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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 4 部分：中药煎服要求

Requirements for Prescription, Dispensing, Delivery, Decoction and Taking
of Chinese Medicine

Part 4: Requirements for Decoction and Taking of Chinese Medicine

世界中联国际组织标准
International Standard of WFCMS

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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；
- 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4部分。

主要起草单位：江西中医药大学、深圳市卫生健康发展研究和数据管理中心、江西省中医药管理局、深圳市标准技术研究院、深圳市卫生健康委员会、深圳市中医院、深圳市罗湖区中医院、深圳市人民医院、深圳技术大学、上海中医药大学、纽约中医学院、加拿大中医学院、澳门科技大学、美国杏林健康科技有限公司、澳大利亚中医药学会、深圳统标科技有限公司、澳大利亚澳华中医学会、澳洲全国中医药针灸学会联合会、加州中医药大学。

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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《世界中医药学会联合会国际组织标准管理办法》和SCM 0001-2009《标准制定和发布工作规范》。

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引 言

中医药是中华民族的文化瑰宝。中医诊疗服务过程，从病人就诊开始，到医生辨证论治，开具正确的中药处方，再到中药的调剂，各个环节中均有相应关键节点：在中医辨证论治的指导下，中医师如何遣方用药；药房和中药处方如何管理；药事人员如何合规地审方，如何正确地调剂，即中药饮片的给付/配方；患者如何自行选购合格的中药饮片进行准确配方和合理煎煮；病人又如何正确服用中药。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，影响中药用药安全与有效，损害消费者切身利益，进而降低中医药服务质量和声誉。

本文件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，规范行业行为和药事人员职业操守，营造中药种植、生产、流通、用药的安全与有效，促进中药贸易公平、公正、和谐和科学发展的良好氛围，让世界各国人民共享中医药发展成果，为全人类的健康作出应有的贡献。因此，有必要将分散的中药服务环节和流程整合成为一个完整的体系，以标准的形式固化下来，构建一个质量可以追溯的中药服务流程，进而达到减少医疗差错，改善医患关系，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的目的。

本文件为第 4 部分，是中药药事服务流程的末端环节，也是把控药事服务质量的最后机会。它规范了中药饮片的煎煮流程和中药的服用方法，展示了中医药的特色和优势，是用药安全与有效的重要环节，它与第 1 部分、第 2 部分和第 3 部分形成无缝对接。所以，本文件对于指导临床用药安全与有效具有现实的指导意义。

中药处方、调剂、给付与煎服要求——第4部分：中药煎服要求

1 范围

本文件对医疗机构和药品零售企业中药饮片代煎进行了规范，对煎药室的设施与设备、人员资格、一般中药饮片与特殊中药饮片的煎煮和服用方法等作了规定。

本文件适用于开展中药煎药服务的各级各类医疗机构和药品零售企业。

2 规范性引用文件

下列文件对于本文件的应用是必不可少的。凡是注日期的引用文件，仅所注日期的版本适用于本文件。凡是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 5749 生活饮用水卫生标准

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/T 10004 包装用塑料复合膜、袋干法复合、挤出复合

GB 12904 商品条码 零售商品编码与条码表示

GB 14930.1 食品安全国家标准洗涤剂

GB 14930.2 食品安全国家标准消毒剂

GB/T 17710 信息技术 安全技术 校验字符系统

GB/T 30219 中药煎药机

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

JB/T 20116 中药汤剂包装机

YBB 00132002 药用复合膜、袋通则

ZGZYXH/T 37 中药机器煎药规范

ISO/IEC GUIDE 37 保护消费者权益的产品使用说明

ISO 780 包装.货物搬运的图形标志

ISO 7010 图形符号 安全色和安全标志 已注册安全标志

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

ISO 21469 机械安全.与附属产品接触的润滑剂.卫生要求

IEC 60204-1 机械的安全.机器的电气设备.第1部分：一般要求

3 术语和定义

下列术语和定义适用于本文件。

3.1

煎服

中药饮片煎煮和服用的方法。

3.2

中药汤剂

以中医理论为基础，传统的临床广泛使用的用药形式和剂型。它将中药饮片或粗颗粒加水煎煮或沸水浸泡后，去渣取汁而得到的液体制剂。

3.3

标准汤剂

中药汤剂的衍生产品，由中药配方颗粒应运而生。中药配方颗粒源于中药饮片水煎液,它是以传统中药饮片为原料，经过提取、分离、浓缩、干燥、制粒、包装等生产工艺，加工制成的一种统一规格、统一剂量、统一质量标准的新剂型。是中药饮片的深加工产品，具有使用方便、便于携带等优点。

3.4

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。

3.5

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使用的处方药品。

3.6

标准化煎药中心

将计算机和煎药机联网，由计算机控制煎药过程的煎药室。

3.7

武火

即强火，煎药的火力较强，保持汤剂强烈沸腾的火力。

3.8

文火

即弱火，煎药的火力较弱，保持汤剂小沸的火力。

4 人员资格要求

4.1 煎药人员应符合当地卫生、健康和行业管理的要求，经过中药煎药相关知识和技能培训并考核合格后方可从事中药煎药工作。煎药工作人员应有计划地接受相关专业知识和操作技能的岗位培训。

4.2 煎药人员应每年至少体检一次。传染病、皮肤病等患者和乙肝病毒携带者、体表有伤口未愈合者及其他有可能污染药品的疾病者不得从事煎药工作。

4.3 煎药人员应注意个人卫生。煎药前要进行手的清洁，工作时应穿戴专用的工作服并保持工作服清洁。

5 设施与设备要求

5.1 设施要求

5.1.1 煎药室应远离各种污染源，周围的地面、路面、植被等应避免对煎药造成污染。

5.1.2 煎药室的房屋和面积应根据本医疗机构的规模和煎药量合理配置。煎药室分为中药煎煮区和中药收发区，应建立相应的规章制度及其台账。

——中药煎煮区应设有准备、清洗、煎煮、药渣储存等功能区域。当1台机时宜不少于10m²，每增加1台机时宜增加不少于5m²，5台煎药机以上时宜不少于5m²/台。煎药室面积也应根据各国家或地区的相关规定进行调整。

——中药收发区应设有接收或办理工作台、收存中药柜、待发出中药储藏柜等功能，应不少于10m²。

5.1.3 煎药室应宽敞、明亮，地面、墙面、屋顶应平整、洁净、无污染、易清洁，应设有有效的通风、除尘、防积水、消防等设施，各种管道、灯具、风口以及其他设施应避免出现不易清洁的部位。

5.2 设备要求

5.2.1 煎药室应配备完善的煎药设备，并根据实际需要配备储药设备、冷藏设备以及量杯（筒）、过滤装置、计时器、贮药容器、药瓶架等。

5.2.2 煎药工作台面应平整、洁净。煎药容器应以陶瓷、不锈钢等材料制作的器皿为宜，禁用铁质等易腐蚀器皿。

5.2.3 储药容器应做到防尘、防霉、防虫、防鼠、防污染。用前应严格消毒，用后应及时清洗。

5.2.4 煎药室宜配备相应的煎药机和包装机，其操作规程和保养应符合规定，详见附录A。

5.3 设备设施管理要求

应根据本单位的实际情况制定相应的煎药室工作制度和相关设备的标准化操作程序（SOP），工作制度、操作程序应装订成册并张贴挂在煎药室适宜位置，并严格执行。药品零售企业煎药室的管理和工作制度参照执行。

6 煎药操作方法

6.1 一般中药饮片煎煮方法

6.1.1 煎药时应使用符合本国卫生标准的饮用水。待煎药物应先行浸泡，浸泡时间一般为20-30分钟。但吸水性强的药物相对缩短，15分钟即可；较难吸水的则要适当延长浸泡时间，并定时翻转，促进其吸水，以润透为度。煎煮开始时的用水量一般以浸过药面2-3cm为宜，花、草类药物或煎煮时间较长的应酌量加水。若煎药机煎煮浸泡加水量可根据待煎药剂数，加入相应水量。加水量参考附录A。

