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Department of Health Care Services



GAVIN NEWSOM
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**REQUEST FOR SECTION 1135 WAIVER FLEXIBILITIES RELATED TO NOVEL
CORONAVIRUS DISEASE (COVID-19) NATIONAL EMERGENCY/PUBLIC HEALTH
EMERGENCY**

Dear Ms. Glaze:

The Department of Health Care Services (DHCS) writes to request approval for the below detailed flexibilities under Section 1135 of the Social Security Act (42 U.S.C. § 1320b-5) as related to the Novel Coronavirus Disease (COVID-19). As you know, the COVID-19 outbreak was declared a national emergency on March 13, 2020, and was previously declared a nationwide public health emergency on January 31, 2020 (retroactive to January 27, 2020).

The below list represents California's initial requested flexibilities under the Section 1135 authority in connection with the COVID-19 outbreak and emergency. Because circumstances surrounding the COVID-19 emergency remain quite fluid, DHCS may subsequently request approval for additional flexibilities, which we can commit to doing promptly as soon as the need is discovered. Consistent with Section 1 of the President's March 13, 2020, national emergency declaration, DHCS requests a retroactive effective date of January 27, 2020, for the requested Section 1135 flexibilities to coincide with the effective start date of the Public Health Emergency, unless otherwise specified.

In addition, DHCS requests confirmation that any approved flexibility granted with respect to fee-for-service Medi-Cal benefits and providers would apply equally, to the extent applicable, to our various federally approved delivery systems, such as Medi-Cal managed care plans, county organized health systems, county mental health plans, and Drug Medi-Cal organized delivery systems (DMC-ODS) and to the State's standalone Children's Health Insurance Program.

1. Provider participation, billing requirements and conditions for payment, including but not necessarily limited to:

- Waiver of certain provider enrollment requirements in order to maintain capacity to meet beneficiary access needs during the emergency and to enable payment to affected providers for rendered services. During the approved emergency period, DHCS proposes to streamline enrollment of providers using relatively limited information, i.e. provider information sufficient to build a case file for claims processing. DHCS would apply such flexibility to providers on a statewide basis, and would require provider agreements but not disclosure statements. DHCS would deny enrollment under this streamlined process if a provider is found on the following exclusionary databases: Suspended and Ineligible; Office of Inspector General; or the Medicaid and Children's Health Insurance Program State Information Sharing System. As an initial matter, DHCS proposes to waive requirements such as: application fees pursuant to 42 C.F.R. §455.460; criminal background checks associated with Fingerprint-based Criminal Background Checks pursuant to 42 C.F.R §455.434; site visits pursuant to 42 C.F.R §455.432; screening levels pursuant to 42 C.F.R. §424.518; in-state/territory licensure requirements 42 C.F.R §455.412 and disclosures and disclosure statement pursuant to 42 C.F.R. §455.104.

Additionally, we are seeking to temporarily cease revalidation of providers who are located in California or are otherwise directly impacted by the emergency.

- Waiver/flexibility with MCO and PIHP requirements to complete credentialing of providers required under 42 C.F.R. § 438.214.
- Waiver/flexibility to allow providers to receive payments for services provided to affected beneficiaries in alternative physical settings, such as mobile testing sites, temporary shelters or other care facilities, including but not limited to, commandeered hotels, other places of temporary residence, and other facilities that are suitable for use as places of temporary residence or medical facilities as necessary for quarantining, isolating or treating individuals who test positive for COVID-19 or who have had a high-risk exposure and are thought to be in the incubation period or to expand overall capacity to meet high demand.
- Waive DMC-ODS requirements in STC 132e(ii), the DMC-ODS billing manual and DMC-ODS contracts to allow flexibility of documentation requirements, including timelines related to review of medical necessity and suspend financial disallowances for noncompliance with documentation standards, including but

not limited to missing client signatures on treatment plans, lack of documentation of consent for telehealth consult.

- Waive requirements in STC135, STC136, and STC138 in DMC-ODS requiring minimal clinical service hours and group visit requirements to qualify for claiming reimbursement for intensive outpatient and residential SUD treatment as long as care is consistent with the individual care plan, and waive the requirement for disallowances when those service hours are not met for individual patients (to allow services and facilitate social distancing).
- Waive requirements under DMC contract boilerplate Exhibit A, Attachment 1, Section III(PP)(12)(i)(b)(ii) and (PP)(12)(ii)(b) (for Drug Medi-Cal) which requires client signature on treatment plan, in recognition of the need to provide treatment by telehealth and telephone. Also waive Supplement 3 to Att. 3.1-A, page 1 (and Supp. 2 to Att. 3.1-B, page 1) which requires "documentation of the beneficiary's participation in, and agreement with, the client plan."

