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www.(cgulations.gov

s«-m.>ve-s-mu, 1,1.P. H., Administr.1tor

ntets *for* MC'dic.-ifc &Mcdi<J;idsc Mccs

Department of Health and Hum.inSCfVic:cs

7500 Sec u rity Bouleva rd

Baltimore, MD212'1'1

Re: CM$-4HP -P: Mediu: re Program; Contract Year 2019Policy and rechnical Changesto the Medicare Adva ntage, Mediccne Cost Plan, Med tU re-Fee-for-Se rvice, the Medicare Prescription Drug Benefit Pfoga,ms.andthePACEProgram

## oe a rAdministratorverm<J:

Suno v i on Ph cri maceut:ical s Inc. (Svoovion) thanks you for the opportunity to comment o nthe proposed Medic , Prog,<a m; contractYear 2019Policyand Technical Changesto theMedicare Adv,mt.igsc, Mcd tC..irc costPt.-in,Medic.3re Fee-­

for -Servi ce, the Medic a re Pre scription DrugBenefitProg1ilms,ilcndt h e,PAU

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P'rogr3m (CM$· 41$ i -P; RIN 093 AT08), 8 2 Fed. Reg. 563 36 (November 2, 8

2017)

.>nd pJ rt ic:ul.lr1yon th<'Medic::a re Pre..scriprion DrugBenefit{or Part 0) proposals

ir, lh fulc m.lking. The Proposed Ruleincludes numerous proposalsaffect ing nd ici.::ary<1:t<:l"SSto mcdi<.atio1•s under theprogram, manyof which implicate

pr<?'Atip tio ndrug manufoc:tv, crs likeSonovion. We thusappreciate the opportunityto sh.are ourcomrncnls with the Agency in*the* hopes ofimproving and refiningthe proposedrule ch.in&cs.

Sunovion is <>g l o balbioph.>, m.,ccutCi JIco mpanyfocusedonthe innovative application of scienceJ nd mcdi.cine to help peoplewithserious medical conditions. Vrthpa tientsJ,l th<.'ce nter of everythingwe do, Sunovion has charted newpaths *to* life-tr.::ansfor min,gt e tments that reflect o ngoing

investments inresearchanddevclopmcnl Jnd a••u nwavering co mmitment to

support people with psychiatric,neurologic:.>l Md, piratorycondi tions.. Our com me nts arc focused on rive aspec::ts of th e propos ed rute:

{l} weoppo te the proposa l to permit Prescription Drug Pl.lns(POPS) to

subs.titute gell('ric medications mid-plan yearwith minimum notic:c to bcn cfi<,.i-' i ;

# .\_r,,;

"' sunovion

Innovation today,h1•.iUhk•rtomorrows

*W* We(equest clarifica tion oftheAgency•s proposalregarding the processofdefining

M f,equen ttyabused drugs'°that would besubject to Me d ica re PJflOaccess restrkrionsin

the contextof Comp,chcoSivc Addictio n and Re<:ov e,y Acl {CARA)impl ementatio n;

(:$) wesupport the proposal to permit Med ica re Advantage Pla n. to spcci.:iliz<!'i npanicula r diseasestates; a nd

('1) We suppo rt I.h e Agency'spursui t of policies that would require ph.!rmacy bCO('fi t

managers(PBMs) and PDPsto pa:ssthrough rebates , discounts andothe<Directand

lnditcct Remu neration(DIR) f to bc,nclici.iries i<t t h e po in t ofs.;M,

Ourspecific comments.-ippc.i r bel ow.

L W,S;:Aited SubsrinstionofYcncri<:s - Mid-VearFormularyCh.,nw CMSproposes to permit immediate mid-plan ye¥ su titution of.ag.enericfor;,bf;;indo-:.d

me<:f ica tio n th.atw.'.lson the Plantormuta rya ndcliminalionofcoveJageforthe brand with no noticeto the beneficiaryother than a genetaladvance notice that suchsubstitutions mightoccur d ufing the planyear. Sunovionobjects to this proposal and urgesthe Agen<:ynot to udoptit. The pfoposal remove-s bas ic pa t ient protectionsth.itare needed for the JlfOp('( fv nctioningof t he Parr Opfoga im. Beneficiaries requir advan<«I noticeof formula rychanges.even if bra nded to

gcnekr medications.,to en,s.ure *they* havesufficient time to: (1) discuss th('anticipatedchanges

with theirhealthcare p<ok"Ssio n.:il; (2 ) p repare for pres.criptioM that mayhavea differe nt name, different 3ppC.lf;)ncc. .indd rffe re n t p ayment (including <O·p.iymcnt) process; a nd (3) t nsure they are not s.vrpfiS. cdat the pharmacycounter when;i (liff« C<lt medication is dispensed. Med ic.:itio n ad h ere n¢e isalreadya wel!-doaJmentedchallenge-,J 1ld rates ofnon-adherence are p;,11ci uforty a¢ute *fof* p.:it ic n ts wit h ser io usmentalillness.. we *arc* COl'l<Cfocd th at e n act ingthis policychange would serve to exacerbate thisproblem.