6.1.2 每剂药一般应煎煮两次，将两煎药汁混合后再分装。煎煮时间应根据方剂的功能主治和药物的性质确定。一般药物煮沸后再煎煮20-30分钟；解表类、清热类、芳香类药物不宜久煎，煮沸后再煎煮15-20分钟；滋补药物先用武火煮沸后，改用文火慢煎约30—60分钟。第二煎的煎煮时间应比第一煎的时间略缩短。煎药过程中要搅拌药料2-3次。搅拌药料的用具应以陶瓷、不锈钢等材料制作的棍棒为宜，搅拌完一药料后应清洗再搅拌下一药料。

6.1.3 煎药量应根据儿童和成人分别确定。儿童每剂一般煎至100-300ml，成人每剂一般煎至400-600ml，一般每剂按两份等量分装，或遵医嘱。

6.1.4 中药自煎方法

6.1.4.1 选择煎锅

最好使用砂锅，或不锈钢锅，或陶瓷器皿，不应使用铁锅、铝锅、铜锅。

6.1.4.2 煎煮火候

一般先用武火（大火）煎煮，煮沸后改用文火（小火），保持微沸状态。

6.1.4.3 煎药时间、方法与次数

煎药时间、方法与次数的要求如下：

——每剂药可煎煮 2 次；

——中药饮片煎煮前，宜浸泡 20-30 分钟，并根据中药饮片的质地、当地的温度和湿度调整浸泡时间。

——煎药水量以高出中药饮片 2-3 cm 或每次煎出药液 200-400 ml 为宜；

——第 2 次煎煮加水量较第 1 次减半，以煎出药液 100-200 ml 为宜；

——特殊药物或老人、儿童，应遵医嘱而行。

6.2 特殊中药饮片煎煮方法

6.2.1 凡注明有先煎、后下、另煎、烊化、包煎、煎汤代水等特殊要求应按照要求或医嘱操作：

——先煎：一般情况下，应煮沸分钟后，再投入其它药料（已先行浸泡）同煎。-

——后下：应在第 1 煎药料即将煎至预定量时，投入同煎 5-10 分钟。

——另煎：应切成小薄片，煎煮约 2 小时，取汁；另炖药应放入有盖容器内加入冷水（一般为药量的 10 倍左右）隔水炖。此类药物的原处方如系复方，则所煎（炖）得的药汁还应与方中其它药料所煎得的药汁混匀后，再行分装。某些特殊药物可根据药性特点具体确定煎（炖）药时间（用水适量）。

——溶化（烊化）：应在其它药煎至预定量并去渣后，将其置于药液中，文火煎煮，同时不断搅拌，待需溶化的药溶解即可。

——包煎：应装入包煎袋闭合后，再与其他药物同煎。包煎袋材质应符合药用要求（对人体无害）并有滤过功能。

——煎汤代水：应将该类药物先煎 15-25 分钟后，去渣、过滤、取汁，再与方中其它药料同煎。

6.2.2 对于久煎、冲服、泡服等有其他特殊煎煮要求的药物，应按相应的规范操作。先煎药、后下药、另煎或另炖药、包煎药、煎汤代水药在煎煮前均应先行浸泡，浸泡时间一般不少于 30 分钟。

6.2.3 各类特殊中药饮片参见附录 C。

6.3 煎药质量、技术的基本要求

药渣煎透度应做到“三无”（无糊状块、无白心、无硬心），合格率应达到 100%。药汁浓度应做到汁浓味厚，合格率≥95%。住院病人对中药汤剂质量满意度≥95%。

6.4 煎药注意事项

6.4.1 实行煎药前双人复核制及煎药卡（或复写的原始处方）全程跟踪制。领药、拆包（小包装中药饮片）、洗药、泡药、煎药、装药、送药等各道工序均应认真核对药物与煎药卡（或复写的原始处方）是否相符；操作过程中，煎药卡（或复写的原始处方）应作为标签放在该药物的醒目位置。

6.4.2 煎药时应防止药液溢出、煎干或煮焦。煎干或煮焦者禁止药用。

6.4.3 应注意特殊药物的投下时间和煎煮方法。

6.4.4 内服药与外用药应使用不同颜色或形状的容器区分和标示。

6.4.5 煎药的药液应有服用方法标签。

6.4.6 完成一位病人的煎药工作后，应对煎药容器进行清洗，才能进行下一位病人的煎药工作，以防止交叉感染。煎药工作结束后应及时清场，重复使用的装药容器应及时清洗并高温消毒，严防污染。清场、消毒情况应有明显的状态标志。包装药液的材料应符合药品包装材料本国标准。

6.4.7 使用煎药机煎煮中药，煎药机的煎药功能应符合本文件的相关要求。应在常压状态煎煮药物，煎药温度一般不超过 100℃。煎出的药液量应与方剂的剂量相符，分装剂量应均匀。密封包装，在包装的中药药液上注明患者姓名，煎煮日期、剂数。于阴凉处或冰箱冷藏。

6.4.8 药渣应保存 24 小时备查。

6.4.9 煎药过程应记录于《代煎中药取药、煎药、送药记录表》中，格式参考附录 D。

7 煎服方法

7.1 通用要求

7.1.1 汤剂的服用方法一般来说，煎剂必须温服。方剂或剂量的中药材可煎剂两次，将煎汁混合，分成两份，供日用。有的药一放水就溶解，如芒消，有的药汁如蜂蜜加水无需煎煮，适合直接混用水或煎汁内服。

7.1.2 急性病例必须每天服用两剂甚至三剂，慢性患者可能需要一天或两天服用一剂。至于服药时间，一般来说，补虚药宜饭前服，降毒药宜饭后服，杀虫剂、泻药宜空腹服（早上）。