2. Service authorization and utilization controls, including but not necessarily limited to:

- Waiver of prior authorization requirements for accessing covered State plan and/or waiver benefits (for example outpatient drugs pursuant to 42 U.S.C. §1396r-8(d)(5)) in recognition of various circumstances which makes submission of medical necessity documentation difficult, impractical or impossible. Such circumstances include but are not limited to: relocation or isolation of Medi-Cal beneficiaries; inaccessibility of resources provided by the facilities; relocation, reassignment, or isolation (due to illness) of pharmacy staff, primary care prescribers and staff, and/or specialty prescribers and staff in the affected areas. During the authorized period, DHCS intends for providers to submit uniquely identified manual claims for services that typically require prior authorization to the fiscal intermediary (FI). The FI will process the claims without regard to prior authorization requirements or documentation for medical necessity of the service.
- Where Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) is lost, destroyed, irreparably damaged, or otherwise rendered unusable, contractors have the flexibility to waive replacements requirements such that the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required. Suppliers must still include a narrative description on the claim explaining the reason why the equipment must be replaced and are reminded to maintain documentation indicating that the

DMEPOS was lost, destroyed, irreparably damaged or otherwise rendered unusable or unavailable as a result of the emergency.

- Waiver of State plan and waiver-imposed utilization controls on covered benefits to the extent such limits cannot be exceeded based on medical necessity in the relevant approved State plan or waiver authority.
- Waiver of limitations on who can prescribe certain covered Medi-Cal benefits, such as: nonemergency medical transportation (42 C.F.R. §440.170, to allow licensed practitioners to prescribe instead of only a physician, podiatrist, or dentist); home health services (42 C.F.R. §440.70, to allow licensed practitioners to prescribe services such as DME, medical supplies, enteral nutrition and home health agency services instead of only a physician); physical, occupational and speech therapies (42 C.F.R. §440.110, to allow licensed practitioners to prescribe); prosthetics (42 C.F.R. §440.120, to allow licensed practitioners to prescribe within their scope of practice).
- Waiver of the in-home face-to-face and/or in-home requirement for conducting reassessments and instead provide the option to conduct reassessments via telephone or other remote option for the following In-Home Supportive Services (IHSS) programs: Personal Care Services Program (PCSP), IHSS Plus Option (IPO) and Community First Choice Option Program (CFCO), programs which are authorized under the Medicaid State Plan and sections 1915(j) and 1915(k) of the Social Security Act. The State also requests a waiver to extend the reassessment period in all IHSS programs to once every 18 months and to temporarily suspend quality assurance home visits.
- Waiver of State Plan Attachment 3.1 B (p.17) which limits dispensing of a covered drug up to a 100-day supply. DHCS is requesting authority to temporarily suspend these limitations for all drugs, excluding narcotics/opioids, thus allowing up to 100-day supply to be dispensed, without a TAR/SAR, if medically necessary and the prescriber writes for that quantity. DHCS is also requesting authority to suspend other frequency and maximum daily quantity edits.
- Waiver of Section 1927 of the Social Security Act and State Plan Supplement 2 #11 requiring documentation of published studies documenting the safety and effectiveness of unlabeled medication use, or recommendations for use by experts in the disease field in order to approve a TAR for unlabeled use. DHCS

is requesting authority to cover and reimburse unlabeled medications shown to be safe and effective, but not yet having the required published documentation for use in COVID 19.

