Arbitration pursuant to Section 134 (3) SGB V

In the arbitration proceedings, docket number 1 D 24-20, the arbitration panel adopted the following version of the master agreement pursuant to Section 134 (4) and (5) of Social Code Book (*Sozialgesetzbuch -SGB*) V ("SGB V") in its ruling dated 16 April 2021:

The arbitration panel is still weighing the question whether and how to incorporate provisions on maximum and threshold amounts into the master agreement. The arbitration proceedings are dormant at this time because the contractual parties are still engaged in talks in this matter. Once negotiations have concluded, the master agreement may have to be amended by mutual agreement or a ruling to that effect by the impartial members of the arbitration panel.

Master agreement pursuant to Section 134 (4) and (5) SGB V

between

National Association of Statutory Health Insurance Funds,
Reinhardtstraße 28, 10117 Berlin, Germany,

and

Bitkom – Bundesverband Informationswirtschaft,
Telekommunikation und neue Medien e. V.,
Albrechtstraße 10, 10117 Berlin,

Bundesverband der Arzneimittel-Hersteller e. V. (BAH),
Ubierstraße 71 – 73, 53173 Bonn,

Bundesverband Internetmedizin (BiM) e. V.,
Große Elbstraße 135, 22767 Hamburg,

Bundesverband der Pharmazeutischen Industrie e. V. (BPI),
Friedrichstraße 148, 10117 Berlin,

Bundesverband Digitale Wirtschaft e. V. (BVDW),
Schumannstraße 2, 10117 Berlin,

Bundesverband Gesundheits-IT (bvitg e. V.),
Friedrichstraße 200, 10117 Berlin,

BVMed – Bundesverband Medizintechnologie e. V.,
Reinhardtstraße 29b, 10117 Berlin,

Digital Health Germany e. V.,
Sophienstraße 1, 51149 Köln,

EUROCOM e. V. – Herstellervereinigung für
Kompressionstherapie und orthopädische Hilfsmittel,
Reinhardtstraße 15, 10117 Berlin,

SPECTARIS – Deutscher Industrieverband für Optik,
Photonik, Analysen- und Medizintechnik e. V.,
Werderscher Markt 15, 10117 Berlin,

Spitzenverband
Digitale Gesundheitsversorgung e. V. (SVDGV),
c/o Ada Health, Karl-Liebknecht-Straße 1, 10178 Berlin,

VDGH – Verband der Diagnostica-Industrie e. V.,
Neustädtische Kirchstraße 8, 10117 Berlin,

Verband Forschender Arzneimittelhersteller e. V. (vfa),
Hausvogteiplatz 13, 10117 Berlin

– hereinafter "Associations of Manufacturers of Digital Health Applications" –

– National Association of Statutory Health Insurance Funds and Associations of Manufacturers of Digital Health Applications hereinafter collectively "Contractual Parties" –

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Preamble

[1]Pursuant to Section 134 (4) SGB V, the National Association of Statutory Health Insurance Funds and the relevant umbrella organizations formed to represent the economic interests of the manufacturers of digital health applications at the federal level enter into the following master agreement on standards governing agreements on remuneration sums pursuant to Section 134 (1) SGB V as well as for establishing and determining actual prices pursuant to Section 134 (5) SGB V.

[2]The objective consists of supporting and facilitating the agreements on remuneration sums for the digital health applications between individual manufacturers and the National Association of Statutory Health Insurance Funds. [3]The master agreement sets forth the bases for negotiations between manufacturers of digital health applications (hereinafter "Manufacturer(s)") and the National Association of Statutory Health Insurance Funds (Manufacturers and National Association of Statutory Health Insurance Funds collectively hereinafter "Negotiating Partners") regarding the remuneration sums to be set for digital health applications in a binding fashion.

Part 1
Determining actual prices pursuant to Section 134 (5) sentence 1 SGB V

§ 1 Establishing and determining actual prices

(1) [1]Actual prices within the meaning of Section 134 (5) sentence 1 SGB V are established for each digital health application in reference to the respective unique directory number(s) pursuant to Section 20 (1) sentence 2 of the Digital Health Applications Ordinance (*Digitale Gesundheits-Anwendungen-Verordnung - DiGAV*).

(2) [1]The manufacturer may set the sales price and create a pricing model for its digital health application as it sees fit. [2]Specifically, the manufacturer is free – e.g., depending on possible length of use – to set different sales prices in consideration of what it deems to be the required minimum period of use for the digital health application pursuant to Section 2 (1) sentence 2 number 19 of the Digital Health Applications Ordinance.

(3) [1]The manufacturer notifies the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM*) pursuant to Section 2 (1) number 24 of the Digital Health Applications Ordinance of the actual price within the meaning of Section 134 (5) sentence 1 SGB V as part of the process for inclusion in the directory kept by Federal Institute for Drugs and Medical Devices pursuant to Section 139e (1) SGB V (directory of digital health applications). [2]Such actual price equals the sales price set by the manufacturer pursuant to paragraphs 1 and 2, which refers to a use to which a unique directory number

has been assigned (Section § 20 (1) sentence 2 of the Digital Health Applications Ordinance), as adjusted by the following components:

a) discounts that the manufacturer has granted – in Germany and on average – in reference to the use of the relevant digital health application within the meaning of paragraph 1 within a period of three months prior to filing the application pursuant to Section 139e (2) SGB V;

b) costs attributable to optional services, functions or areas of application (e.g., links to social networks, additional tie-in options for devices and apps as well as scheduling functions or own modules certified as independent medical devices), which are not inseparable components of the digital health application to be entered into the directory of digital health applications within the meaning of paragraph 1 and, as such, are not reimbursable;

c) costs attributable to services such as consulting or coaching, or to services provided by a private healthcare provider, which are not inseparable components of the digital health application to be entered into the directory of digital health applications within the meaning of paragraph 1 and, as such, are not reimbursable; and

d) costs for hardware that is not an inseparable component of the digital health application to be entered into the directory of digital health applications within the meaning of paragraph 1 and, as such, is not reimbursable.

[3]Insofar as the digital health application is included in the directory of digital health applications to a lesser extent than what the manufacturer sought, the manufacturer is obligated to adjust the actual price in accordance with sentence 2 and communicate it to the Federal Institute for Drugs and Medical Devices.