7.1.3 安神药宜睡前服用，健胃药宜饭后服用。

7.2 各类特殊方中中药饮片煎煮服方法

7.2.1 解表方

7.2.1.1 煎法

多为辛散轻扬之品，不宜久煎，以免药性耗散，作用减弱。

7.2.1.2 服法

宜温服，服后饮适量热开水，覆衣被取微微汗出以解散表邪，治愈表证。解表方发汗，以周身微汗为度，汗后应脉静身凉，不可过汗造成伤阴或亡阳。

7.2.2 泻下方

7.2.2.1 煎法

大黄为泻下方中主药，宜后下。

7.2.2.2 服法

遵医嘱。

7.2.3 补益方

7.2.3.1 煎法

一般宜适当慢火久煎，务使药力尽出。

7.2.3.2 服法

服药时间以空腹或饭前为佳，若急症则不受此限制。

7.2.4 开窍方

7.2.4.1 煎法

开窍剂大多为芳香药物，不宜久煎，以免药性挥发，影响疗效。

7.2.4.2 服法

本类方剂多制成丸散剂或注射剂，丸散剂在使用时宜温开水化服或鼻饲。

7.2.5 理气方

7.2.5.1 煎法

由于理气药多属芳香辛燥之品，不宜久煎。

7.2.5.2 服法

遵医嘱。

7.2.6 祛湿方

7.2.6.1 煎法

水煎煮，祛湿剂中的芳香温燥之品不宜久煎。

7.2.6.2 服法

多宜温服；湿邪在外在上者，可热服从表微汗以解。

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附录 A
(资料性)
包装机、煎药机操作规程和保养

A.1 包装机操作规程和保养

A.1.1 预热

接通电源，确认设备不漏电，按电源开关加热压膜铁块，待有音乐声且恒温指示灯已亮，表示达到工作温度。

A.1.2 清洗

用热开水冲洗贮液桶及进出药液管道后，将抽出机药液输入贮液桶，通过刻度计算包装数，若药量不符应重新调节重煎（药液卡随药液转挂于包装机）。

A.1.3 包装

按下设定包装数量开关、药液流出开关和包装机操作开关，进行包装，如发现封口不牢，药量不足，袋内有气泡等情况，应随时调整，重新包装。

A.1.3.1 包装准备工作

在首锅药煎煮同时，打开包装机电源开关，进入包装前预加热状态，此时两个小显示灯为红色状态。预温完成后，此时小灯转为绿色，进入包装待机状态。

A.1.3.2 压出药液

当指示温度达到120℃，继续加热20分钟，停止加热，检查是否关闭装液锅下面的排液阀门，确认关闭后，打开煎药锅向上排液阀门，并用压力板把药锅内的药液压出。

A.1.3.3 包装

排出首袋废弃液（150ml左右）后，开启自动排液并转动开关，进行自动包装，所包装袋数为2R（R为剂数）。

A.1.3.4 冲洗

打开排液阀，排掉剩余药渣，并注入一定量清水冲洗，反复2-3次。

A.1.3.5 装袋

将包装好的药包，根据标签检查核对，确认无误后，对号入袋。

A.1.4 保养

A.1.4.1 每天开机前，用机油在六根包装转动轴两旁部位喷少量润滑，并使封合光滑面润滑。

A.1.4.2 每天煎药完毕关机后，用微湿的抹布把封合面及周围擦拭干净。把装液玻璃锅内三个小滤管卸下，冲洗干净，刷洗锅内壁和锅底，确保干净，再把小滤管重新装上。

A.1.4.3 定期（一周一次）卸下排液管，把管道内壁药垢用长条薄片刮下后，冲洗干净；同时用手捏（轻力）箱内橡胶管，使内壁药垢脱落。然后装上排液管，注入一定量水在锅内，剪掉包装袋下面封合部分，打开冲洗开头，把管内药垢排出，每次少量水，反复数次，直至排出水液干净为止。

A.2 煎药机操作规程和保养

- A. 2. 1 冷水浸泡药材，浸泡加水量可参考下式。加水量（成人量）可按下列公式计算： $Q=2R*200+R*W$ （注：Q为总加水量，R为剂数，W为常量值，其值为170ml） 儿童量加水公式： $Q=2R*150+R*K$ （K=100，单位为毫升），挂上煎药卡（浸润时间20-30分钟）。
- A. 2. 2 用电笔测试，确认设备不漏电。
- A. 2. 3 将定时器旋至零处，接通电源，再经测试，确认设备不漏电。
- A. 2. 4 关闭进水口及药液出口。
- A. 2. 5 将已浸润药材连同浸液置锅内摊匀，随即挂煎药卡。
- A. 2. 6 关盖，锁牢，关闭排气阀。
- A. 2. 7 设置煎煮温度（120℃）
- A. 2. 8 设定煎煮时间（约60分钟），开始加热，达到预定温度后，观察压力表，指针应在1—1.2之间。保温20—30分钟（期间将压渣板旋松、旋紧2次以上，以起搅拌作用），完成后将定时键旋至零。
- A. 2. 9 压出渣出液，将压渣板旋紧。
- A. 2. 10 打开药阀，利用炉内压力将药液压进包装机贮药罐，对照刻度，检查药液量，如不足量酌加水重煎至要求量。
- A. 2. 11 打开压力表旁排气阀，确认炉内无压力后，逆时针旋松压渣板，松锁，开盖。
- A. 2. 12 清理药渣，用常用水冲洗药锅，接着再用开水冲一次，以保证下一锅煎煮质量。
- A. 2. 13 每天煎药完毕后，先向锅内注水浸泡，使其冷却，然后取出中心滤锅，分别把滤锅和煎药锅内外壁刷洗干净，注入一定量（2000 ml左右）水。
- A. 2. 14 在无煎药情况下，应关闭电源，并注入一定量水。
- A. 2. 15 煎药机在无药液或水情况下，切不可加热干烧，以免损坏机器。

附录 B
(规范性)
煎药室的管理与工作制度

B.1 医疗机构煎药室的管理

- B.1.1 煎药室应由药学部门统一管理。应有专人负责煎药室的组织协调和管理工作。
- B.1.2 药学部门应根据本单位的实际情况，制定相应的煎药室工作制度和相关设备的标准化操作程序（SOP）。工作制度、操作程序应装订成册并张挂在煎药室适宜位置，并严格执行。煎药人员在领药、煎药、装药、送药、发药时应认真核对处方（或煎药凭证）有关内容，建立收发记录，内容真实、记录完整。每方（剂）煎药应有一份反映煎药各个环节的操作记录。记录应保持整洁，内容真实、数据完整。
- B.1.3 急煎药物应在 2 小时内完成，建立中药急煎制度并规范急煎记录。
- B.1.4 煎药设备设施、容器使用前应确保清洁，应有清洁规程和每日清洁记录。用于清扫、清洗和消毒的设备、用具应放置在专用场所妥善保管。煎药室应定期消毒。洗涤剂、消毒剂品种应定期更换，并符合 GB 14930.1 和 GB 14930.2 等有关卫生标准和要求，不得对设备和药物产生腐蚀和污染。
- B.1.5 传染病病人的盛药器具原则上应使用一次性用品，用后按照医疗废物进行管理和处置。不具备上述条件的，对重复使用的盛药器具应加强管理，固定专人使用，且严格消毒，防止交叉污染。
- B.1.6 应加强煎药的质量控制、监测工作。药剂科负责人应定期（每季度至少一次）对煎药工作质量进行评估、检查，征求医护人员和住院病人意见，并建立质量控制、监测档案。

B.2 医疗机构煎药室的工作制度

- B.2.1 煎药室在药学部门领导下，负责住院和门诊病人的中药煎药工作。
- B.2.2 煎药室应配备一名中药师（士）负责煎药业务指导及管理工作。煎药工作人员应经基础专业知识培训，经考试、考核合格，发予《上岗证》方可从事煎药工作。同时应建立业务指导考核制度。药剂科负责人每半年要对煎药人员的业务进行总结、考核和评价。煎药人员和指导人员的考核成绩应达到“良好”以上。实行优者奖，劣者罚。
- B.2.3 煎药人员到药房领取中药剂时，应核对病人姓名、科别、地址、床号、日期、剂数，确认无误后在领药登记本上签收。
- B.2.4 煎药应严格遵守技术操作规程和医嘱，按规定浸泡后，根据中药性能选择火候、时间进行煎煮，药剂量要符合要求。
- B.2.5 凡注明有先煎、后下、另煎、兑服、烩化等特殊要求的煎煮，要按医嘱执行，确保煎药质量。
- B.2.6 煎药卡从领药时起，必须紧随药袋、浸泡容器、煎煮容器和盛药容器转移，每个工序都有操作人员签名。中药煎煮好后应按医嘱要求包装。
- B.2.7 对于非一次性真空包装的中药药液，传染病人与普通病人的盛药容器应严格分开，必须经过彻底清洗干净和高温消毒方可再用，严防污染。
- B.2.8 煎药人员应衣帽整齐，佩戴胸卡，遵守劳动纪律，坚守工作岗位，上下班时做好交接班工作。
- B.2.9 内服药与外用药应用不同颜色煎药卡，用不同形状容器严格区分。
- B.2.10 汤药送抵病房或药房，应请护士或收药人核对后在送药登记本上签收。

- B. 2. 11 急煎药按中药急煎制度执行，新入院和急重病人的药剂，应即领、即煎、即送，不得延误时间。
- B. 2. 12 加强煎药的质量控制，定期抽查；发现问题要及时处理，分析原因并报药学部门。
- B. 2. 13 注意安全，做好防火、防毒、防盗措施，下班前关好门、窗、水、电。
- B. 2. 14 其他人员非公事不得进入煎药室。