- Waiver to allow acute care hospitals with excluded distinct part inpatient psychiatric units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit.
 - Waive the requirement at Section 1812(f) of the Social Security Act for a 3-day prior hospitalization for coverage of a skilled nursing facility (SNF) stay.
 - Waive the requirements that Critical Access Hospitals limit the number of beds to 25 and that the length of stay be limited to 96 hours.
 - For individuals with developmental disabilities receiving services under the State Plan 1915(i) authority, the state requests:
 - Waiver of the in home face-to-face requirements for review of the service plan and conducting reassessments.
 - Waiver to utilize telephonic, live video or other remote methods for the provision of services.
 - Waiver to provide services in alternate locations when necessary.
3. **State fair hearing requests and appeal deadlines for managed care enrollees**, including but not necessarily limited to:
- Modification of the timeframe under 42 C.F.R. §438.408(f)(2) for enrollees to exercise their appeal rights to allow an additional 120 days to request a fair hearing when the initial 120th day deadline for an enrollee occurred during the authorized period of the immediate Section 1135 waiver.
4. **Benefit Flexibilities**, including but not necessarily limited to:
- Request for recognition of any COVID-19 testing and related treatment of a Medicaid beneficiary outside of an emergency room setting as constituting “emergency services” or services for an “emergency medical condition” for purposes of various Medicaid requirements including, but need not be limited to, 42 U.S.C. §1396u-2(b)(2) and 42 U.S.C. §1396b(v)(2)-(3).
 - Waiver of requirement for Tribal 638 clinics that services be provided within the clinic four walls except for homeless populations per 42 C.F.R. §440.90 to allow

for screening and testing away from patient areas and allow for services to homebound and others. Tribal 638 clinics would be able to bill these visits at the federally established AIR rate methodology.

- Allow for federal financial participation for expenditures related to temporary housing for the homeless as a result of the emergency, including but not limited to, commandeered hotels, other places of temporary residence, and other facilities that are suitable for use as places of temporary residence or medical facilities as necessary for quarantining, isolating or treating individuals who test positive for COVID-19 or who have had a high-risk exposure and are thought to be in the incubation period.

5. **Telehealth/Virtual Visits**, including but not necessarily limited to:

- Flexibility to allow for virtual/telephonic communication/telehealth modalities for covered State plan benefits, including but not limited to Behavioral Health Treatment, where medically appropriate and feasible.
- Waiver of face-to-face encounter requirement for reimbursement in 42 C.F.R. §405.2463(a)(B)(3) and 42 C.F.R. §440.90 (a) for FQHCs, RHCs, and Tribal 638 Clinics relative to covered services via telehealth provided by clinic providers. Additionally allow flexibility to provide these covered services via telehealth without regard to date of last visit and for new or established clinic patients.
- Request to allow for reimbursement of virtual communication using the Healthcare Common Procedure Code System G0071, for FQHCs, RHCs and Tribal 638 clinics. Additionally allow flexibility to provide this service without regard to date of last visit and for new or established clinic patients
- Waiver of face to face encounter requirement for reimbursement in 42 C.F.R. §405.2463(a)(B)(3) and 42 C.F.R. §440.90 (a) for FQHCs, RHCs, and Tribal 638 Clinics to allow for interprofessional consultation reimbursement for e-consult provided by clinic providers for new or established clinic patients.
- Waive provisions in Supplement 3 to Attachment 3.1-B for individual group counseling within the State Plan prohibiting use of telehealth in the Drug Medical program and allow for group or individual counseling by telehealth. Allow services to be provided through telephone or telehealth anywhere in the community, including clinician-to-clinician telephone or telehealth consultation. Allow Licensed Practitioners of the Healing Arts to perform all duties of a Medical Director, and allow medical necessity to be determined via telehealth in Crisis Stabilization and Crisis Residential (Specialty MH).
- Waive State Plan requirements for a "face-to-face contact between the beneficiary and a treatment staff person of the facility on the day of service" for Adult

Residential Treatment Services and Crisis Residential (Supp. 2 to Att. 3.1-B, p. 11, 12; Supp. 3 to Att. 3.1-A, pp. 2i, 2k) and allow that requirement to be fulfilled by telephone or telehealth.

6. Payment Rates, including but not necessarily limited to:

- Waiver of State Plan Attachment 4.19-B Page 3d which limits reimbursement rates for clinical lab services to no more than 80% of Medicare and requires a 10% reduction in the established fee schedule rates for clinical laboratory services. To increase the state's capacity to diagnose COVID-19 cases and support clinical laboratories evaluating those tests, the state seeks to establish rates for U0001 and U0002 at 100% of Medicare MAC rates and waive the 10% payment reduction effective retroactively to February 4, 2020, the date these codes were established by CMS.
- Waiver of State Plan Attachment 4.19-D which establishes the provision for reimbursement of Intermediate Care Facilities for the Developmentally Disabled (ICF-DD). ICF-DD clients normally participate in Regional Center day programs which reduces the need for staffing in facilities while clients are in day programs. ICF-DD rates account for this reduced staff time. Regional Center day programs are being suspended to prevent the spread of COVID-19 resulting in clients needing to stay within their facilities and increasing the cost for facilities to have adequate staff. The assumed participation time in the day programs are not built into ICF/DD-N or ICF/DD-CN rates. The state seeks to waive the current ICF-DD rate setting methodology to provide an add-on to facility rates to compensate for the increased cost of staff time not accounted for in the current facility daily rates during the duration of the emergency.