§ 2 Period for which actual prices remain in effect; price adjustment

(1) [1]The actual price determined by the manufacturer in accordance with § 1 para. 3 is in effect from the day on which the digital health application is entered into the directory of digital health applications until such time as

a) the manufacturer in question enters into a binding remuneration agreement with the National Association of Statutory Health Insurance Funds pursuant to Section 134 para. 1 SGB V; or

b) the arbitration panel pursuant to Section 134 (3) SGB V establishes the remuneration sum pursuant to Section 134 (2) SGB V,

but in any case at least until one year has passed since the digital health application was entered into the directory of digital health applications.

(2) [1]During the period of applicability mentioned in paragraph 1, the manufacturer may change and reset the sales price within the meaning of § 1 paras. 1 and 2 for its digital health application within the meaning of § 1 para. 1 only once over a 12-month period. [2]In such a case, the manufacturer must adjust the actual price in due consideration of the adjustments made pursuant to § 1 para. 3 sentence 2 and immediately communicate it to the Federal Institute for Drugs and Medical Devices. [3]Starting from the time the adjusted actual price is entered into the directory of digital health applications, the provision pursuant to paragraph 1 applies *mutatis mutandis* to such adjusted actual price.

§ 3 Claims for compensation

(1) [1]If the remuneration sum negotiated pursuant to Section 134 para. 1 SGB V is lower than the manufacturer's actual price, the difference is to be refunded to the health insurance funds for the period between the end of the first year after the digital health application's listing in the directory of digital health applications and the effective date of the remuneration agreement pursuant to Section 134 para. 1 SGB V. [2]Any invoice affected by the claims for compensation is to be corrected pursuant to para. 3 sentence 9.

(2) [1]If the remuneration sum negotiated pursuant to Section 134 para. 1 SGB V is higher than the manufacturer's actual price, the difference is to be disbursed to the manufacturer by way of subsequent reimbursement for the period between the end of the first year after the digital health application's listing in the directory of digital health applications and the effective date of the remuneration agreement pursuant to Section 134 para. 1 SGB V. [2]Any invoice affected by the claims for compensation is to be corrected pursuant to para. 3 sentence 9.

(3) [1]When health insurance funds and the manufacturers assert claims for compensation pursuant to paragraphs 1 and 2, respectively, the claimant is obligated to transmit the data listed in **Annex 1** to the respondent. [2]Claims for compensation that do not conform to the mode of data transmission set forth in Annex 1 and the formal requirements contained therein may be rejected. [3]Claims for compensation lapse unless they are asserted against the respondent, and the data pursuant to Annex 1 is provided, within a cut-off period of two years. [4]The cut-off period commences upon the publication in the directory of digital health applications of the remuneration sum agreed, or established by the arbitration panel. [5]Claims for compensation are due and payable 30 calendar days from the respondent's receipt of the data mentioned in sentence 1. [6]Default occurs without the need for the claimant to issue a separate reminder notice. [7]The respondent owes default interest on claims for compensation due at the rate pursuant to Section 288 (2) of the Civil Code. [8]In the event that the respondent objects to the calculation of claim amount transmitted to it by submitting specific questions to the claimant, the term of payment for the claim for compensation is extended to 60

calendar days. [9]For each invoice affected by the claims for compensation, the manufacturer will transmit to the health insurance fund a corrected invoice in accordance with the guideline of the National Association of Statutory Health Insurance Funds pursuant to Section 302 (2) SGB V for form and content of the accounting procedure for digital health applications pursuant to Section § 33a SGB V (DiGA accounting guideline) (see https://kkv.gkv-diga.de/).

(3a) [1]In the event that the specific questions communicated pursuant to para. 3 sentence 8 cannot be settled within the allotted period of 60 calendar days, the claimant may task an auditor bound by a duty of confidentiality to review the matter. [2]The respondent supports such review by granting access to the documents needed for reviewing the legitimacy of the claims for compensation. [3]If the auditor so tasked finds the calculation of the claim for compensation to be inaccurate, the claimant bears the costs of the review. [4]If the claim for compensation was calculated correctly according to the review, the respondent bears the costs of the review.

(4) [1]The data listed in Annex 1 for the assertion of claims for compensation are to be transmitted in accordance with the DiGA accounting guideline. [2]Until the process for the assertion of claims for compensation has been fully mapped in the DiGA accounting guideline, the following transitional process applies:

[3]Data pursuant to Annex 1 is transmitted by email or mail. [4]Data transmitted to the manufacturer must be sent to the business or email address pursuant to § 5 para. 6. [5]The transmission path for communications to health insurance funds follows the mapping file "Directory of Health Insurance Funds" pursuant to the technical annex of the DiGA accounting guideline (see https://kkv.gkv-diga.de/). Email transmissions are subject to the requirements of Annex 7 of the Joint Technical Principles (*Gemeinsame Grundsätze Technik - GGT*).

Part 2
Negotiation procedure for National Association of Statutory Health Insurance Funds and individual manufacturers to set remuneration sums pursuant to Section 134 (1) sentence 1 SGB V

§ 4 Negotiations, scheduled negotiations, place of negotiation

(1) [1]The Negotiating Partners for agreements on remuneration sum pursuant to Section 134 (1) sentence 1 SGB V are the manufacturers and the National Association of Statutory Health Insurance Funds. [2]The manufacturer is entitled to have a third party represent it in the negotiations. [3]In such a case, the manufacturer must ensure that, following receipt of the proposed schedule pursuant to paragraph 2, the third party submits to the National Association of Statutory Health Insurance Funds a written power of attorney either in the original or by facsimile. [4]For this purpose, the manufacturer may use the sample power of attorney in **Annex 2**. [5]Upon submission, the third party will be treated just like the

manufacturer in the negotiations; any and all provisions of this master agreement that pertain to the manufacturer apply *mutatis mutandis* to the third party.