B. 3 药品零售企业煎药室的管理和工作制度

药品零售企业煎药室的管理和工作制度参照执行。

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附录 C
(规范性)
煎药室的管理与工作制度

C.1 医疗机构煎药室的管理

- C.1.1 煎药室应由药学部门统一管理。应有专人负责煎药室的组织协调和管理工作。
- C.1.2 药学部门应根据本单位的实际情况，制定相应的煎药室工作制度和相关设备的标准化操作程序（SOP）。工作制度、操作程序应装订成册并张挂在煎药室适宜位置，并严格执行。煎药人员在领药、煎药、装药、送药、发药时应认真核对方（或煎药凭证）有关内容，建立收发记录，内容真实、记录完整。每方（剂）煎药应有一份反映煎药各个环节的操作记录。记录应保持整洁，内容真实、数据完整。
- C.1.3 急煎药物应在 2 小时内完成，建立中药急煎制度并规范急煎记录。
- C.1.4 煎药设备设施、容器使用前应确保清洁，应有清洁规程和每日清洁记录。用于清扫、清洗和消毒的设备、用具应放置在专用场所妥善保管。煎药室应定期消毒。洗涤剂、消毒剂品种应定期更换，并符合 GB 14930.1 和 GB 14930.2 等有关卫生标准和要求，不得对设备和药物产生腐蚀和污染。
- C.1.5 传染病病人的盛药器具原则上应使用一次性用品，用后按照医疗废物进行管理和处置。不具备上述条件的，对重复使用的盛药器具应加强管理，固定专人使用，且严格消毒，防止交叉污染。
- C.1.6 应加强煎药的质量控制、监测工作。药剂科负责人应定期（每季度至少一次）对煎药工作质量进行评估、检查，征求医护人员和住院病人意见，并建立质量控制、监测档案。

C.2 医疗机构煎药室的工作制度

- C.2.1 煎药室在药学部门领导下，负责住院和门诊病人的中药煎药工作。
- C.2.2 煎药室应配备一名中药师（士）负责煎药业务指导及管理工作。煎药工作人员应经基础专业知识培训，经考试、考核合格，发予《上岗证》方可从事煎药工作。同时应建立业务指导考核制度。药剂科负责人每半年要对煎药人员的业务进行总结、考核和评价。煎药人员和指导人员的考核成绩应达到“良好”以上。实行优者奖，劣者罚。
- C.2.3 煎药人员到药房领取中药剂时，应核对病人姓名、科别、地址、床号、日期、剂数，确认无误后在领药登记本上签收。
- C.2.4 煎药应严格遵守技术操作规程和医嘱，按规定浸泡后，根据中药性能选择火候、时间进行煎煮，药剂量要符合要求。
- C.2.5 凡注明有先煎、后下、另煎、兑服、烩化等特殊要求的煎煮，要按医嘱执行，确保煎药质量。
- C.2.6 煎药卡从领药时起，必须紧随药袋、浸泡容器、煎煮容器和盛药容器转移，每个工序都有操作人员签名。中药煎煮好后应按医嘱要求包装。
- C.2.7 对于非一次性真空包装的中药药液，传染病人与普通病人的盛药容器应严格分开，必须经过彻底清洗干净和高温消毒方可再用，严防污染。
- C.2.8 煎药人员应衣帽整齐，佩戴胸卡，遵守劳动纪律，坚守工作岗位，上下班时做好交接班工作。
- C.2.9 内服药与外用药用不同颜色煎药卡，用不同形状容器严格区分。
- C.2.10 汤药送抵病房或药房，应请护士或收药人核对后在送药登记本上签收。

- C. 2. 11 急煎药按中药急煎制度执行，新入院和急重病人的药剂，应即领、即煎、即送，不得延误时间。
- C. 2. 12 加强煎药的质量控制，定期抽查；发现问题要及时处理，分析原因并报药学部门。
- C. 2. 13 注意安全，做好防火、防毒、防盗措施，下班前关好门、窗、水、电。
- C. 2. 14 其他人员非公事不得进入煎药室。

C. 3 药品零售企业煎药室的管理和工作制度

药品零售企业煎药室的管理和工作制度参照执行。

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附录 D
(资料性附录)
代煎中药取药、煎药、送药记录表

表 D.1 煎药室领药记录本 (门诊)

年 月 日

序号	姓名	年龄	剂数	发药人	领药人	序号	姓名	年龄	剂数	发药人	领药人

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表 D.2 煎药室领药记录本（住院）

年 月 日

序号	科别	床号	姓名	剂数	发药人	领药人	备注

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表 D.3 煎药室煎药记录本（门诊）

年 月 日

序号	姓名	浸泡时间		煎煮时间		操作人
		开始	结束	开始	结束	

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表 D.4 煎药室煎药记录本（住院）

年 月 日

序号	科别	床号	姓名	浸泡时间		煎煮时间				操作人
				开始	结束	1 煎		2 煎		
						开始	结束	开始	结束	

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表D.5 煎药室送药记录本（门诊）

年 月 日

序号	取药单号	姓名	剂数	送药人	签收人	序号	取药单号	姓名	剂数	送药人	签收人

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表D.6 煎药室送药记录本（住院）

年 月 日

序号	取药单号	姓名	剂数	送药人	签收人	序号	取药单号	姓名	剂数	送药人	签收人

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Foreword

The series of standards of *Requirements for prescription, dispensing, delivery, decoction and taking of Chinese medicine* are divided into 4 parts.

- Part 1: *Requirements for Prescription of Chinese medicine*
- Part 2: *Requirements for Dispensing of Chinese medicine*
- Part 3: *Requirements for Delivery of Chinese medicine*
- Part 4: *Requirements for Decoction and Taking of Chinese medicine*

This document is the fourth part: *Requirements for Decoction and Taking of Chinese medicine*.

The main drafting organizations of this document are: Jiangxi University of Chinese Medicine, Shenzhen Health Development Research and Data Management Center, Jiangxi Administration of Traditional Chinese Medicine, Shenzhen Institute of Standards and Technology, Shenzhen Municipal Health Commission, Shenzhen Hospital of Traditional Chinese Medicine, Shenzhen Luohu District Hospital of Traditional Chinese Medicine, Shenzhen People's Hospital, Shenzhen Technology University, Shanghai University of Traditional Chinese Medicine, New York College of Traditional Chinese Medicine, College of Traditional Chinese Medicine of Canada, Macau University of Science and Technology, USA Hingli Health and Technology Co., Ltd, Chinese Medicine & Acupuncture Society of Australia, Shenzhen Unified Standard Technology Co., Ltd., Australian Austro-Central China Medical Association, Federation of Chinese Medicine and Acupuncture Societies of Australia (FCMA) and Five Branches University of California.

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Introduction

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 pieces under the theoretical guidance of TCM dialectical treatment, and last, to decocting and patient's 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 complete 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: Requirements for 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 4-Decocting and taking of Chinese medicines, the end process of medication service of Chinese medicines, and also the last opportunity to control the quality of Chinese medicines service. It standardizes the decocting process and taking directions of Chinese medicines, and shows the characteristics and advantages of Chinese medicines. It is also important to the safety and effectiveness of people's medication.

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 to establish and improve the standard of Chinese medicine service system and certification system, regulating the behavior of the industry and

professional ethics, integration of traditional Chinese medicine service process, build Chinese medicine planting, production, circulation, safe and effective medication, promote trade fair, justice, harmony and good atmosphere of scientific development, let people all over the world share the fruits of development of Chinese medicine, Make due contribution to the health of mankind..

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1 Scope

This document regulates the decoction method in medical institutions and pharmaceutical retail enterprises. And regulations on the facilities and equipment of the decocting room, the qualifications of the personnel, the decoction of ordinary decoction pieces and the special decoction pieces.

This document is applicable to the management and evaluation of standardized decoction centers, medical institutions and drug retail enterprises.

2 Normative reference

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

ISO/IEC GUIDE 37:2012 Instructions for use of products by consumers

ISO 780 Packaging -- Distribution packaging-Graphical symbols for handling and storage of packages

ISO 7010 Graphical symbols -- Safety colours and safety signs -- Registered safety signs"

ISO 16528-1 Boilers and pressure vessels -- Part 1: Performance requirements

ISO 16528-2 Boilers and pressure vessels-Part 2: Procedures for fulfilling the requirements of ISO 16528-1

ISO 18665 Herbal decoction apparatus

ISO 18668-1:2016 Coding system for Chinese medicines-Part 1: Coding rules for Chinese medicines

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

ISO 18668-3:2017 Coding system for Chinese medicines-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 20334:2018 Coding system of formulae

ISO 21469:2006 Safety of machinery-Lubricants with incidental product contact-Hygiene requirements

IEC 60204-1:2009 Safety of machinery-Electrical equipment of machines-Part 1 : General requirements

3 Terms and definitions

3.1

Decocting and taking of Chinese medicines

methods of decocting and taking of Chinese medicines decoction pieces..

