualifications of the dispensing personnel shall meet the requirements of local health, industry management and FDA.
- **4.2** Specimen of the dispensing stuff's signature or special seal shall be submitted to related administrative institution for future reference.
- **4.3** Dispensing stuff should undertake physical examinations at least once a year. Practitioners suffering from mental disorder or infectious diseases or dermatosis, which might affect medicinal qualification, should not dispense medicines until they have recovered.

5 Arrangement and facilities for dispensing room

5.1 Requirements on the arrangement

The arrangement of dispensing room should meet the operational requirements and comply with the rules for basic facilities of TCM pharmacy.

5.2 Requirements on the facilities

- **5.2.1** There should be adequate area and space in the dispensing rooms, and the walls, floor and ceiling should be smooth and free of cracks. There must be no granular material falling off. The wall should be covered with waterproof, moisture-proof and mildew proof decorating materials, which should also withstand scrubbing. Facilities used for air conditioning, moisture adjustment, moisture-proof, mildew proof, fire prevention, anti-mouse, waterproof, anti-theft, sun shading and others should be installed.
- **5.2.2** TCM decoction pieces dispensing devices or equipment mainly include decoction piece drawers or shelfs, dispensing worktop, weighing equipment (including pieces steelyard, electronic scale, etc.), grinding tools (copper herb grander or mini-type crusher), refrigerated cabinets, fresh air and dust removing facilities (if needed), and cabinets for expensive, toxic and anesthetic medicines. TCM patent medicine dispensing devices or equipment mainly include drug shelves, dispensing worktop, cabinets for expensive medicines and refrigerators.

6 Layout of decoction pieces and classification and placement of patent medicine

6.1 Layout of decoction pieces

Decoction pieces layout should meet the following requirements:

- -- For reducing labor intensity and for the convenience of dispensing and adding decoction pieces.
 - -- For avoiding errors and accidents.
 - -- For the convenience of memorizing each piece's location.
 - -- For decoction pieces management.
 - -- For division of labor and cooperation.

6.2 Chinese patent medicine classification and placement

Standard names of decoction pieces should be written on the tabs.

7 Dispensing procedures

7.1 Receiving and reviewing

- **7.1.1** When the prescriptions being received, practitioners should carry out rescriptions being received, practitioners should tabs. the standard names are listed in the standard SZDB/Z partment, patientse unlisted medicines, the names could be referred to tc.), , dosage, specification and quantity.
- **7.1.2** Checking the compatibility avoidances, pregnancy contradictions, toxic medicines and the prescriptions with Pericarpium Papaveris. Appendix table A.1 and A.2 are for the references of compatibility avoidances and pregnancy contradictions.
- **7.1.3** Checking the properties, administration and dosage of medicines. Checking the validity of medication and clinical diagnosis. Conduct timeliness deployment on prescription beyond expiration and dosage. Prescriptions below standard or without validity are not allowed to be dispensed.

7.2 Dispensing.

- **7.2.1** Weighting tools should be used according to the size and weight of medicine. Scale or electronic scale should be reset before using.
- **7.2.2** When one formula is prescribed in multiple dosages, weights of each dosage should be reduced sequentially and gradually, and the weight error should be controlled within 5%.
- **7.2.3** When dispending, practitioners should avoid herbs dropping or mixing-up of decoction pieces between drawers.

- **7.2.4** In order to make it easier for checking, the herbs should be placed in sequence of the prescription, and lined up in separate piles instead of being mixed.
- **7.2.5** Doctor's prescription should be followed during dispensing. As for the toxic medicines, if they are not noted unprocessed use, the processed ones should be dispensed. Failing to distinguish the crude medicine from the processed one or replace the processed one with the processed ones should be avoided.
- **7.2.6** As for the fresh medicines in the prescriptions, the dirt on them should be removed. After which, they should be cut up into pieces and packed separately, rather than store them with dry ones, which may get them rotten and influence the medical effects.
- **7.2.7** As for the special-dealt medicines, including pre-decocting, post-decocting, wrapped, dissolving or melting, separate decocting should be packed into small and separate packages and note the usage. The common special-dealt medicines are listed in appendix table A.3.
- **7.2.8** Medicinal of hard texture like minerals, animal shells and seeds are to be dispensed after mashing and crushing, which is helpful to extract the active agents. Common items requiring crush and mash are listed in appendix table A.4.
- **7.2.9** Medicines demanding temporary processing should be done as the procedures written accordingly.
- **7.2.10** Decoction pieces in small package should be dispensed as the procedures written accordingly.
- **7.2.11** Emergency prescription should be dispensed in advance in order to avoid delaying treatment.
- **7.2.12** After dispensing and checking, the dispenser should sign their names or seal and send it to the reviewers'.