(2) [1]At least one month prior to the commencement of the negotiation period, the National Association of Statutory Health Insurance Funds presents the manufacturer with three suggestions each for the first and any subsequent scheduled negotiation. [2]The dates suggested must ensure that all scheduled negotiations are separated by a reasonable period of time. [3]Suggested dates are transmitted by mail to the manufacturer's business address (registered offices). [4]On the basis of these suggested dates, the Negotiating Partners will schedule rounds of negotiation within ten business days by mutual agreement and finalize a correspondence list of the competent contacts (including an email address for each Negotiating Partner).

(3) [1]The scheduled negotiations so agreed must allow negotiations to conclude within six months[1] (negotiation period).

(4) The following applies with respect to the timing of the start of the negotiation period:

a) [1]For digital health applications that have been finally listed in the directory of digital health applications, the negotiation period commences at such time as the digital health application has been listed with the directory of digital health applications for six months[2]. [2]The manufacturer and the National Association of Statutory Health Insurance Funds may mutually agree to have the negotiation period commence sooner.

b) [1]For digital health applications that have been listed in the directory of digital health applications for trial purposes, the negotiation period commences at such time as the manufacturer receives notice from the Federal Ministry for Drugs and Medical Devices of final listing in the directory of digital health applications pursuant to Section 139e

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1 [1]The cabinet draft for the Digital Healthcare and Nursing Modernization Act (*Digitale Versorgung und Pflege-Modernisierungs-Gesetz - DVPMG*) under item 14 b aa) provides for a change to Section 134 (2) sentence 1 SGB V, which is to shorten the twelve-month period specified therein to nine months. [2]The Contractual Parties have agreed that, to the extent that the Digital Healthcare and Nursing Modernization Act is rendered into force with the change to Section 134 (2) sentence 1 SGB V, the provision of § 4 (3) of this master agreement is amended to the effect that the time allotment of "six months" is deleted and replaced with "five months," although this does not apply to the digital health applications finally listed in the directory of digital health applications by the end of March of 2021 (exemption). [3]For the latter digital health applications, the time allotment of "six months" will remain in effect.

2 [1]The cabinet draft for the Digital Healthcare and Nursing Modernization Act (*Digitale Versorgung und Pflege-Modernisierungs-Gesetz - DVPMG*) under item 14 b aa) provides for a change to Section 134 (2) sentence 1 SGB V, which is to shorten the twelve-month period specified therein to nine months. [2]The Contractual Parties have agreed that, to the extent that the Digital Healthcare and Nursing Modernization Act is rendered into force with the change to Section 134 (2) sentence 1 SGB V, the provision of § 4 (4) a) of this master agreement is amended to the effect that the time allotment of "six months" is deleted and replaced with "four months," although this does not apply to the digital health applications finally listed in the directory of digital health applications by the end of March of 2021 (exemption). [3]For the latter digital health applications, the time allotment of "six months" will remain in effect.

(4) sentence 6 SGB V. [2]If such notice marks the final listing of the digital health application in the directory of digital health applications, the manufacturer enters into negotiations about remuneration sums pursuant to Section 134 (1) sentence 1 SGB V. [3]In the event that final listing in the directory of digital health applications is denied for the digital health application, and the digital health application is removed from the directory after having been provisionally listed for trial purposes, the manufacturer enters into negotiations about claims for compensation pursuant to § 3 paras. 1 or 2 with respect to the period starting with the 13th months after the digital health application was listed in the directory of digital health applications.

(5) [1]As a rule, negotiations encompass three scheduled negotiations per digital health application. [2]In justified cases, the Negotiating Partners may add a scheduled negotiation by mutual agreement.

(6) [1]The first scheduled negotiation is to take place within four weeks from the start of the negotiation period. [2]After the first scheduled negotiation, a longer period of time is to be allotted for preparations for the next scheduled negotiation. [3]The following scheduled negotiations are each to be separated by an adequate period of time for preparation and follow-up. [4]As a rule, the last negotiation is to be scheduled to predate the end of the negotiation period by at least four weeks.

(7) [1]Negotiations take place in Berlin. [2]The Negotiating Partners are free to determine one or several places of negotiation. [3]For this purpose, they will coordinate with one another for scheduling purposes. [4]Up to two scheduled negotiations may be conducted by online video call; under exceptional circumstances due to the pandemic, all scheduled negotiations may be conducted by online video call. [5]The Negotiating Partners will coordinate the details of such online video call, including the exact Web tool to be used, and determine who will communicate the access and dial-in data to the other Contractual Partner at least seven business days ahead of the scheduled negotiation using the email address provided in the correspondence list. [6]The Web tool must be capable of fulfilling the requirement as to confidentiality pursuant to Section 134 (1) sentence 5 SGB V; the Web tools listed in **Annex 3** meet the requirements of this legal provision. [7]In the event that the Negotiating Partners are unable to reach an agreement as to specific places of negotiation or a Web tool with which to conduct individual rounds of negotiation, negotiations will take place at such Berlin locations and rely on such Web tools as the National Association of Statutory Health Insurance Funds and the manufacturer may each determine, alternating between the two choices; sentences 4 and, with respect to the duty to provide information, 5 apply *mutatis mutandis*.

(8) [1]If either Negotiating Partner fails to appear for a scheduled negotiation or the scheduled negotiation is not completed, the other Negotiating Partner may demand that such negotiation be rescheduled. [2]In such a case, the scheduled negotiation in question must take

place within the negotiation period; it is convened by the Negotiating Partner that may call for its rescheduling.

§ 5 Individual scheduled negotiations

(1) [1]A group of five individuals, at most, may participate in the scheduled negotiations for each Negotiating Partner. [2]In justified cases, the number of participants may be raised to seven individuals per Negotiating Partner with the approval of the other Negotiating Partner. [3]If a Negotiating Partner wishes to have more than five individuals participate in a scheduled negotiation, and no agreement can be reached about expanding the group of participants, the number permitted pursuant to sentence 1 remains in effect. [4]In the event that such Negotiating Partner refuses to abide by this rule, it is deemed not to have appeared for the scheduled negotiation. [5]The other Negotiating Partner may then demand that the negotiation be rescheduled. [6]In such case, the scheduled negotiation in question must take place within the negotiation period; it is convened by the Negotiating Partner that may call for its rescheduling.

(2) [1]The language of the proceedings is German. [2]On both sides, an interpreter bound by a duty of confidentiality pursuant to § 12 para. 9 may participate in the scheduled negotiations. [3]He/she does not count toward the "group of five individuals" pursuant to paragraph 1.