SunovionJppreciatcs that CMSproposes to req uire Plansto *ge,()(!((l(ly* notify beneficiariesinrhe Expl.rn attOnofCoverage{EOC) thattheplanmayswitch m«l icutionsmid-year, and th;,tunde-r t h<­ propos.3l POPswilln-ot be a ble to u ndertake thiss.wtich if the ge nericmedicationwasavailable priof to t he- Ng inningof the Planyear. Howevef,inOuf<x' .p<:1ica:nce the EOC notice isinsuffici<-nt to prot«tbeneficia ries. It the Agency fina1i1,e s.its pfoposal, the Agencywould beopen to critique forJ)C'frnittinga classic "baitandswit¢h," whc-rea b<-nd ic.i.:iry,believingtheyare enrollingin., Pl.into secure accessto a specifk mec:fi<ation.lcumsmid-planyearwithout notice th-at the ir medication ic.;n o lo nger covered.'Ind they.:rerequired tosubstitute a"ne·vl' gc-m: ric. This will

harm benefidary(;onfideOC<'inth<'P urt O pro gr a m,and undermine be1l('fi<.i, ryconfidence intheir POP.

Ptsrt D Pfans already have a plethoraofut iliz.:itioo co nttols, includingstep thera pyand p(ior authorization, thattheyu, n immedi.-itely d eplo ytosteer beneficiaries to newgenericsth-at *are*

add e d on formula rymid-planyN r. Webelievethat the exis tingtools.;, re *more* th un adequate to

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lrln<.ui>tion today, healthier tomotra.•1:,,

## ensu re that p;tticntsin uppropriate circumstance.,u; tili;,eg<'netk s. Forthesereasons, Sunovio,1

asksth t theproposedfcgul tion be withdrawn.

1. .Q.efi ni J!8an d Lim if in e AccH'S$ to "'f «:Queo tly Abused Drues"

Svnovion supports the Agency'sroleinimplementingptovisionsof theComprehensiveAddiction and Recove ry Actof 2015 (CARA), a nd isgrateful I.h ut the Agency is prioritizingthrSn ew reg ulatory initiutiveaspart of the Proposed Rul<,' AstheAgency acknowledges, tflcthtc.it *to*ourcountrya

## <csult of prescriptiondnsgabuseissigr1ificanL.indthere is a real need to, a <omprehensive effort

l<>c:utb opioidabuse.

## Sunovioll offers*one*comment on the proposed n.ticsimplementing CARA:a d n.ig willbe d efi ned as "'fr<'quentlyabused"'ba$00 upon (l) the USo ,ugEnforcement Agency(D( A)s.cncdv lingstatus, (2) professionalguidelines.,J nd (3) ananalysis of Medicare andscientifk d.:ita. We*note*that there are *1.)*myriad ofd rugs used forindi<Jtiooso thc, thun pilin(and thatart not optOids ) thatwillbe 'Kheduled bythe DEA,iod udin& 'lltcntiondeficit disorder medications,sl<'Cp .igents , andother$ withimportant ther-Jp tic benefits that could inadvertentlyf;)tl within th broaddefinition.

AlthoughcertJinm«l icatiot1s.i1escheduled andsubject to profcs.siooal guidelines, theymaynot be subject to frcq11.-cnt.i buse a nd should not be resuicted undc..-CARAcontrols.

Forthat reac;on, Suno\liOr'l r« o rnmcndsthat anyclassification of a mcdi,cf.)ti,onas "frequently abused" be subje(t toexpedited notice<lndcomment rulemaking (inth<'S.lr'rlc m a nnerinwhich CMSis so licitfogcomrncr1bonincludinganopioidsas frequentlya buS<:'d). 1.:itherthan be su bje<:t to the informal com,nent processoftheCall l etter, so that a follpublic tC\lic.'\vof the clink.al considcrJtioosl)("yondOEAs chedulingcan beconsidered. 1n theottemative, if CMSdoesnot choose toch.inge its proposed rule, weaskCMS inits prc.'.lmbte to theFinal Rule to d J rifythJ t OEA:schedulingalonewill notpresumptivelyclassifyil rrK-diG'.ltio n as *a* "frequently Jbuscd dru' g· ond th.:it theAgencywiUe xercisec:.rnti on in la:bd liog m<-.dications(other thanopioids) as

Mfrcquentlya bused," inorder to minimizeth,e iskorstigmutizingmedically nec:essa ry

medicationsand reducing ae<.ess forpa:t icn ts inoecd.