7.3 Reviewing

- **7.3.1** Recheck the amount and dosages of the dispensing medicine and whether there's any wrong, excessive and foreign matters being mixed in or missing.
- **7.3.2** Checking whether there is a gap between the weighed drug dosage and the prescription dosage. The dosage of each drug in the prescription should be accurate, and the dosage error of each drug should be controlled within \pm 5%. Reweigh if necessary.
- **7.3.3** Recheck the medication problems such as antagonisms, mutual inhibitions of the medicine, contraindication in pregnancy and overdosage, and the correctness of dispensing toxic, anesthetic and expensive medicine.
- **7.3.4** Recheck whether the special-dealt medicines have been packed separately and noted the usage, such as the medicines which need to be decocted first or later, wrapped-boiling, melt with heat without boiling, decocted separately, taken after mixing it with water, etc.

- **7.3.5** Reviewing whether the drugs requiring special treatment such as pre-decocting, post-decocting, wrapped, melting, separate decocting, dissolving etc. are packaged separately and indicate the usage.
- **7.3.6** Recheck the quality of medicine, whether it is rotten due to insect bites or gets mouldy.
- **7.3.7** Recheck whether there is any problem of mistaken substitution, failing to distinguish the crude medicine from the processed one, or whether the medicine is mashed correctly.
- **7.3.8** Recheck the name, department, dispensing date and dosage of the tabs on the decocting canister and on the prescription for the resident prescription and the decoct medicine.
- **7.3.9** The medicine should not be packed until the reviewers checked and signed or sealed.

8 Dispensing manages of special decoction pieces

It should comply with the relevant regulations of the health management departments of various countries and regions, and can also refer to Appendix A for implementation.

Annex A (informative annex) List of special Chinese medicines

A 1. Dispensing manages of special decoction pieces

A 1.1 Dispensing and Management of Toxic Pieces for Medical Use

Toxic medicine cabinet should be set for the toxic medicines, the toxic medicines be kept by the certain stuffs in the certain account and be locked and tabbed in the special cabinet.

The doctors' signatures on the prescriptions are needed when medical units supplying and dispensing toxic medicines. During dispensing, the stuffs should be conscientious and have a sense of responsibility to account precisely and note the doctors' advices clearly, and the medicines should not be sent to the patients before the dispensing stuffs and reviewers with higher titles than pharmacist signed and sealed. The toxic medicines which are not noted with unprocessed should be dispensed with processed ones. Any questions about the prescriptions should be made clear to the doctors who prescripted before dispensing.

Specific account cards should be made for the toxic medicines, which should be reviewed every day and settled every month to ensure the consistency between accounts and goods. The registration book should be adopted to record the names, ages, workplaces, contact information of the patients, the names, amounts and expiring date of the medicines and the names of prescription doctors and dispensing stuffs.

The prescription should be used only once and the prescriptions and certificates should be kept for two years for future reference.

The national regulation for toxic medicine variety scope, management, usages and dosages is recorded in SZJG 37.1-2011.

A.1.2 Management and dispensing of anesthetic decoction pieces

The dispensing stuffs should dispense the anesthetic medicines with the specific prescriptions, and the pharmacist departments have the right to refuse dispensing to the illegal or improper prescriptions.

The prescriptions of dispensing anesthetic medicines should be recorded in the specific notebook, recording includes: date of dispensing, department, patient's name, medical record number, gender, age, diagnosis, the dosage of Pericarpium Papaveris, doctor's name, dispensing stuff and reviewer.

Shall not take medicine repeatedly with one prescription. After taking the medicine, the prescription shall be kept by the medical institution for 3 years for inspection.

A.1.3 Management and dispensing of expensive decoction pieces

The variety scope of expensive Chinese medicine is recorded in SZJG 37.1-2011

The first-class expensive Chinese medicine should be recorded into the account book, including: date, abstract of event, the amount of stock and selling, dispenser, reviewer. The prescription of dispensing should be set down one by one and be stored centralized, and the patient's name and the prescription number should be set down under the abstract of event.