(3) [1]At the onset of the first scheduled negotiation, the Negotiating Partners inform one another who leads negotiations on their side ("lead negotiator"). [2]The lead negotiator may be replaced. [3]Such replacement must be communicated to the other Negotiating Partner prior to the commencement of the next scheduled negotiation.

(4) [1]A scheduled negotiation may take up to three hours of time. [2]In justified cases, the Negotiating Partners may extend the duration by mutual agreement.

(5) [1]Prior to each scheduled negotiation, the Negotiating Partners jointly appoint a secretary bound by a duty of confidentiality pursuant to § 12 para. 9. [2]He/she does not count toward the "group of five individuals" pursuant to paragraph 1. [3]A report noting the results is to be prepared during the proceedings for each scheduled negotiation. [4]The report's wording is jointly determined at the end of the meeting, and the report is signed by the lead negotiators in duplicate. [5]If the proceedings are conducted by online video call, the report is displayed using the screen-sharing function and finalized together. [6]The secretary transmits the finalized report by email to the lead negotiators, each of whom will then send a signed advance copy thereof by email, along with the original by mail, to the other Negotiating Partner. [7]Time spent finalizing and signing the report does not count toward the negotiation period.

(6) [1]On the occasion of the first scheduled negotiation, the manufacturer must provide the National Association of Statutory Health Insurance Funds with a postal business address as well as an email address, via which claims for compensation pursuant to § 3 para. 1 or 2 may be asserted for a transitional period until the process for the assertion of claims for compensation has been fully mapped in the DiGA accounting guideline pursuant to § 3 para. 4. [2]The National Association of Statutory Health Insurance Funds is obligated to share these addresses with the health insurance funds. [3]The manufacturer is obligated to notify the National Association of Statutory Health Insurance Funds of any subsequent address changes. [4]Sentence 2 applies *mutatis mutandis* to any changed address.

§ 6 Documentation needed for setting remuneration sum pursuant to Section 134 (1) sentence 1 SGB V

(1) [1]The manufacturer transmits to the National Association of Statutory Health Insurance Funds the evidence pursuant to Section 139e (2) SGB V as well as the results of any trial pursuant to Section 139e (4) SGB V. [2]These are

a) the CE conformity marking or the CE marking of the digital health application pursuant to applicable provisions under medical device law, including the results of additional reviews by the Federal Ministry for Drugs and Medical Devices pursuant to Section 3 (2) of the Digital Health Applications Ordinance;

b) the declaration pursuant to Section 5 (11) in conjunction with Annex 2 of the Digital Health Applications Ordinance, including details on and reasons for any instance of deviation from the requirements of Annex 2 (Section 5 (10) sentence 3 of the Digital Health Applications Ordinance), along with – where available – corresponding certificates pursuant to Section 7 of the Digital Health Applications Ordinance;

c) the declaration pursuant to Section 4 (6) sentence 2 in conjunction with Annex 1 of the Digital Health Applications Ordinance, including details on and reasons for any instances of deviation from the requirements of Annex 1 (Section 4 (6) sentence 4 of the Digital Health Applications Ordinance), along with – where available – corresponding certificates pursuant to Section 7 of the Digital Health Applications Ordinance;

d) the study reports pursuant to Sections 10 (7) and 11 (2) in conjunction with Sections 10 (7) and 12 (2) in conjunction with Section 10 (7) of the Digital Health Applications Ordinance as well as – where available – publications on the study reports in independent peer-reviewed journals; and

e) insofar as the digital health application was listed in the directory of digital health applications for trial purposes, the evidence pursuant to Section 139e (4) sentence 3 SGB V listed in the notice pursuant to Section 17 (1) sentence 2 of the Digital Health Applications Ordinance.

(2) [1]The manufacturer must once furnish the National Association of Statutory Health Insurance Funds with information on the amount of the actual remuneration sum pursuant to Section 134 para. 1 sentence 4 number 2 SGB V when the digital health application is provided to self-payers and in other European countries, to the extent that the digital health application is available there. [2]For this purpose, the remuneration sum is to be stated – in each instance, as updated (four weeks prior to such notification). [3]For all countries with respect to which

the manufacturer is to transmit the actual remuneration sums, it supplies the price it has determined where the digital health application is provided to self-payers – exclusive of VAT and adjusted for any discounts that it grants to self-payers, on average, in reference to the use of the digital health application within a period of three months prior to the current status. [4]In addition, it transmits the price paid in each instance by payers in the other European countries, as adjusted for any discounts that the manufacturer grants to payers in reference to the use of the digital health application within a period of three months prior to the current status, along with any mandatory discount.
[5]If the manufacturer of a digital health application is unable, for legal or factual reasons, to collect the information needed to determine the actual remuneration sums and communicate the same, it is to supply such information as may best allow the actual remuneration sums to be estimated. [6]The manufacturer of a digital health application and the National Association of Statutory Health Insurance Funds will then jointly determine any information to be provided in the alternative.

(3) [1]The manufacturer transmits to the National Association of Statutory Health Insurance Funds the full notice from the Federal Ministry for Drugs and Medical Devices on the listing of the digital health application in the directory of digital health applications (Section 139e (3) and (4) SGB V). [2]The contents and determinations found in such notice are binding upon the Negotiating Partners.

(4) [1]The manufacturer transmits to the National Association of Statutory Health Insurance Funds the number of activation / prescription codes redeemed for the digital health application during the period from the listing of the digital health application in the directory of digital health applications until five business days before transmission (item 5 of the technical annex of the DiGA accounting guideline).

(5) [1]The Negotiating Partners are entitled to transmit other documents relevant to pricing to the other Negotiating Partner, including but not limited to

a) analyses of use-related data generated while the digital health application is listed in the directory of digital health applications; or

b) studies on positive care effects of the digital health application in question, which are completed after the digital health application is listed in the directory of digital health applications; or

c) analyses of service or accounting data for the digital health application in question, which are collected after the digital health application is listed in the directory of digital health applications and before negotiations commenced.