3.2

Chinese medicines decoction

the liquid Chinese medicines are obtained by decocting or soaking the Chinese medicines in water, removing the solid residuals and extracting the juice.

3.3

Standard decoction

the standard decoction is guided by the traditional Chinese medicine theory and based on clinical application. With reference to modern extraction methods, a single-flavored decoction of Chinese medicines is prepared by a standardized process. The standard decoction is used to standardize clinical medication and to ensure the accuracy of medication and the consistency of dosage.

3.4

Dispensing granules of Chinese medicines

granule made of single Chinese medicines prepared according to traditional standards and extracted and concentrated for prescription of Chinese medicines. It is also known as concentrated granules of single Chinese medicines. In business and folk, it's also named decocting-free decoction pieces, new decoction pieces, refined decoction pieces, beverage decoction pieces, scientific Chinese medicines, etc.

3.5

Chinese medicines decoction piece

Chinese medicines can be directly used in traditional Chinese medicine clinics or as prescription medicines for manufacturing preparation after processing.

3.6

Standardized decoction center

the computers and the decocting machines are networked, and the decocting process is controlled by computers in the decoction room

3.7

Strong fire

the fire of the decoction is strong enough to maintain the strong boiling power of the decoction

3.8

Slow fire

the fire of decocting medicine is weak, keep the boiling water of decoction

4 Personnel qualification requirements

4.1 Decocting personnel should be trained in knowledge and skills related to Chinese medicine decocting, and can be engaged in Chinese medicine decocting work after passing related examinations. Decocting personnel should receive post training related to professional knowledge and operational skills.

4.2 The decoction personnel should have a physical examination at least once a year. Patients with infectious diseases, dermatosis, hepatitis B virus carriers, non - healed wounds on the body surface and other diseases that may pollute drugs may not be engaged in the work of decocting medicine.

4.3 Decocting personnel should pay attention to personal hygiene. Hand cleaning should be done before decocting. When working, you should wear a special work clothes and keep your work clothes clean.

5 Facilities and equipment requirements

5.1 Facility requirements

5.1.1 The decocting room should be far away from all kinds of pollution sources, and the surrounding ground, road surface and vegetation should avoid polluting the decocting medicine.

5.1.2 The housing and area of the decocting room should be reasonably allocated according to the size of the medical institution and the amount of decocting. The decocting room is divided into the decocting area of traditional Chinese medicine and the sending and receiving area of Chinese medicine. The corresponding rules and regulations and their accounts should be set up.

—Section for decocting Chinese Medicine : There should be functional areas such as preparation, cleaning, boiling and storage. When there is one machine, the decoction area should not be less than 10m². When increasing a machine, the decoction area should be increased not less than 5m². When there are 5 machines, the decoction area for each machine should not be less than 5m². The area of the decoction room should also be adjusted according to the relevant regulations of each country or region.

—Section for receiving and sending Chinese medicine : Such functions as receiving or processing worktable, cabinet for storing Chinese medicine, storage cabinet for sending and waiting for Chinese medicine should be set up. The section area should be not less than 10m².

5.1.3 The decocting room should be spacious and bright. The ground, wall and roof should be smooth, clean, pollution-free and easy to clean. It should be equipped with effective ventilation, dust removal, water-proof, fire protection and other facilities. All kinds of pipes, lamps, tuyere and other facilities should avoid the place that is not easy to clean.

5.2 Request for facility

5.2.1 The medicine room should be equipped with decocting device, medicine storage equipment, refrigeration equipment and measuring cup (cylinder), filter device, timer, medicine storage container and bottle rack and according to the actual needs .

5.2.2 The work table of the decocting medicine should be smooth and clean. Decocting containers should be made of ceramics, stainless steel and other materials, and iron and other corroded utensils shall be prohibited.

5.2.3 The storage containers shall be dust-proof, mildew-proof, insect-proof, rodent-proof and pollution-resistant, and shall be sterilized strictly before use and should be cleaned in time

5.2.4 The medicine room can be equipped with corresponding medicine-decocting machine and packaging machine, which operation and maintenance should be consistent with the provisions of annex A.

5.3 Requirements for Equipment and facilities management

According to the actual situation of the unit, the pharmaceutical department shall formulate the corresponding working system for the decocting room and the standardized operation procedures for the relevant equipment (SOP). Work system and operation procedures should be bookbinding and hung in the appropriate location of the decocting room and strictly implemented.

6 Decocting method of operation

6.1 General decocting method of Chinese herbal medicine

6.1.1 When decocting medicine, we should use drinking water that meets national health standards. The medicine to be decocted should be soaked in advance. The soaking time is usually 20-30 minutes. But for the drugs with strong water absorption, the soaking time should be shorted to 15 minutes. If the drugs are difficult to absorb water, the soaking time should be extended properly. Flip regularly to promote its water absorption in order to be soaked thoroughly. The amount of water used at the beginning of the decoction is generally 2-3cm. Water should be added to the flowers or herbs for a longer time. If using decocting machines, the water and water to be could be counted according to the number of decocting agents. Add the corresponding amount of water. Water intake is referred to annex A.

6.1.2 Each medicine should be decocted for two times, and mix the two decocted juice and then pack it. The decocting time shall be determined according to the nature and functions of prescribed drugs. The general medicine is boiled and then decocted for 20-30 minutes. The exterior-relieving, heat clearing and aromatic drugs should not be decocted for a long time. Boil and decoct for 15-20 minutes. The nourishing medicine is first boiled with strong fire and then simmer for 30 to 60 minutes. The decocting time for the second should be slightly shorter than that of the first second. Stir the medicine 2-3 times during the decocting process. The mixer should be made of ceramic, stainless steel and other materials. After mixing the ingredients, the mixture should be cleaned and stirred.

6.1.3 The amount of decocting should be determined according to children and adults. The amount of decocting for children is usually 100-300ml per dose, and the amount of

decocting for adults is usually 400-600ml per dose. In general, take two equal doses per dose, or follow the doctor's advice.

6.1.4 Self decocting method of Chinese Medicine

6.1.4.1 Choose pans for decocting

It is recommended to use a casserole, stainless steel pot, or ceramic ware. Shall not use iron pans, aluminum pans, or copper pans.

6.1.4.2 Decocting temperature

Generally, first use strong fire to decoct, and then use the slow fire to keep the state of boiling.

General first high heat (big fire) Decoction, then boil with gentle heat (slow fire), simmer it.

6.1.4.3 Decocting time, method and frequency

Requirements for decocting time, method and frequency are as follows:

- 2 times for each dose;
- Decoction pieces should be soaked for 20-30 minutes before decoction. And adjust the soaking time according to local temperature humidity and the texture of the decoction pieces.
- 200-400 ml decocting water, or the amount of water is higher than 2-3 cm of the drugs. 100-200 ml decoction is preferred for each time.
- For the second time decocting, the amount of water added is halved compared with the first time, and 100-200 ml decoction is preferred.
- special drugs or old people and children should follow the doctor's advice

6.2 Special decocting methods

6.2.1 Any special requirements, such as decocting first, decocting later, decocting separately, melting, wrap decocting, decoction used for drinking water, should be operated according to the requirement or doctor's advice.

— Decocting first: In general, it should be boiled for 20-30 minutes and then put other ingredients into it (soaked first) for decocting.

— decocting later: in second is to a predetermined amount of fried spices, put the same fry for 5-10 minutes. When the second decocting ingredients are about to be decocted to a predetermined quantity, put them in the same decoction for 5-10 minutes.

—decocting separately: Cutting into small slices, decocting them for about 2 hours, take the juice. The other drugs should be cut into thin slices, and then put them into container with a lid, and add cold water (usually about 10 times as much as the dose of Medicine) to decoct for 2-3 hours, then take the juice. If the prescription of this kind of drug is compound, the decocted juice should be mixed with the decoction of other ingredients and then packed separately. For some special drugs, the time for decocting (stew) can be determined according to the characteristics of medicine.