Relevant management stuff should replenish medicines in time to ensure clinical medicines according to the consumption of outpatient medicines every day. The valuable medicines consumed on that day shall be registered and recorded in the account in time, and shall be consistent with the accounts receivable.

Expensive Chinese medicine should be checked regularly, outdated or moldy phenomenon should be prevented, and perishable medicine should be stored in locked freezers.

Table A.1 Chinese medicines with incompatibility

A. 2 List of special Chinese medicines

A. 2.1 Chinese medicines with incompatibility are shown in Table A.1

Eighteen clashes Radix Glycyrrhizae antagonises Radix Euphorbiae Kansui, Radix Euphorbiae Pekinensis, Flos Genkwa and Sargassum; Aconite (Radix Aconiti, Radix Aconiti Kusnezoffii, Radix Aconiti Lateralis Preparata) antagonises Bulbus Fritillaria (Bulbus Fritillariae Cirrhosae, Bulbus Fritillariae Thunbergii, Fritillaria Ussuriensis Maxim, Fritillaria Pallidiflora Schrenk, Fritillaria Hupehensis), Fructus Trichosanthis (Fructus Trichosanthis. Semen Trichosanthis. Pericarpium Trichosanthis, Radix Trichosanthis), Rhizoma Pinelliae, Radix Ampelopsis, Rhizoma Bletillae; veratrum antagonises Radix Ginseng, Radix Salviae Miltiorrhizae, Radix Glehniae, Radix Scrophulariae, Radix Sophorae Flavescentis, Herba Asari, Paeonia lactiflora Pall (Radix Paeoniae Alba and Radix Paeoniae Rubra) Nineteen Sulfur restrains Natrii Sulfas, hydrargyrum restrains white arsenic, incompatibilities stellerae restrains litharge, Fructus Crotonis restrains Semen

A. 2.2 Chinese medicines with contraindications during pregnancy are shown in Table A.2

Radix Ginseng restrains Faeces Togopteri.

Pharbitidis, Flos Caryophylli restrains Radix Curcumae, Radix Aconiti and Radix Aconiti Kusnezoffii restrain rhino horn, Natrii Sulfas restrains Rhizoma Sparganii, Cortex Cinnamomi restrains Hallovsitum Rubrum,

Table A.2 Chinese medicines with contraindications during pregnancy

Prohibited drugs	Rhizoma Sparganii, Rhizoma Curcumae, Hirudo, Tabanus, Radix
	Euphorbiae Kansui, Radix Euphorbiae Pekinensis, Flos Genkwa, Semen
	Pharbitidis, Fructus Crotonis, Semen Euphorbiae, Radix Phytolaccae,
	Calomelas, Mylabris, Realgar, Moschus, Fructus Gleditsiae Abnormalis,
	Herba Leonuri, Semen Strychni, Radix Aconiti Lateralis Preparata,
	Eupolyphaga Seu Steleophaga, Radix Cyathulae, Natrii Sulfas Exsiccatus,
	Natrii Sulfas, Resina Ferulae, Rhododendron molle, Scolopendra, etc.
Drugs given	Venenum Bufonis, Radix Physochlainae, Rhizoma Arisaematis, Resina
cautiously	Toxicodendri, Semen Impatientis, Sulfur, Radix Aconiti Preparata, Radix
	Aconiti Kusnezoffii Preparatai, Rhizoma Typhonii, Fructus Aurantii
	Immaturus, Fructus Aurantii, Radix et Rhizoma Rhei, Folium Sennae,
	Cortex Cinnamomi, Flos Campsis, Semen Momordicae, Radix
	Achyranthis Bidentatae, Flos Carthami, Semen Persicae, Radix
	Notoginseng, Semen Pruni, Rhizoma Polygoni Cuspidati, Herba
	Selaginellae, Semen Vaccariae, E <mark>chi</mark> nopslatifolius <mark>Ta</mark> usch, Radix
	Rhapontici, Rhizoma Curcumae Longae, Stigma Croci, Squama Manis,
	Borneolum Syntheticum, Lignum Sap <mark>p</mark> an, Medulla Tetrapanacis, Radix
	Dichroae, Pollen Typhae, Haematitum, Herba Dianthi, etc.