§ 7 Deadlines and mode of transmission for documentation

[1]The Negotiating Partners must transmit any and all documents within the meaning of § 6 to the other Negotiating Partner at least ten business days prior to the first scheduled negotiation – by electronic means, in encrypted form and using the correspondence address on record. [2]Insofar as a Negotiating Partner declares at the time pursuant to sentence 1 that it will introduce documents pursuant to § 6 para. 5 to the negotiations at a later point in time, and it specifies the records in question, such documents may be transmitted during the scheduled negotiation as well, but in any case at least ten business days ahead of the second scheduled negotiation. [3]Documents pursuant to § 6 para. 5, which the other Negotiating Partner receives less than ten business days prior to the second scheduled negotiation, are excluded from the negotiations and are not to be taken into account unless the Negotiating Partners mutually agree otherwise.

§ 8 Bases of agreement of remuneration sum pursuant to Section 134 (1) sentence 1 SGB V

(1) [1]For purposes of determining and establishing a remuneration sum for the digital health application pursuant to Section 134 para. 1 SGB V, the Negotiating Partners may consider any and all documents of significance to pricing. [2]Such documents include but are not limited to

a) such records as the manufacturer may transmit to the National Association of Statutory Health Insurance Funds pursuant to § 6 paras. 1-4,

b) information published in the directory of digital health applications; and

c) other documents relevant to pricing pursuant to § 6 para. 5.

(2) [1]The remuneration sum pursuant to Section 134 (1) sentence 1 SGB V is agreed on the basis of an unfettered assessment of all information relevant to pricing that may flow from the documents pursuant to paragraph 1, as well as due consideration given to such statutory requirements as may apply in each individual case. [2]For this purpose, the following pricing criteria, in particular, are to be taken into account:

a) the extent of the digital health application's proven medical benefit pursuant to Section 8 (2) of the Digital Health Applications Ordinance, along with patient-relevant effect(s) with regard to improving patient health, shortening the length of an illness, prolonging survival time or improving quality of life; and/or

b) the extent of proven patient-relevant improvement(s) of structure and processes in patient care pursuant to Section 8 (3) of the Digital Health Applications Ordinance that is/are geared toward supporting the health behavior of patients or integrating the processes between patients and healthcare providers and specifically

encompass(es) the areas listed in Section 8 (3) of the Digital Health Applications Ordinance.

[3]Upon the permanent listing of the digital health application in the directory of digital health applications, a given medical benefit and/or a given patient-relevant improvement of structure and processes in patient care is deemed to have been substantiated.

(3) [1]The remuneration sum pursuant to Section 134 (1) sentence 1 SGB V is to be set in EUR.

§ 9 General stipulations on remuneration sums pursuant to Section 134 (1) sentence 1 SGB V

[1]Agreements on remuneration sums pursuant to Section 134 (1) sentence 1 SGB V may contain performance-based price components. [2]Specifically, an agreement may tie remuneration sums to specific achievements – e.g., positive care effects within the meaning of Section 8 (1) of the Digital Health Applications Ordinance – that are to be defined by the Negotiating Partners and must be demonstrated.

§ 10 Halting and suspending negotiation procedure

(1) [1]The manufacturer may halt negotiations to establish a remuneration sum pursuant to Section 134 (1) sentence 1 SGB V, be it in whole or in part, or decline to appear altogether, provided that it notifies the National Association of Statutory Health Insurance Funds no later than 14 days from the second scheduled negotiation that it will not continue the negotiation procedure, and demonstrates that it has filed a request to remove the digital health application matching the respective unique directory number(s) pursuant to Section 20 (1) sentence 2 of the Digital Health Applications Ordinance from the directory of digital health applications.

(2) [1]The manufacturer may suspend negotiations to establish a remuneration sum pursuant to Section 134 (1) sentence 1 SGB V, be it in whole or in part, and it need not eventually resume such procedure, provided that it informs the National Association of Statutory Health Insurance Funds, along with notice and proof pursuant to paragraph 1, of the removal of the digital health application matching the respective unique directory number(s) pursuant to Section 20 (1) sentence 2 of the Digital Health Applications Ordinance from the directory of digital health applications. [2]What matters for this purpose is the removal from the webpages of the directory of digital health applications. [3]No remuneration sum is agreed, or established by the arbitration panel, for a digital health application if negotiations are suspended in this manner.

(3) [1]The provisions pursuant to paragraphs 1 and 2 apply *mutatis mutandis* to renegotiations within the meaning of § 11.

(4) [1]In deviation from paragraphs 1 and 2, a compensation amount pursuant to § 3 para. 1 or § 3 (2) is to be agreed in accordance with § 8 for a digital health application listed in the directory of digital health applications for trial purposes – for the period starting with the 13th month from its initial listing in the directory of digital health applications. [2]The right to suspend such negotiation pursuant to paragraph 2 is excluded.

(5) [1]In the event that the digital health application is again listed with the directory of digital health applications in Germany, the actual price pursuant to Section 134 (5) sentence 1 SGB V that is newly determined by the manufacturer remains in effect for a period of twelve months from the date of listing in the directory of digital health applications. [2]In this context, the length of the previous listing of the digital health application in the directory of digital health applications, from the date of entry until removal pursuant to para. 2 sentence 1, is to be applied to the twelve-month period pursuant to sentence 1. [3]The remuneration sum in effect starting with the 13th month is to be established on the basis of the notice from the Federal Ministry for Drugs and Medical Devices pursuant to Section 139e (3) and (4) SGB V that is valid at the time of relisting, which is in effect as of the date on which the digital health application was re-entered into the directory of digital health applications.

§ 11 Renegotiation occasioned by material changes

(1) [1]Upon material changes within the meaning of § 18 (1) number 2 c) of the Digital Health Applications Ordinance that materially bear on pricing, the manufacturer and the National Association of Statutory Health Insurance Funds are entitled to enter into negotiations about a possible adjustment of the agreed remuneration sum pursuant to Section 134 (1) sentence 1 SGB V. [2]Such right may be exercised no sooner than six months from the time the remuneration sum was agreed, or established by the arbitration panel.