7. Eligibility Flexibilities, including but not necessarily limited to:

- Request to expand Hospital Presumptive Eligibility to include the over 65/aged & disabled population. California SPA 13-0027-MM7 authorizes California's implementation of the Hospital Presumptive Eligibility (HPE) requirements of the Affordable Care Act, found at 42 C.F.R. §435.1110 with an effective date of January 1, 2014. With the onset of COVID-19 in California, the need to expand this benefit to some of the more vulnerable populations has become necessary. Through the 1135 waiver authority, the state seeks to expand its HPE populations to include individuals over the age of 65, blind, and/or disabled by ensuring that the most vulnerable of individuals have access to care.
- Waiver of costs associated with the testing of the COVID-19 and, for those that test positive, all costs associated with the treatment of this virus for certain beneficiaries subject to a share of cost. California administers a Medically Needy

share-of-cost program that provides Medi-Cal for several different coverage groups. These Medically Needy coverage groups include children under age 21, pregnant individuals, parents and other caretaker relatives and individuals that are aged 65 or older, disabled, or blind. Certain individuals in the Medically Needy program are required to pay a share-of-cost based on household income that exceeds the maintenance need level for their family size. A majority of the Medically Needy population with a share-of-cost are individuals at higher risk due to age, pregnancy, and chronic health conditions including heart, lung or kidney disease. Waiving the share-of-cost for the COVID-19 testing, diagnosis and treatment for this population will guarantee there are no financial barriers to seeking medical services related to this public health emergency and potentially reduce the spread of the virus

8. **Administrative Activities**, regarding deadlines and timetables for performance of required activities, DHCS requests extension of time for activities conducted by the state, Medi-Cal managed care organizations (MCOs), and/or county mental health and substance use disorder prepaid inpatient health plans (PIHPs), due to social distancing to reduce the spread of COVID-19 and to allow state, MCO, and PIHP resources to prioritize COVID-19 response efforts including but not necessarily limited to:
- Waiver of the timeframe required for submission to CMS of contracts under 42 C.F.R. § 438.3(a). DHCS requests this waiver to allow MCOs flexibility regarding obtaining, in a timely manner, required contract signatures, which requires face-to-face interactions at board meetings.
 - Waiver of Plan requirements to meet network adequacy standards required under 42 C.F.R. § 438.68 and timely access standards for routine services required under 42 C.F.R. § 438.206(c). This waiver is necessary to ensure health care providers are able to provide necessary and timely care to beneficiaries experiencing symptoms related to COVID-19.
 - Modification of the timeframe for submission of annual network certification to CMS required under 42 C.F.R. § 438.207. DHCS requests an extension of its annual network certification to October 1, 2020.
 - Flexibility/modification of the timeframe for submission of monthly T-MSIS reporting.
 - Waiver regarding the timely completion of external quality review (EQR) activities required under 42 C.F.R. § 438.358, including all site visits performed by the EQR organizations and required network validation activities. DHCS requests this waiver/flexibility to limit site visit requirements as well as to allow administrative relief for MCOs and PIHPs during the period

Jackie Glaze
Page 9
March 16, 2020

of the emergency. DHCS requests suspension of EQR activities until June 30, 2020.

- Modification to the timeframe for submitting to CMS and publicly posting the EQR technical report required under 42 C.F.R. § 438.364(c)(2)(1). DHCS requests to extend the deadline to July 1, 2020.
- Modification of the timeframe for submission of DHCS' quality strategy report required under 42 C.F.R. § 438.340. DHCS requests an extension to October 1, 2020.
- Modification of the timeline for the DMC-ODS Evaluation to October 1, 2020.

During such difficult times for California and the nation, DHCS greatly appreciates the prompt attention exhibited by CMS to these matters and we look forward to the continued partnership.

Sincerely,



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Jackie Glaze
Page 10
March 16, 2020

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