1. Medis:ate Advantase Plansa nd OiSf'.a" $Ql"didizatioo

The AeencyhJs J ISO p roposed to ptOVidc Medicare Advantage (MA) Plansn wflexibilitylo offer cosH haringreductions and ltugetcd :.upplementill benefitsfor he. lth u re sefVices tha t .i re medic.ally related to specificdiseaseco nditions. Sunovionagreesthat, p ovidingMA Pl .ins the

>.bility to s p« iali,c in particulard isease statescould helpwithOV('ratlhcJ lth m.inagementof

chronka ltyill lx-nefic.iaries, andmayhave the potential to improvem«J icationmanagementand

<omptiancc.:i,s well. Whilewe appreciate the role of"sped -'Ineeds pfonsH(or S NPs) t o assistwith thesegoals, MAPlansshould be empoweredtospeciailz<'inmore focused waystoc:over p,artk u lar dise as e states. In that regard,wei pprcciatc-lh<'Agency ,efo, encing the possibilitvofspc ciftc MA p rogramsforchronic:o bstructvie potmooi,y d iS('JSC-{COPO). a con dition*tor* which p-,tie-nts

, emainin needofspeciJ lized J nd co, o dinated *c rc*111.:anugement.

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lo g(.'flctal, weurgeCMS to req uirethatanyspecialiie-d Pfanoffcfings structured to meet

(:')(is t ingandcurrent cons.ensu s bas.ed trea tment gvid<'lin<'$.. Fo r example, ferCOPO,CMS s hou ld req uireMAplansoffering,s ped ali7ed COPO progr.lm.s to ( Orl'Sult the 2017Global Initiative to,

Chro nic Ob str uct ive l ung Disease("GOLD'"'}repol't 1whi<:h offo1sconsensus recom mendations on the effect ive m a nageme-nt ofCOPD,<'lllphasi.dng the importanceof individualized treatment *to,* patie nt.. In addition,CMS s ho u ld consider requiringsuch COPOPla nstooonsider the N;:itio n ol

ActionPIM fo,COPOr«entlypublishedbytheNational lnsrif1.Jtes of tl CJlth {NIH). wtiich includes

recommendationstoincreilsecoordinct:ionacrossthe continuumof*CMC.* Wecom mend the

Age ncy rorrLSiniliative in permitting more spec.ia lized (:a re t hroughth<'MApfogram, provided that th<-a gc. nc:yco ntinues*to* adhere to polid e.c.;to d iS<:o, u age diw imin.ilion in its implementation.

1. Reouirin-ePCM:;to Pa:;I:b; rougbRebates.,D iscountsandorhP.r O IR *Fff* toBcorfiicwries

at thePoni tofSale

Sunovion apptec:i.u es t he Age,lcy•st('QuC$l ro, informationon the varietyof propos.11$t o 3ddtess how PS Ms a re ha ndlin,g m.-, nufoCb.,1rt r'r"cb a tes . and endo rses theconcept thata porti01lof manufactu,re r bate.s should be,:,.:iss c'.d t hroughto the beneficia ryat thP.po int·of-sa le ina

mannt'!-1' t hat ptotectslhc confidentialityof the adualrebateagreemt>nt a mount. r.ot*for* too long,

P8M$havebetotct.uining, rather than passing through,rebate doll.us, \vhi,ch pr<'Vcnts benefic ia ry

.:icc<:S' Sto towerd ru,gcostsandwhichincreases thegovernment'sshar<-o fcostsin the Part D program. AlthoughSunovionwill not provide s pe<;ifi,c,commcnls o n the different proposals udvaoced by CMS, Sunovion doP.send o rse and incorporate byreference thecommentsofits tradP. assoc ia t io n, PhRMA,on the issue,and urges (he-Age n,cyto propo u'Spccificruleassoon as possible in response to the infoon ation the Ag ('OCy <oll« ts in thisrulemakingproceeding.

We thunkyou forconsid&ra tio n of these comments, and wel,come aoyquestions,0 followtJP that

you mayhave. Pleasefeel*tree*to contact meat (866) 6-8818 ore ri,c. if we canprovide any additionalinform1, tio n.

SinC('(Cly,



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