(2) [1]The negotiation procedure in cases of renegotiations pursuant to paragraph 1 is shortened to allow the remuneration sum to be adjusted quickly. [2]In deviation from § 4 para. 3, the negotiation period equals twelve weeks. [3]In deviation from § 4 para. 5 sentence 1, renegotiations take the form of two scheduled negotiations per digital health application as a rule. [4]In deviation from § 4 para. 4, the negotiation period commences at such time as either Negotiating Partner receives a request in written or text form from the other Negotiating Partner to enter into renegotiations. [5]In deviation from § 4 para. 2 sentence 1, the National Association of Statutory Health Insurance Funds presents the manufacturer with two proposed dates each for the first and the subsequent scheduled negotiation no later than ten business days from the receipt of the request pursuant to sentence 3, such negotiations to be scheduled by the Negotiating Partners by mutual agreement within five business days. [6]The provisions of § 4 paras. 6 sentence 3, 7 and 8, as well as § 5 apply *mutatis mutandis*.

(3) [1]A remuneration sum renegotiated pursuant to paragraph 1 or newly established by the arbitration panel replaces the previous sum upon the publication of the new sum in the directory of digital health applications pursuant to Section 139e SGB V. [2]There is no need to terminate the agreement regarding the remuneration sum in effect until such time.

§ 12 Duties of confidentiality as part of negotiations between manufacturers and National Association of Statutory Health Insurance Funds

(1) [1]The Negotiating Partners undertake to hold in confidence

a) the contents of any remuneration negotiation; and

b) any information or document introduced to the remuneration negotiations in physical or non-physical form that is not accessible to the public and is to be deemed confidential on the basis of its nature

(collectively "confidential information"), and to adopt such measure as may be required to prevent third-party access to and/or use of confidential information. [2]Confidential information especially includes the trade and business secrets gleaned as part of the negotiations, such as non-public information on the digital health application and how it works, its technical processes, formulas, software codes, product designs and costs, non-public information on inventions as well as non-public financial information of the Negotiating Partner, along with all non-public and protected information of the other Negotiating Partner and its affiliated enterprises.

(2) [1]The receiving Negotiating Partner will use confidential information of the other Negotiating Partner only for purposes of negotiating the remuneration sum for the digital health application in question. [2]This further encompasses the use of confidential information as part of proceedings before the arbitration panel pursuant to Section 134 (2) SGB V as well as possible appeals against arbitral awards.

(3) [1]The duty of confidentiality does not extend to the remuneration sum agreed, or established by the arbitration panel. [2]The National Association of Statutory Health Insurance Funds is entitled to inform the health insurance funds about the outcome of remuneration negotiations and, if applicable, the arbitration proceedings that follow. [3]In particular, this concerns the amount of the remuneration sum agreed or established, the date on which the remuneration sum went into effect, the term of the agreement on the remuneration sum, including any adjustment to the remuneration sum during such term, any compensation amount, including the period for which compensation is offered, any provision concerning performance-based elements of remuneration as well as such other elements of the agreement as may be of relevance to the settling of accounts between health insurance funds and the manufacturer. [4]Exempted from the duty of confidentiality is

also such information as may have to be shared by the receiving Negotiating Partner under mandatory legal provisions and/or court or other official rulings.

(4) [1]A Negotiating Partner may share confidential information with its staff and consultants as needed, provided that such individuals agreed in writing to be bound by a duty of confidentiality equaling or exceeding the scope hereof. [2]The Negotiating Partners' staff who, with respect to official business, are already bound by a duty of confidentiality under their respective collective or employment agreements need not accept such duties of confidentiality in writing. [3]Moreover, each Negotiating Partner will limit disclosure of confidential information to such staff and consultants as may be directly involved in processing the remuneration negotiations.

(5) [1]As a function of the provision of confidential information, the receiving Negotiating Partner comes into no further rights to the confidential information; specifically, it is not entitled to register trademarks for any confidential information received.

(6) [1]In each instance in which this duty of confidentiality is culpably breached, the offending Negotiating Partner will pay to the other Negotiating Partner a contractual penalty to be assessed by the other Negotiating Partner, the adequacy of which may be appealed to a competent court. [2]This shall be without prejudice to any further claims for compensation and/or damages of the Negotiating Partners, including but not limited to claims under the law for the protection of business secrets, competition or copyright law. [3]Such further claims for compensation and/or damages are to be adjusted by any contractual penalty paid.

(7) [1]The Negotiating Partners will notify one another without undue delay of any instance of unauthorized use, disclosure or security breach in connection with the confidential information provided.

(8) [1]The duties of confidentiality pursuant to paragraphs 1-7 apply for a period of seven years after the remuneration agreement pursuant to Section 134 para. 1 SGB V is terminated or ended.

(9) [1]The interpreter(s) involved in negotiations and the secretary/ies must sign a written confidentiality agreement comprising the terms pursuant to paragraphs 1-8 prior to participating in a scheduled negotiation.

(10) [1]The Negotiating Partners are free to enter into individual agreements to supplement the duty of confidentiality under this master agreement.

§ 13 Distribution of costs

(1) [1]The Negotiating Partners bear the costs of scheduled negotiations (e.g., minute-keeping, catering and space rental) in equal parts.

(2) [1]The Negotiating Partners will jointly keep an overview of costs incurred for purposes of mutual cost allocation. [2]Insofar as a Negotiating Partner has incurred expenses in a greater amount, it will bill the other Negotiating Partner for half of the difference following the conclusion of negotiations.

(3) [1]The (gross) amount so billed is to be transferred to the account provided on the invoice within 14 banking days of invoice receipt.

(4) [1]The Negotiating Partners bear their own staff-related expenditures for the participants of negotiations, along with travel expenses (including hours spent traveling).

§ 14 Terminating agreements on remuneration sums

[1]The Negotiating Partners may terminate the agreement on the remuneration sum pursuant to Section 134 (1) sentence 1 SGB V after one year, at the earliest. [2]The notice period equals three months prior to the end of the quarter. [3]Notice of termination must be given in writing. [4]In agreements on the remuneration sum pursuant to Section 134 (1) sentence 1 SGB V, the Negotiating Partners may install provisions that deviate from sentences 1 and 2. [5]The previous agreement continues in full force until a new agreement goes into effect.

Part 3
Billing rules

§ 15 Billing remuneration sums

(1) [1]Billing in the context of digital health applications is subject to the provisions of Section 302 SGB V as well the DiGA accounting guideline.