A. 2.3 Decoction pieces needed to be decocted in special methods are shown in Tbale A.3

Tbale A.3 Decoction pieces needed to be decocted in special methods

Decocted earlier	Carapax et Plastrum Testudinis, Carapax Trionycis, Haematitum, Concha
	Haliotidis, Concha Ostreae, Os Draconis, Magnetitum, Gypsum
	Fibrosum, Fluoritum, Gypsum Rubrum, Pyritum, Gecko, Concha
	Margaritifera, Cornu Cervi Degelatinatum, Concha Arcae, Radix Aconiti
	Preparata, Radix Aconiti Kusnezoffii Preparata, Radix Aconiti Lateralis
	Preparata, Rhizoma Typhonii, Radix Phytolaccae, Rhizoma Arisaematis,
	Rhizoma Pinelliae, Herba Dendrobii, etc.
Decocted later	Herba Menthae, Fructus Amomi Villosi, Fructus Ammomi Rotundus,
	Lignum Aquilariae Resinatum, Semen Armeniacae Amarum, Ramulus
	Uncariae Cum Uncis, Radix et Rhizoma Rhei, Folium Sennae, Radix
	Cynanchi Paniculati, Herba Artemisiae Annuae, Herba Houttuyniae,etc.
Wrap-boiling	Semen Descurainiae, Semen Plantaginis, Flos Inulae, Pollen Typhae, liuyi
	powder, daige powder, yiyuan powder, Gecko, Indigo Naturalis,
	Lasiosphaera seu Calvatia, Talcum, Spora Lygodii, Catechu,etc.
Administered after	Calculus Bovis, Radix Notoginseng, Margarita, Cinnabaris, Moschus, Fel
dissolved	Ursi, Calculus Equi, Calculus Macacae Mulattae, Cornu Saigae Tataricae,
	Lignum Aquilariae Resinatum, amber, Eretmochelys Imbricata, Bulbus
	Fritillariae Cirrhosae, Fritillaria Hupehensis, Omphalia, etc.
Melt	Colla Corii Asini, Colla Corni Cervi, Carapax et Plastrum Testudinis, Mel,
	maltose, etc.

Decocted separately	Radix Ginseng, Rhizoma Gastrodiae, Cornu Saigae Tataricae, Radix
	Panacis Quinquefolii, Stigma Croci, Cordyceps, Cornu Cervi
	Pantotrichum, etc.
Dissolving	Natrii Sulfas, Natrii Sulfas Exsiccatus, etc.

A. 2.4 Decoction pieces needed to be pounded temporarily are shown in Table $\mathbf{A.4}$

TableA.4 Decoction pieces needed to be pounded temporarily

Fruits and seeds	Flos Caryophylli, Semen Canavaliae, Fructus Jujubae, Fructus Meliae
	Toosendan, Fructus Schisandrae Chinensis, Fructus Arctii, Semen
	Ginkgo, Semen Dolichoris Album, Semen Trichosanthis, Semen Cassiae,
	Fructus Alpiniae Galangae, Fructus Ammomi Rotundus, Semen Sinapis
	Albae, Fructus Chebulae, Fructus Can <mark>a</mark> rii, Semen Pruni, Fructus
	Quisqualis, Fructus Piperis Nigri, Fructus Piperis Longi, Semen Alpiniae
	Katsumadai, Fructus Tsaoko, Semen Litchi, Semen Ph <mark>a</mark> rbitidis, Fructus
	Amomi Villosi, Semen Persicae, Semen Raphani, Fructus Alpiniae
	Oxyphyllae, Fructus Akebiae, Fructus Gleditsiae Abnormalis, Semen
	Sesami Nigri, Semen Torreyae, Semen Ziziphi Spinosae, Fructus Viticis,
	Nux Prinsepiae, Semen Citri Reticulatae, etc.
Roots and stems	Bulbof Edible Tulip, Fritillaria Ussuriensis Maxim, Rhizoma Panacis
	Japonici, Radix <mark>P</mark> hysochlainae, Rhizoma Panacis Majoris, Rhizoma
	Dryopteris Crassi <mark>rh</mark> izomae,etc.
Minerals	Alumen, Pyritum,etc.
Animals	Cornu Ammonis, Cornu Cervi Degelatinatum, Squama Manis, Carapax
	Trionycis, Carapax et Plastrum Testudinis, etc.
Others	Catechu, Cortex Cinnamomi, etc.
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