——Melting: It should be decocted to a predetermined quantity and removed after being dregs, then placed in the solution and cook in slow fire. At the same time, keep stirring until the to-be-dissolved drugs are dissolved.

—— Wrap decocting: It should be wrapped in a bag and then closed with other drugs. The material of bag frying bag should conform to the medical requirements (harmless to human body) and has filtration function.

——decoction used for drinking water: the drugs should be decocted for 15-25 minutes, remove residue, filter and take juice, then decoct with other ingredients.

6.2.2 For other decoctions, such as decocting for a long time, taking (medicine) after mixing it with water, wine, etc. and to be taken after being infused in hot water or decoction, they should be operated according to the relevant specifications. The drugs needs decocting first then taking, decocting separately, and wrapping or decocting for drinking water should be soaked first before decocting,. The soaking time is usually less than 30 minutes.

6.2.3 for all kinds of special herbs, please see Annex B.

6.3 Basic requirements for quality and technology of decocting medicine

Degree for dregs should reach the standard of "three noes" (no paste, no white material, no hard material). The qualified rate should reach 100%. The concentration of medicine juice should be thicker and thicker, and the qualified rate should be more than 95%. The patients' satisfaction with the quality of Chinese medicine decoction is more than 95%.

6.4 Precautions for decocting medicine

6.4.1 Carry out the double check system and the decocting card (or the original prescription of the copy) before decocting.

6.4.2 When decocting should prevent liquid overflow, dry fried or boiled fried or boiled dry coke. Coke is prohibited from medicinal. It should be carefully checked whether the such procedures as taking medicine, dismantling bags(small package of pieces), washing medicine, soaking medicine, decoction, charging and delivery are in conformity with the decocting card (or the original prescription for the rewriting).During the operation, the decocting card (or the original prescription for rewriting) should be placed as a label in the eye-catching position of the drug.

6.4.3 Attention should be paid to the dropping time and decoction method of special drugs

6.4.4 Internal and external medicines should be separated and marked with containers of different colors or shapes.

6.4.5 The method of taking medicine should be labeled.

6.4.6 After completing the work of decocting drugs for a patient, the medicine containers should be cleaned in order to prevent cross infection. Otherwise, we cannot carry out the decocting work for the next patient. After the end of the decoction, it should be cleared in time. Repeated containers should be cleaned in time and sterilized at high temperature to prevent pollution. There should be obvious signs of clearance and disinfection. The

material for packing liquid should conform to the national standard for drug packaging materials.

6.4.7 When decocting Chinese medicine with the decocting machine, the decocting function of the decocting machine should meet the relevant requirements of this document. The medicine should be decocted at normal pressure, and the temperature of decoction should not exceed 100 degrees. The amount of the decocted liquid should be in accordance with the dose of the prescription, and the dosing dose should be uniform. Put in in sealed packets, and mark name of the patient, the date of decocting and the number of agents in the package, and store in a cool place or a refrigerator.

6.4.8 The residue should be kept for 24 hours for reference.

6.4.9 Decocting process should be recorded in records for preparation of medicinal herbs, decocting drugs and drug delivery, and the Format refers to annex D.

7 Decocting and taking method of Chinese medicine

7.1 General requirements

7.1.1 In general, Chinese medicines decoction should be taken while warm. Chinese medicines are generally decocted twice and then are mixed as one. Next, it will be divided into two portions for one day use. Some Chinese medicines will dissolve instantly as they are put in water, such as mirabilite. Some medicines, such as honey, do not need to be decocted and can be taken directly with water or decoction.

7.1.2 Acute patients must take two or even three doses per day, and chronic patients may need to take one dose every day or every two days. As for the proper time for taking Chinese medicines, in general, the tonic medicines need to be taken before meals and the antidote should be taken after meals. Vermifuge and laxatives should be taken on an empty stomach (such as in the morning).

7.1.3 Sedative medicines need to be taken before sleep, and stomachic tonic should be taken after meals.

7.2 Decocting and taking instructions for special Chinese medicines

7.2.1 Diaphoretic formula

7.2.1.1 Decocting method

The drugs with pungent and dispelling nature are used often, so the drugs should not be decocted for a long time so as to the property of drugs is dispersed and the effect is weakened.

7.2.1.2 Taking method

It should be taken warm, and drink a proper amount of hot water after taking. The clothes were covered so as to sweat slightly to dissolve the exterior evil and cure the exterior syndrome. The exterior-relieving formula induces perspiration. With slight

perspiration in the body as the best result, and then the pulse should be calm and cool. Profuse perspiration must be avoided for it can cause injury to yin or cause dead.

7.2.2 Purgation formula

7.2.2.1 Decocting method

Rhubarb is the main drug in the purgation formula, which should be decoct later.

7.2.2.2 Taking method

As directed by doctor.

7.2.3 Tonifying formula

7.2.3.1 Decocting method

Generally, it is advisable to decoct with slow fire for a long time so as to the efficacy of the drug could be decocted fully.

7.2.3.2 Instructions on taking

On empty stomach or before meals. If in emergencies, it is not subject to this restriction.

7.2.4 Formula for inducing resuscitation

7.2.4.1 Decocting method

Most of the drugs are aromatic drugs, so they should not be decocted for a long time so as to avoid volatilization of drugs and affect the efficacy.

7.2.4.2 Instructions about how to take medicine

The formula is mostly made of pills, powder or injection, and the pill powder should be melted in warm water or taken by nasal feeding.

7.2.5 Qi-regulating formula

7.2.5.1 Decocting method

Because most medicine for regulating qi are aromatic, pungent and dry, it should not be decocted long

7.2.5.2 Taking method

As directed by doctor.

7.2.6 Damp-clearing formula

7.2.6.1 Decocting method

Cook with water. The aromatic, warm and dry decoction pieces of desiccating formula should not be cooked for long.

7.2.6.2 Taking method

It should be taken while warm. When the patient's dampness pathogen is outside and on top, it can be taken while hot to sweat slightly to relieve the dampness pathogen.

8 Management and working system for the Decocting room

8.1 Management of medicine room in medical institutions

8.1.1 The decocting room should be managed by the pharmaceutical department. The pharmacy department should be responsible for the organization, coordination and management of the decocting room.

8.1.2 In accordance with the actual situation of the unit, the pharmacy department shall formulate the corresponding operating system of the decocting room and the standardized operation procedure (SOP) of the related equipment. The working system and operating procedures should be set up and put in the suitable position of the decocting room and strictly enforced. The decoction personnel should carefully check the relevant contents of the prescription (or the voucher of decocting medicine) when they draw medicine, decoct medicine, charge medicine, deliver medicine or send medicine, and establish the record of receiving and receiving. The contents are true and the records are complete. Each decocting should have an operation record reflecting all links of decocting. Records should be kept clean and tidy with real content and integral data.

8.1.3 The urgent decocting should be completed within 2 hours, and the urgent decocting system of Chinese medicine should be established and the urgent record should be set.

8.1.4 Facilities and containers for decocting should be cleaned before use. There should be clean regulations and daily cleaning records. Equipment and utensils for cleaning, cleaning and disinfection should be kept in a special place for safekeeping. The decocting room should be sterilized regularly. The varieties of detergent and disinfectant should be replaced regularly, and meet the health standards and requirements of GB 14930.1 and GB 14930.2, and the corrosion and pollution of equipment and drugs should not be produced.

8.1.5 For patients with infectious diseases, they should use disposable products in principle. After use, it is managed and disposed in accordance with medical waste. Those who do not possess the above conditions should strengthen the management of the repeated use of drugs and equipment. Fix the use of special personnel, and sterilize strictly so as to prevent cross contamination.

8.1.6 The quality control and monitoring of the decoction should be strengthened. The head of the pharmacy should evaluate and inspect the quality of the decoction on a regular basis (at least once a quarter), consult the medical staff and the inpatient, and establish the quality control and monitoring files.

8.2 Working system for medicine rooms in medical institutions

8.2.1 Under the leadership of the pharmacy department, the decocting room is responsible for the traditional Chinese medicine decocting work of the in-patients and outpatients.