(2) [1]As part of the procedure pursuant to Section 302 (1) SGB V, the manufacturer, for each instance in which the digital health application in question provides a service, creates an invoice for the responsible health insurance fund subject to the DiGA accounting guideline within a cut-off period of two years from the time the health insurance fund confirms the activation / prescription code. [2]Until the remuneration sum pursuant to Section 134 (1) sentence 1 SGB V has been published in the directory of digital health applications, invoicing is based on the actual price pursuant to § 1. [3]If a maximum amount exists for the digital health application under this master agreement, invoicing is based on the maximum amount in effect at the time the manufacturer provides a service until the remuneration

sum pursuant to Section 134 (1) sentence 1 SGB V has been published in the directory of digital health applications.

(3) [1]An invoice is due and payable pursuant to Section 3 (2) of the DiGA accounting guideline. [2]Default occurs without the need for the manufacturer to issue a separate reminder notice. [3]Health insurance funds owe default interest on claims due at the rate pursuant to Section 288 (2) of the Civil Code.

(4) [1]Health insurance funds assert claims for the correction of invoices vis-à-vis manufacturers, submitting data pursuant to **Annex 4**, within a cut-off period of one year. [2]Claims for the correction of invoices that do not conform to the mode of data transmission set forth in Annex 4 and the formal requirements contained therein may be rejected. [3]The cut-off period commences upon the health insurance fund's receipt of the manufacturer's invoice. [4]The health insurance funds' claims for invoice correction are due and payable 30 calendar days from the manufacturer's receipt of a corresponding notice. [5]Default occurs without the need for a separate reminder notice. [6]The manufacturer owes default interest on claims for invoice correction due at the rate pursuant to Section 288 (2) of the Civil Code. [7]In the event that manufacturers object to the claims for invoice correction transmitted by health insurance funds by submitting specific questions, the term of payment for the claim for invoice correction is extended to 60 calendar days.

(4a) [1]The manufacturers' claims for remuneration with respect to digital health applications finally listed in the directory pursuant to Section 139e SGB V must not be adjusted by such claims as health insurance funds may assert against manufacturers. [2]Sentence 1 does not apply to undisputed or effectively established claims of health insurance funds. [3]In deviation from sentence 1, set-off is further permitted if and to the extent that a given health insurance fund claim refers to periods during which the digital health application was listed with the directory pursuant to Section 139e SGB V for trial purposes. [4]Sentences 1-3 apply *mutatis mutandis* to the manufacturer's set-off of health insurance fund claims. [5]A right of set-off may be installed in the agreement pursuant to Section 134 (1) SGB V; such component of the agreement is not subject to arbitration.

(5) [1]As part of the procedure pursuant to Section 302 (6) SGB V, the settlement procedure may be replaced on 1 January 2022, at the earliest, with the credit procedure pursuant to a)-c) by way of an agreement to that effect between a manufacturer and a health insurance fund on four weeks' advance notice and with effect at the start of the following quarter for activation / prescription codes redeemed from such time, such new arrangement to cover the totality of settlement cases between such manufacturer and health insurance fund, as opposed to individual settlement cases. [2]In the event that the manufacturer wishes to return to the settlement procedure pursuant to paragraphs 1-5, the manufacturer must so notify the appropriate health insurance fund in writing four weeks in advance with effect at the

start of the following quarter for activation / prescription codes redeemed from such time. [3]The credit procedure is completed in accordance with the DiGA accounting guideline.

a) [1]A health insurance fund that uses the credit procedure to settle services received by its insured persons with the manufacturer, creates a credit for each such service provided by the digital health application of such manufacturer in accordance with the DiGA accounting guideline. [2]Until the remuneration sum pursuant to Section 134 (1) sentence 1 SGB V has been published in the directory of digital health applications, the credit is based on the actual price pursuant to § 1. [3]If a maximum amount exists for the digital health application under this master agreement, the credit is based on the maximum amount in effect at the time the manufacturer provides the service until the remuneration sum pursuant to Section 134 (1) sentence 1 SGB V has been published in the directory of digital health applications. [4]The health insurance fund transmits the credit to the manufacturer in accordance with the DiGA accounting guideline within four weeks of the service having been used. [5]Irrespective of such transmission, a credit is due and payable by the manufacturer four weeks from the time the health insurance fund confirms the prescription code. [6]Default occurs without the need for the manufacturer to issue a separate reminder notice. [7]Health insurance funds owe default interest on credits due at the rate pursuant to Section 288 (2) of the Civil Code.

b) [1]Manufacturers assert claims for the correction of credit vis-à-vis health insurance funds, submitting data pursuant to **Annex 5**, in accordance with the DiGA accounting guideline within a cut-off period of one year. [2]The cut-off period commences upon the manufacturer's receipt of the credit statement compiled by the health insurance fund. [3]The manufacturer's claims for credit correction are due and payable 30 calendar days from the health insurance fund's receipt of a corresponding notice. [4]Default occurs without the need for a separate reminder notice. [5]Health insurance funds owe default interest on claims for credit correction due at the rate pursuant to Section 288 (2) of the Civil Code. [6]In the event that health insurance funds object to the claims for credit correction transmitted by a manufacturer by submitting specific questions, the term of payment for the claim for credit correction is extended to 60 calendar days.

(6) [1]Insofar as a pilot project pursuant to Section 67 (3) SGB V calls for deviating procedures for the electronic transmission of prescriptions as well as for the settlement of services pursuant to Section 33a SGB V, such procedures prevail for any participating health insurance funds and manufacturers pursuant to this § 15.

Part 4
Arbitration panel costs, terminating master agreement, final provisions

§ 16 Reimbursement of arbitration panel costs by Associations of Manufacturers of Digital Health Applications vis-à-vis manufacturers

[1]The Associations of Manufacturers of Digital Health Applications are entitled to be reimbursed for any cost incurred pursuant to Section 42 (3) of the Digital Health Applications Ordinance by manufacturers engaged in arbitration proceedings pursuant to Section 134 (2) sentence 1 SGB V.

§ 17 Terminating master agreement

[1]This master agreement may be terminated on six weeks' notice with effect at the end of calendar half-year by the National Association of Statutory Health Insurance Funds on the one hand and by a simple majority of the Associations of Manufacturers of Digital Health Applications that signed this master agreement and existed as legal entities at the time of termination on the other. [2]In the event of termination, a given master agreement continues in full force and effect until a new master agreement has been put in place. [3]If no new master agreement is adopted within six months of the receipt of the notice of termination, the impartial members of the arbitration panel will finalize the new master agreement in coordination with the Contractual Parties to the master agreement at the request of either Contractual Party. [4]If the new master agreement is not adopted by a deadline set by the Federal Ministry for Drugs and Medical Devices, sentence 3 applies *mutatis mutandis*.

§ 18 Final provisions

(1) [1]Following the execution hereof, the Contractual Parties to the master agreement will jointly determine, in annual intervals or more frequently, whether and to what extent the terms of the master agreement should be amended.

(2) [1]Changes or amendments to this master agreement must be made in writing. [2]The same applies to a waiver of this requirement as to written form.

(3) [1]In the event that individual provisions of this master agreement are or become invalid, this shall be without prejudice to the validity of the remaining provisions in cases of doubt. [2]In the place of the ineffective provision or to fill a loophole found in this agreement, an adequate provision is to be agreed, such provision to approximate what would have been agreed on the basis of the meaning and purposes hereof had the matter been considered from the start.

(4) [1]Paragraphs 2 and 3 also apply to any agreement about remuneration sums pursuant to Section 134 (1) sentence 1 SGB V.

Annex 1: Mandatory information for asserting claims for compensation pursuant to § 3

The assertion of claims for compensation pursuant to § 3 requires that the following information be provided on how the claim amount was calculated in intelligible, concise and clearly structured form:

1. transmission of information pursuant to Section 2 of DiGA accounting guideline for the invoice underlying the claim for compensation;

2. number and list of activation / prescription codes accounted for;

3. date of redemption by insured person for each activation / prescription code accounted for;

4. amount of difference per activation / prescription code;

5. total claim (2*4) in EUR;

6. account information; and

7. if claimant (health insurance fund / manufacturer) has third party process claims for compensation: declaration to the effect that payor is authorized to effect payment to third party specified with debt-discharging effect.

Annex 2: Sample power of attorney

Sample power of attorney
for third party's representation of manufacturer in negotiations of remuneration sum pursuant to Section 134 (1) sentence 1 SGB V

[Name of authorized representative, represented by, address, email address]

- Authorized Representative -

is hereby authorized to represent the manufacturer

[manufacturer's name, represented by, address]

- Manufacturer -

in the negotiations regarding the remuneration sum pursuant to Section 134 (1) sentence 1 SGB V of the digital health application

[product]

- Digital Health Application-

with the National Association of Statutory Health Insurance Funds, Reinhardtstraße 28, 10117 Berlin, Germany.

The power of attorney extends to all actions and legal transactions needed for the negotiations as well as the execution of an agreement on the remuneration sum pursuant to Section 134 para. 1 SGB V for the Digital Health Application. Specifically, it encompasses

1. setting dates for scheduled negotiations in accordance with master agreement pursuant to Section 134 (4) SGB V;

2. representation at scheduled negotiations as well as in any subsequent proceedings before the arbitration panel pursuant to Section 134 (3) SGB V;

3. establishing and suspending contractual relationships, including but not limited to the execution of the remuneration agreement;

4. issuing and accepting unilateral declarations of intents, including but not limited to declarations to halt or suspend negotiations; and

5. accepting and transmitting relevant documents.

This power of attorney does not cover the issuance and acceptance of declarations of intent to terminate a remuneration agreement for the Digital Health Application, or to initiate renegotiations occasioned by material changes to the Digital Health Application.

The power of attorney is to be submitted to the National Association of Statutory Health Insurance Funds as an original or by facsimile. Upon submission, the Authorized Representative will be treated just like the manufacturer in the negotiations; any and all provisions of this master agreement that pertain to the manufacturer apply *mutatis mutandis* to the Authorized Representative. Specifically, this is true for the duties of confidentiality and secrecy addressed pursuant to Section 134 Abs. 4 SGB V in the master agreement.

_____ _____

Place, date Signature, Manufacturer

_____ _____

Place, date Signature, Authorized Representative

Annex 3: Web tools safeguarding confidentiality pursuant to Section 134 (1) sentence 5 SGB V

For the following Web tools, confidentiality pursuant to Section 134 (1) sentence 5 SGB V is deemed to be protected:

- Microsoft Teams
- Cisco Webex
- Skype for Business
- Zoom

Annex 4: Mandatory information for registering health insurance fund claims for correction of invoices pursuant to § 15 para. 4

The assertion of a claim for invoice correction pursuant to § 15 para. 4 requires that the following information be provided on how the claim basis was assessed and the claim amount was calculated in intelligible, concise and clearly structured form:

1. transmission of information pursuant to Section 2 of the DiGA accounting guideline on disputed invoice;

2. description of claim basis and, to extent available, supporting documents (e.g., wrong invoice recipient / activation code / prescription code / directory number pursuant to directory of digital health applications / wrong actual price or remuneration sum);

3. activation / prescription code

4. amount of difference asserted;

5. account information; and

6. if health insurance fund as claimant has third party process claims for invoice correction: declaration to the effect that manufacturer is authorized to effect payment to third party specified with debt-discharging effect.

Annex 5: Mandatory information for registering manufacturer claims for credit correction pursuant to § 15 para. 5 b)

The assertion of a claim for credit correction pursuant to § 15 para. 5 b) requires that the following information be provided on how the claim basis was assessed and the claim amount was calculated in intelligible, concise and clearly structured form:

1. transmission of information pursuant to Section 2 of the DiGA accounting guideline on disputed credit;

2. description of claim basis and, to extent available, supporting documents (e.g., wrong invoice recipient / activation code / prescription code / directory number pursuant to directory of digital health applications / wrong actual price or remuneration sum)

3. activation / prescription code

4. amount of difference asserted;

5. account information; and

6. if manufacturer as claimant has third party process claims for credit correction: declaration to the effect that health insurance fund is authorized to effect payment to third party specified with debt-discharging effect.