8.2.2 The medicine room should be equipped with a pharmacist responsible for operational guidance and management according to national or regional regulatory

requirements. Medicine-decocting staff shall be subject to the professional knowledge training. After passing examination, they will be issued work permits, and are qualified to engage in the work of decocting. At the same time, business guidance and assessment system should be established. The head of pharmacy department should summarize, assess and evaluate the business of decocting medicine every half a year. The examination results of the decocting personnel and the instructors should reach "good" or above. The award of the superior is carried out, and the inferior is punished.

8.2.3 When the decoction personnel go to the pharmacy to receive the traditional Chinese medicine, they should check the patient's name, section, address, bed number, date, and number of agents. After confirming the registration of the medicine, it should be signed.

8.2.4 Decocting should strictly abide by the rules of technical operation and orders. After being soaked according to stipulations, according to the properties of Chinese medicine, choose the time to cook and cook. The amount of decoction should meet the requirements.

8.2.5 In order to ensure the quality of decocting, it should be carried out according to the doctor's orders if there are such special requirements as decocting first, decocting later, decocting separately, mixing with water or wine and melting.

8.2.6 The medicine-decocting card must be with medicine bag, soaking container, decocting container and medicine container from the time of drawing medicine. Each process has an operator's signature. After the Chinese medicine is cooked well, it should be packed in accordance with the requirements of doctors' order.

8.2.7 For non-one-time Chinese medicine liquid packed in vacuum, the containers for infectious patients and ordinary patients should be strictly separated. It must be thoroughly cleaned and sterilized before using to prevent pollution.

8.2.8 The staff of the decocting medicine should dress and wear tidy, wear chest cards, observe labor discipline, stick to their work posts, and do shift work when they go to work.

8.2.9 Using different color decocting cards for oral medication and external application, and strictly distinguished between different shape containers.

8.2.10 When the decoction is delivered to a ward or pharmacy, nurses or drug collectors should check it and sign in the drug delivery reiteration.

8.2.11 According to the urgent decocting system of traditional Chinese medicine, the medicine for newly hospitalized and severely ill patients should be immediately received, decocted and delivered without delay.

8.2.12 Strengthen the quality control of the decocting medicine and check regularly. When finding problems, handle them in time, analyze the causes and report to the pharmacy department.

8.2.13 Pay attention to safety. Do a good job in fire prevention, antivirus and anti-theft. Close doors, windows, water -tap and cut off electricity after work.

8.2.14 Other people are not allowed to go into the decoction room

8.3 Management and working system for decocting room in drug retail enterprises

The management and working system for drug decocting room in pharmaceutical retail enterprises should be referenced.

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Annex A (informative)

Operation rules and maintenance for packing machine and decocting machine

A.1 Operation rules and maintenance of packing machine

A.1.1 Preheating

Connect the power supply, confirm that the device does not leak electricity, press the power switch to heat the pressed iron block, and wait for the sound of music and the constant temperature indicating lamp is bright, indicating that the working temperature is reached.

A.1.2 Cleaning

After rinsing the storage tank and liquid pipe with hot water, put the extractor liquid into the tank, calculate the number of packages by the scale, and if the amount of medicine is not consistent, it should be re-regulated and decocted again (The medicine liquid card is attached to the packing machine.)

A.1.3 Packing

Press the pack-quantity set switch, medicine liquid outflow switch and packing machine operation switch to carry on the packing. If it is found that the sealing is not firm enough, the dosage is not enough, and the bubbles in the bag should be adjusted. It should be repackaged at any time.

A.1.3.1 Packing preparation

When the first pot is decocted, turn on the power switch of the packaging machine and enter the pre heating state before packing. At this time, the two small display lights are red. After the preheating is completed, the small lamp turns green and enters standby state of packaging .

A.1.3.2 Extrude medicine

When the indicated temperature reaches 120 degrees centigrade, continue to heat for 20 minutes. Stop heating and check whether the drain valve under the liquid pan is closed. After confirming that it is closed, turn the decocting pot to the upper drain valve and use the pressure plate to discharge the medicine in the medicine pot.

A.1.3.3 Packing

After discharging the first bag of waste liquid (150ml or so), the automatic discharge and switch are opened and automatically packed. The number of bags is 2R (R is the number of agents).

A.1.3.4 Rinsing

Turn on the drain valve, drain off the remaining dregs, and rinse with a certain amount of water. Repeat 2-3 times.

A.1.3.5 Bagging

Check the packaged packages according to the label check and confirm the correct number.

A.1.4 Maintenance

A.1.4.1 Before starting every day, use oil to spray a small amount of lubrication on the six sides of the packing shaft, and make the sealing and sliding surface lubricate.

A.1.4.2 Every day after the decoction is finished, turn off the machine and wipe surface and surrounding of the sealing with a damp cloth. Remove the three small filters in the liquid glass pot and rinse them clean. Wash the inner wall and bottom of the pan to ensure that it is clean and then re-install the small filter tube.

A.1.4.3 Discharge the drain pipe regularly (once a week). After cleaning the inner wall of the pipe with thin strips, rinse it clean. At the same time, the rubber tube in the box is pinched by hand to make the scale of the inner wall fall off. Then install the liquid drain tube, pour a certain amount of water into the pot, cut off the sealing part below the packaging bag, open the rinse start, and drain the scale. Each time using a small amount of water, repeated several times until the water is discharged completely.

A.2 Operation rules and maintenance for decocting machine

A.2.1 Soaked in cold water, soaking and adding water can be referred to the following formula. Soaked in cold water, soaking and adding water can be referred to the following formula: $Q=2R*200+R*W$ (Note: Q is the total amount of water added, R is the number of agents, W is a constant value, and its value is 170ml) ; Formula for adding water for children: $Q=2R*150+R*K$ (K=100, the unit is milliliter); Hang up a decoction card (The time of infiltration is 20-30 minutes) .

A.2.2 Test with electric pen to confirm that the equipment is leakproof.

A.2.3 Turn the timer to zero, switch on the power, and then test it to make sure that the device does not leak.

A.2.4 Close the inlet of the intake and the outlet of the liquid.

A.2.5 Spread the soaked medicinal herbs together with the soaked liquid in the pot, then hang the decocting medicine card.

A.2.6 Close the lid, lock up, close the exhaust valve.

A.2.7 Setting up the temperature of the decocting (120℃)

A.2.8 Setting up the temperature of the decocting (about 60 minutes) . After heating, the pressure gauge is observed after reaching the predetermined temperature. The pointer should be between 1 and 1.2. Heat preservation for 20-30 minutes (during the period, the slag plate should be loosened and tightened for more than 2 times to stir). Turn the timing key to zero after completion

A.2.9 The slag is extracted and the slag plate is tightened.

A.2.10 Open the medicine valve, use the pressure in the furnace to pour the medicine into the packing machine, and compare the scale, check the volume of the liquid, if not enough, add the water to until reach the required quantity.

A.2.11 Open the exhaust valve beside the pressure gauge, confirm that no pressure is found in the furnace, then unload the slag plate counterclockwise, loose the lock and open the lid.

A.2.12 Clean the dregs, rinse the pot with common water, then rinse with boiling water again to ensure the quality of the next pot.

A.2.13 After decocting the medicine every day, soak it in the pan to cool it. Then remove the central filter, Clean the inside and outside walls of the filter pan and the decocting pot respectively. A certain amount of water (about 2000 ml) is injected.

A.2.14 In the absence of decocting, the power should be switched off and injected with a certain amount of water.

A.2.15 In the absence of liquid or water, the decocting machine must not be heated and dried to avoid damaging the machine.

Annex B
(normative)
Management and working system for decocting room

B.1 Management of medicine room in medical institutions

B.1.1 The decocting room should be managed by the pharmaceutical department. A special person should be responsible for the organization, coordination and management of the decocting room.

B.1.2 In accordance with the actual situation of the unit, the pharmacy department shall formulate the corresponding operating system of the decocting room and the standardized operation procedure (SOP) of the related equipment. The working system and operating procedures should be set up and put in the suitable position of the decocting room and strictly enforced. The decoction personnel should carefully check the relevant contents of the prescription (or the voucher of decocting medicine) when they draw medicine, decoct medicine, charge medicine, deliver medicine or send medicine, and establish the record of receiving and receiving. The contents are true and the records are complete. Each decocting should have an operation record reflecting all links of decocting. Records should be kept clean and tidy with real content and integral data.

B.1.3 The urgent decocting should be completed within 2 hours, and the urgent decocting system of Chinese medicine should be established and the urgent record should be set.

B.1.4 Facilities and containers for decocting should be cleaned before use. There should be clean regulations and daily cleaning records. Equipment and utensils for cleaning, cleaning and disinfection should be kept in a special place for safekeeping. The decocting room should be sterilized regularly. The varieties of detergent and disinfectant should be replaced regularly, and meet the health standards and requirements of GB 14930.1 and GB 14930.2, and the corrosion and pollution of equipment and drugs should not be produced.

B.1.5 For patients with infectious diseases, they should use disposable products in principle. After use, it is managed and disposed in accordance with medical waste. Those who do not possess the above conditions should strengthen the management of the repeated use of drugs and equipment. Fix the use of special personnel, and sterilize strictly so as to prevent cross contamination.

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B.2 Working system for medicine rooms in medical institutions

B.2.1 Under the leadership of the pharmacy department, the decocting room is responsible for the traditional Chinese medicine decocting work of the in-patients and outpatients.

B.2.2 The medicine room should be equipped with a pharmacist responsible for operational guidance and management. Medicine-decocting staff shall be subject to the professional knowledge training. After passing examination, they will be issued work permits, and are qualified to engage in the work of decocting. At the same time, business guidance and assessment system should be established. The head of pharmacy department should summarize, assess and evaluate the business of decocting medicine every half a year. The examination results of the decocting personnel and the instructors should reach "good" or above. The award of the superior is carried out, and the inferior is punished.

B.2.3 When the decoction personnel go to the pharmacy to receive the traditional Chinese medicine, they should check the patient's name, section, address, bed number, date, and number of agents. After confirming the registration of the medicine, it should be signed.

B.2.4 Decocting should strictly abide by the rules of technical operation and orders. After being soaked according to stipulations, according to the properties of Chinese medicine, choose time and fire intensity to decoct. The amount of decoction should meet the requirements.

B.2.5 In order to ensure the quality of decocting, it should be carried out according to the doctor's orders if there are such special requirements as decocting first, decocting later, decocting separately, mixing with water or wine and melting.

B.2.6 The medicine-decocting card must be with medicine bag, soaking container, decocting container and medicine container from the time of drawing medicine. Each process has an operator's signature. After the Chinese medicine is cooked well, it should be packed in accordance with the requirements of doctors' order.

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B.2.9 Using different color decocting cards for oral medication and external application, and strictly distinguished between different shape containers.

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B.2.13 Pay attention to safety. Do a good job in fire prevention, antivirus and anti-theft. Close doors, windows, water -tap and cut off electricity after work.

B.2.14 Other people are not allowed to go into the decoction room

B.3 Management and working system for decocting room in drug retail enterprises

The management and working system for medicine-decocting room in pharmaceutical retail enterprises should be referenced.

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Annex C
(normative)
List of special Chinese herbal medicine

Table C.1 Compatibility of contraindications

18 incompatible medicaments	Radix Glycyrrhizae being incompatible with Radix Euphorbiae Kansuii Radix Euphorbiae Pekinesis , Flos Genkwa and Sargassum;Radix Aconiti incompatible with Bulbus Fritillariae , Fructus Trichosanthis , Rhizoma Pinelliae , Radix Ampelopsis , Rhizoma Bletillae;Radix Veratro Nigri incompatible with Radix Ginseng , Radix Glehniae , Radix Salviae Miltiorrhizae , Radix Sophorae Flavescentis, Herba Asari and Radix Paeoniae.
19 medicaments of mutual an-tagonism	sulfur being antagonistic to crude mirabilite , mercury to arsenic;Radix Euphorbiae Ebracteolatae to Lithargyrum; Semen Crotonis to Semen Pharbitisis; Flos Caryophylla to Radix Curcumae; crystallized mirabilite to Rhizoma Sparganii; Radix Aconiti and Radix Aconiti Kuznezoffii to Cornu Rhinoceri;Radix Ginseng to Faeces Trogopterorum;Cortex Cinnamomi to Halloysitum Rubrum.

Table C.2 Contraindication during pregnancy

forbidden medicinals	Three prism, zedoary turmeric, Hirudo, gadfly, Euphorbia, Beijing euphorbia, Daphne Daphne, morning lead, bean, thousand gold, Phytolacca, light powder, cantharidis, realgar, musk, pig tooth soap, Herba Leonuri, Strychni, Aconitum, woodlouse, kachyranthes, Rhizoma, Glauber's flower, centipede
Cautiously-used medicinals	Toad, Huashan ginseng, dry lacquer, dry lacquer, acute son, sulphur, Radix Aconiti, kusswood, white aconite, Fructus aurantii trifoliolate, Fructus aurantii trifoliolate, rhubarb, senna, cinnamon, creeper, wooden shelled turtle, Achyranthes, safflower, peach kernel, 37, Yu Li Ren, Polygonum cuspidatum, Royal Cunnus, Yuzhou, rash, Curcuma and Western Red Flowers, pangolin, borneol, hematoxylin, Herba pall, Changshan, pollen yellow, ochre and Dianthus

Table C.3 Specially decocting medicinals

decocting first	Tortoise shell, turtle, ochre, stone cassia, oysters, keels, magnets, plaster, quartz, cold water stone, natural copper, clam shell, pearl mother, antler frost, corrugated seed, Radix Aconiti, Radix Aconitum, Phytolacca, Rhizoma, Dendrobium, water ox horns, red stone, gold, green stone Stalactite, talcum, talcum
decocting later	Peppermint, Amomum villosum, cardamom, aloes, bitter almond, uncaria, rhubarb, senna, Cynanchum paniculate, Artemisia annua, Houlttuynia cordata, and dalbergia odora.
wrap-decocting	Sophia, Plantago, floral floral, raw cattail yellow, 61 scattered, clam powder, Yichang powder, clam powder, indigo, pulverized, talcum, yicjinsha, catechu, Magnolia, gold and green stone
administered after dissolved	Bezoar, Amomum, 37 powder, pearls, cinnabar, musk, Xiong Dan, Ma Bao, monkey jujube, antelope horn powder, Aromax powder, amber powder, tortoiseshell, Fritillaria, Hubei Fritillaria, and thunder shot
melt	Gelatin, antler gum, tortoise glue, honey, maltose
decocting separately	Ginseng, Gastrodia elata, antelope horn, Panax quinquefolium, Crocus sativus, Cordyceps sinensis, pilose antler slices, red ginseng
fusion	Mirabilite, compound of glauber-salt and liquori

Traditional Chinese medicine methods- Shells must be rammed, while seeds must be broken. Please see **Table C.4**.

Table C.4 Common prepared herbal medicine that needs to be temporarily mashed

Fruit and seed	Clove, SA bean, Chinese jujube, Kawa Ko, Fructus Schisandra, burdock seed, white fruit, white lentil, Trichosanthes, cassia seed, nutmeg, cardamom, mustard, Quzi, green fruit, Yu Li Ren, king, pepper, Piper, straw, grass fruit, litchi, seed, nut, semen, Raphani, nourishing wisdom, foresee, pig Gleditsia, black sesame seeds, Torreya seed, sour jujube seed, Fructus Vitex, Fructus Rubus, Citrus Seeds, etc.
Root and rhizome	Arrowhead, flat Fritillaria, Panax japonicus, Huashan ginseng, pearl ginseng, Rhizoma Dryopteris, etc.
Alabastrum	Clove, Biond magnolia flower-bud, etc
Mineral	Alum, natural copper, etc.
Animal	Hippocampus, deer horn cream, pangolin, turtle shell, tortoise shell, etc.
Other medicinals	Catechu, cinnamon, etc

